Manual 47

Investigational Site User Manual for Acquiring and Transferring Sleep Acquisition Data

ARIC Visit 11

Version: 1.2

Date: 2/29/2024

Acquiring & Transferring Sleep Acquisition Data

Manual of Procedures

Table of Contents

Manual Revisions

Version number	Date	Section(s)	Description of Update
1.0	11/15/2023	All	Initial version
1.1	1/19/2024	1.0 Overview	Clarified timing of visit 11 assessments.
1.1	1/19/2024	1.a.ii Exclusions WatchPAT	Inspire Sleep Apnea device and Pacemakers were added to the exclusion criteria.
1.1	1/19/2024	1.c.iii Participant Instructions	Added link to instruction documents. Added the Actigraphy/Sleep monitoring Combined Instruction Sheet.
1.1	1/19/2024	1.c.iv Forms	Added the Participant Sleep Diary
1.1	1/19/2024	2.c. Sleep Profiler Demonstration	Added photo of Serial Number
1.1	1/19/2024	2.d and 2.e Sleep Profiler Device Return and Uploading	Included the Sleep Diary and Sleep Equipment forms
1.1	1/19/2024	3. WatchPAT and CloudPAT	Clarified that CloudPAT is the software for the WatchPAT device
1.1	1/19/2024	3.c WatchPAT demonstration	Clarified placement of device. Added link to Aric website. Added a photo of the device serial number and clarified that it will be documented on the Sleep Equipment Form.
1.1	1/19/2024	3.d WatchPAT Device Return	Included the Sleep Equipment Form
1.1	1/19/2024	3.g WatchPAT troubleshooting	Added error code information
1.1	1/19/2024	4.a Site Data Management	Updated site workflow
1.1	1/19/2024	5. Device Return Information	Updated device return process
1.1	1/19/2024	6. Ordering Supplies	Updated the Sleep Profiler and WatchPAT sections. Added expiration date information.
1.1	1/19/2024	8. Training and Certification	Updated WatchPAT training.
1.2	2/29/2024	2.c Demonstration	Added comment about importance of cleaning skin before applying Sleep Profiler and pressing on sensors to ensure a good study.
1.2	2/29/2024	2.d Device Return	Added staff should check the Sleep Profiler for any cracks, tears, or damage upon device return.

1. Overview

This manual provides guidance to collect and transfer sleep data using the Sleep Profiler and WatchPAT 300 devices for centralized data scoring. Throughout the manual, additional technical manuals and training videos are referenced. The links to these are located in the Appendix.

Participants who decide to participate in the sleep study at Visit 11 will receive their sleep devices on Visit 11 Day 1 if completing the visit over two days. The devices are optional; the participant can opt to wear both devices or one or the other. The devices will be worn concurrently with the accelerometer if also participating in accelerometry. The Sleep Profiler will be worn on Night 1 (the night of Visit 11 Day 1) but may be worn on Night 2 (the night after Visit 11 Day 1) due to device failure. The WatchPAT recording will occur the night after the Sleep Profiler recording (Night 2 or Night 3). It is generally recommended that participants wear the devices on separate nights, as outlined above; however, participants may choose to wear them on the same night if they prefer. The nights the devices are worn should be documented in the Sleep Diary.

Note, for participants completing the accelerometry protocol, the WatchPAT should be worn on the non-dominant wrist with the accelerometer. Participants will be instructed to move the accelerometer higher up on the arm in order to wear the WatchPAT closer to their wrist.

a. Exclusions

The study participant will not be able to wear the study equipment if they have any of the following:

i. Sleep Profiler

1. A CPAP mask with a forehead piece or any other medical device that goes over the forehead and interferes with the device placement. Participants with a CPAP mask without a forehead piece may wear the device, and this should be documented in the Sleep Equipment Form
2. Any facial irritation or head injury that would prevent them from wearing the Sleep Profiler device.
3. Adhesive allergy.

ii. WatchPAT

1. Inability to wear the WatchPAT device, such as injury to hands or wrists.
2. Adhesive allergy.
3. Inspire Sleep Apnea device.
4. Pacemaker.

b. Safety Information

Please refer to the device user manuals (see Appendix A) for additional safety information.

i. Sleep Profiler

1. Do not use the device if it's damaged in any way.
2. Participants should discontinue wearing the device if it causes pain.
3. Allergic reaction or skin irritation from device components may occur.
4. Do not let the device get wet.
5. The device should not be worn while connected to a power source.
6. The device is not defibrillator proof.
7. Do not use the device near an open flame or high heat device.
8. Device may not charge properly if in direct sunlight or if room temperature is above 30°C (86°F). Charging will automatically terminate when an unsafe operating temperature is detected.
9. If device is stored or transported at temperatures < 45°F or > 104°F, the device must be kept in a room with an ambient temperature of 68°F for at least 6 hours, or until the device is within safe operating temperatures (5°C to 40°C), prior to charging or use.

ii. WatchPAT

1. Do not let the device get wet.
2. Avoid placing food or water on any part of the WatchPAT.
3. The WatchPAT 300 cannot be worn while connected to a power source.

c. Equipment and Supplies

Below are the items provided to the study participant to perform the sleep testing.

i. Sleep Profiler

1. Charged Sleep Profiler device with headband, charger, and case
2. 3 packs of Sleep Profiler electrodes
3. 3 Alcohol pads and 3 Skin Prep pads

ii. WatchPAT

1. WatchPAT device with a new AAA battery inserted and case
2. New finger probe
3. RESBP sensor with sticker
4. Tape

iii. Participant Instructions

Written participant instruction templates handouts are found on the ARIC website at the following location: [Researchers > Cohort Studies > Supporting Documents > Visit 11].

1. Sleep Profiler Instructions
2. WatchPAT Instructions
3. Sleep Monitoring Instruction Sheet
4. Actigraph/Sleep Monitoring Combined Instruction Sheet
    a) This instruction sheet should be provided to participants completing <u>both</u> Actigraph and Sleep Monitoring, in lieu of the Sleep Monitoring Instruction Sheet.
5. Sleep Diary

iv. Forms

1. Sleep Equipment Form (SEF)
2. Epworth Sleepiness Scale (ESS)
3. Jenkins Sleep Evaluation Questionnaire (JSQ)
4. Participant Sleep Diary (PSD)
   Note, the ESS and JSQ are completed with **all** ARIC participants, regardless of participation in the sleep monitoring study.

d. Administration

i. Before the Visit

1. Confirm that both devices are charged and initialized, and the device cases are packed with the necessary supplies. See Sections 2b and 3b for more details on initialization.

ii. During the Visit

1. Complete the Epworth Sleepiness Scale and Jenkins Sleep Evaluation Questionnaire.
2. Complete the Sleep Equipment Form and check the Participant Snapshot Report to ensure eligibility.
3. Review the participant instruction handouts with the participant.
4. Demonstrate how to use equipment while following the participant handouts. See Sections 2c and 3c for application details.
5. Dispense equipment, supplies, instructions, and Sleep Diary.
6. Arrange equipment return. Provide participant with the pre-paid shipping materials.

iii. After Visit

1. Update Sleep Equipment Form with device return information.
2. Complete the Participant Sleep Diary (PSD) form in CDART using the information provided in the returned paper Sleep Diary.

iv. After Equipment Return

1. Clean the equipment. See Sections 2e and 3e for instructions.
2. Upload the data as soon as possible. See Sections 2d and 3d for instructions.
3. Document device upload on the Sleep Equipment Form in CDART.

2. Sleep Profiler

The Sleep Profiler will be worn on the Night 1. If the Sleep Profiler recording failed (failed sensor test or device fell off during the night), participants may opt to wear it a second night on Night 2.

a. Software

i. Software Download

1. https://www.advancedbrainmonitoring.com/sleep-profiler/software-download
2. There are instructions for each type of web browser in the link above.

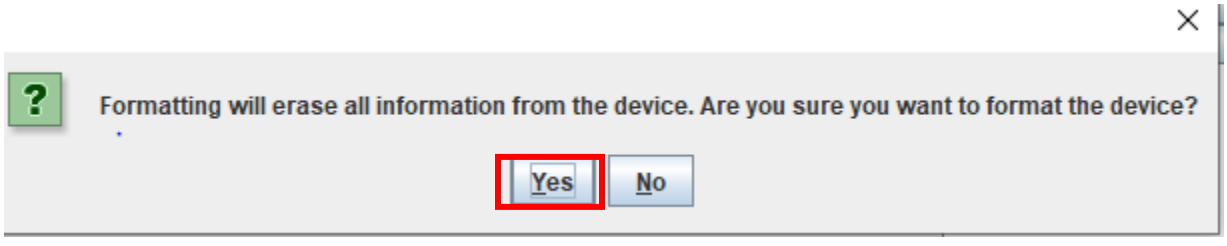
3. You will be provided a username and password to access the study portal.
4. The study portal will be specific to your site.

b. Initialization

i. Connect a charged Sleep Profiler device to the computer with the provided USB cable. The port is on the top of the SP device.

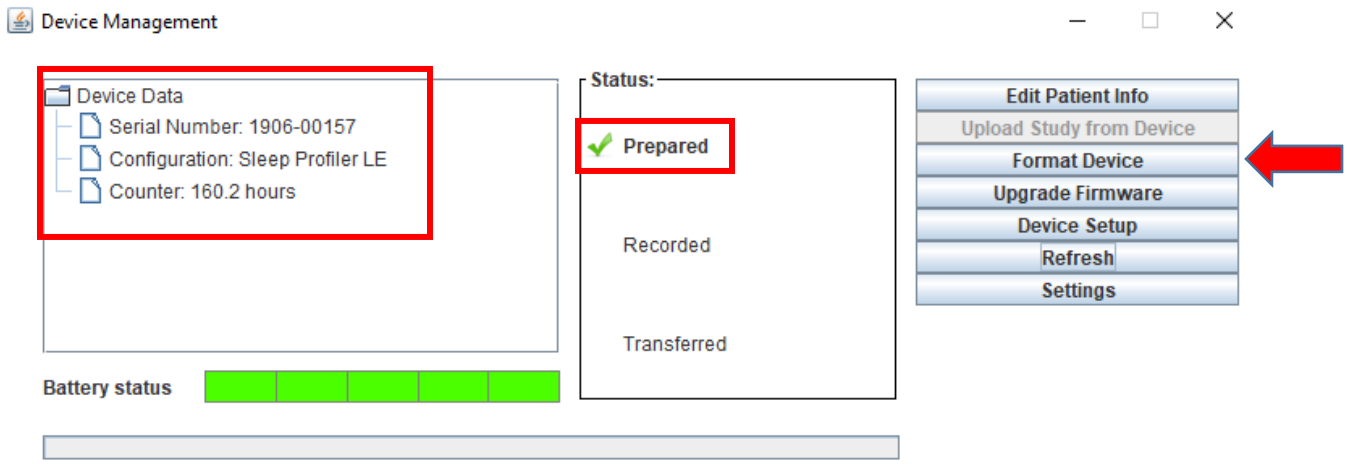
ii. The device will say “Caution, the device is charging.”
iii. Go to the Sleep Profiler Portal at https://cportal.b-alert.com/sleep-profiler/login
iv. Use your provided Username and Password to Login. This login will be emailed to you by the Sleep Profiler manufacturer (ABM) once access has been requested.
v. Select ‘Device Management’ - a pop-up window will appear.
vi. Confirm the battery status is fully charged (5 green bars).
vii. Format the device.
Note: Devices should be formatted between uses. This should be done before the study is initialized **and** when study data is uploaded. Failure to reformat the device may result in incorrect time alignment.

1. If a study ID number is listed in the “Device Data” section, **verify the data from this study ID is on the portal** prior to reformatting the device. The reformatting process will delete study data.
2. Choose “Format Device” in the right hand column.
3. This window will appear, select “Yes.”



4. A message will appear to use the on/off button to power off the device.
5. Turn off the device. You will hear “Device is powered off.”

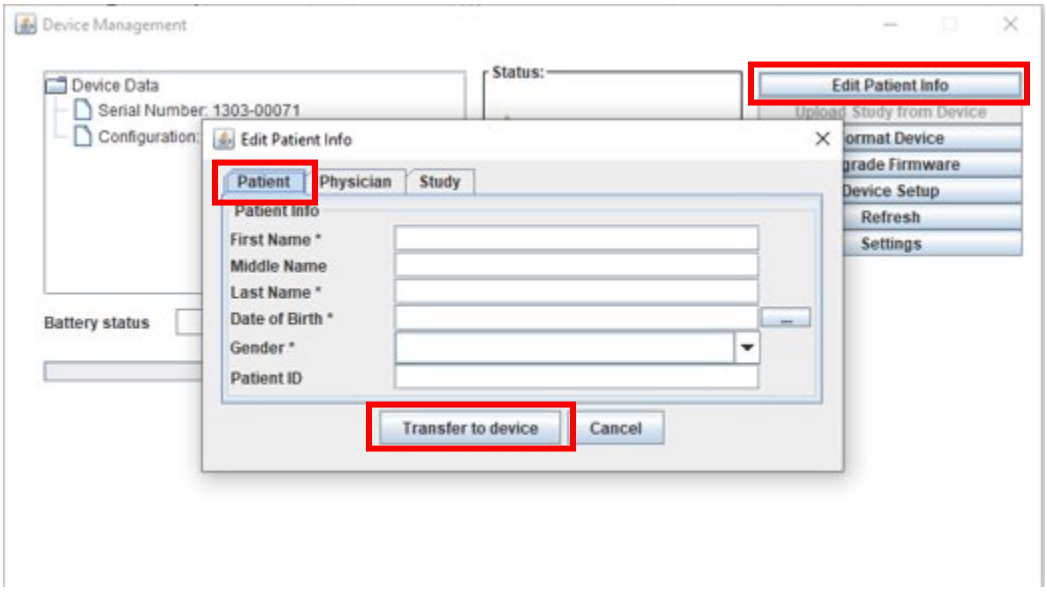
6. Select “OK” once you turn the device off.
7. The device will automatically power back on and you will hear “Caution, the device is charging.”
8. Once formatted, a green checkmark will appear next to the device status “prepared”. If you refresh, you should no longer see any study specific information under the Device Data section.



viii. After the device is formatted, choose “Edit Patient Info” to label the study.

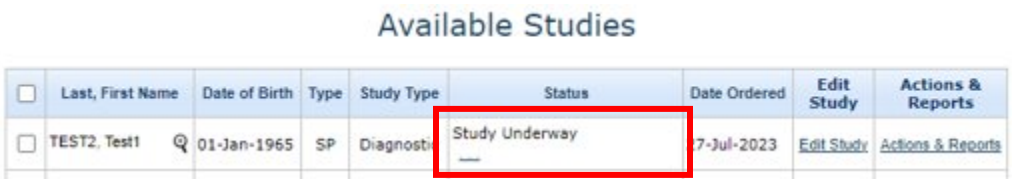
ix. Complete the “Patient” tab.
    1. Use participant’s ID number for First Name, Last Name, and Patient ID.
    2. Gender - Male (all participants)
    3. DOB - 01/01/1960 (all participants)

x. Select “Transfer to Device.”



xi. Device Management should now list the study ID under the Device Data section.

xii. Exit out of Device Management by hitting the x in the right-hand corner.
xiii. The “Available Studies” table will now list the study with the status “Study Underway.”



c. Demonstration

Written and video instructions on how participants will apply the Sleep Profiler are available online (see Appendix A), and a participant handout is available on the ARIC website here: [Researchers > Cohort Studies > Supporting Documents > Visit 11]. During the study visit, explain the items listed below while applying the device to the participant. During demonstration, adjust the headgear to fit their head. Show participants the power button, but do not power the device on during the demonstration, as this will result in the wrong start time. You can demonstrate without cleaning the skin or removing the plastic backing from the sensors; however, please stress the importance of cleaning the skin and pressing down on the sensors to ensure good contact with the forehead.

Return the device to the case after the demonstration. Update the Sleep Equipment Form with the serial number of the Sleep Profiler device and other information to reflect that the device has been sent out. The serial number can be found by lifting the right side of the strip on the Sleep Profiler as shown below.

i. If the participant wears a CPAP mask, the Sleep Profiler device should be applied prior to the CPAP mask. This ensures good study quality and makes it easier to remove CPAP when needing to use the restroom, get a drink, etc.
ii. The participant should wash their forehead with soap and water at bedtime. Before applying the device, instruct the participant to scrub the forehead with an alcohol swab for 15 seconds followed by the skin prep pad.. Allow the forehead to air-dry before applying the device. Note: Stress the importance of this step to ensure a good study.
iii. Snap electrodes on, making sure they snap securely and the tabs are facing down.
iv. Before removing the plastic backing on electrodes, it is recommended that you place the headband device on forehead and around head to tighten/loosen as necessary for correct sizing and placement (making sure the Sleep Profiler label is right side up).
v. Remove plastic backing on electrodes and place in the correct locations, pressing down firmly. Press firmly on the outer edges of all electrodes to ensure good contact with the skin. Note: Stress the importance of this step to ensure a good study.
vi. Secure the headband around the head, making sure the headband is snug but not uncomfortable.
vii. Instruct the participant to get into bed and press the on/off button and the device will say “Device has been powered on. Acquisition started.”
viii. Next the device will say “Device signal quality testing may take several minutes, do not move. Forehead sensor test now starting.” Instruct the participant to lay still on their back for the duration of the test.
ix. If the test fails, the device will say “Forehead sensor test failed” and prompt them to “press down on each sensor so the entire area is in contact with your forehead,” and the sensor test will be repeated.
x. Once the test passes, the device will say “Forehead sensor test completed. Turn out the lights and go to sleep.” After the test passes, they are free to lay however they feel comfortable.
xi. In the morning the participant will turn off the profiler and hear a beep then “Device is powered off.”
xii. Participants can remove the profiler, dispose of the electrodes and charge the device (if the first night failed and they’ve opted to wear the Sleep Profiler for a second night).
xiii. Inform participants that the strips on the device can break or tear and should be handled with care.

d. Device Return

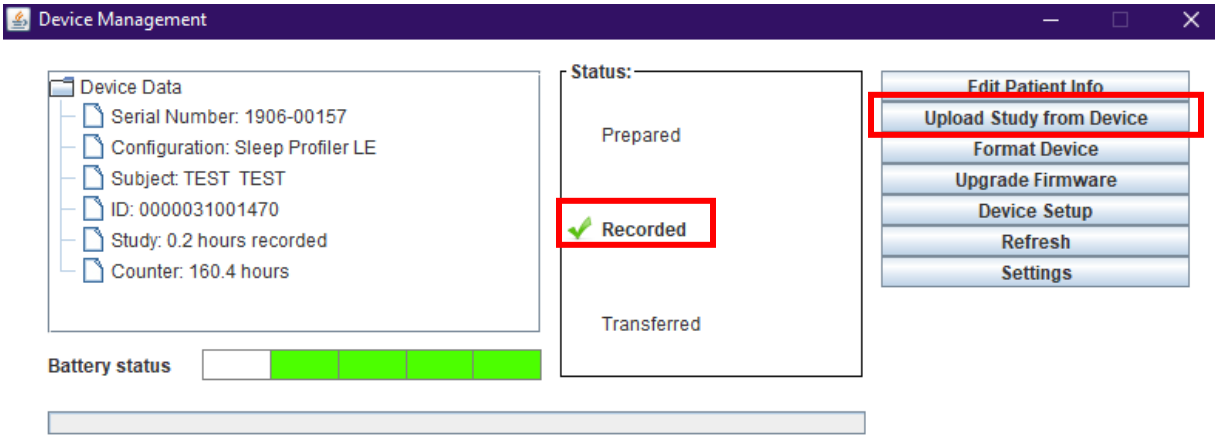
After wearing the equipment, participants will mail both sleep devices and the Sleep Diary back to the clinic using the pre-paid shipping materials. Note, there may be a delay in receiving the Sleep Diary back at the clinic if the participant is also completing the accelerometry protocol, due to the Actigraph’s longer wear period.

Once the device is returned, check the Sleep Profiler strip for any cracks, tears, or damage. If the strip is damaged, replace the strip (see Section 2h).

e. Uploading

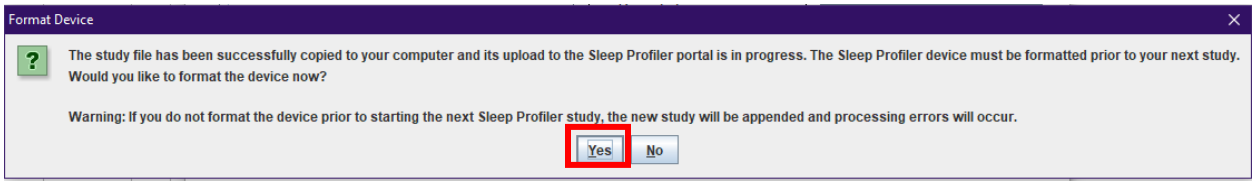
Data from each device should be uploaded as soon as possible after the device is returned. The Sleep Equipment Form should be updated to include the date of device return and date of data download. A synopsis of the steps to upload the Sleep Profiler data is below.

i. Connect the Sleep Profiler device to the computer using the provided USB.
ii. Go to the Sleep Profiler Portal at https://cportal.b-alert.com/sleep-profiler/login
iii. Use your provided Username and Password to login.
iv. Go to Device Management. There should be a green checkmark next to "Recorded" in the Status box.
v. Select "Upload Study from Device."



vi. Format the device.
Note: Devices should be formatted between uses. This should be done before the study is initialized **and** when study data is uploaded. Failure to reformat the device may result in incorrect time alignment.

1. While the device is uploading, you will be prompted to format.
2. Select "Yes" and turn the device off and hit "OK."



vii. Once the status of the upload is complete, close the Device Management box.

viii. The “Available Studies” table will now list the study with the status “Study Processing.” After a few minutes, this will change to “Preliminary Report Available.”

Available Studies

	Last, First Name	Date of Birth	Type	Study Type	Status	Date Ordered	Edit Study	Actions & Reports
☐	TEST, TEST	01-Jan-1960	SP	Diagnostic	Preliminary Report Available	25-Sep-2023	Edit Study	Actions & Reports

ix. Upload is now complete and the Sleep Processing Core will pull the data from the portal.

x. Document on the equipment form that the device has been returned and uploaded.

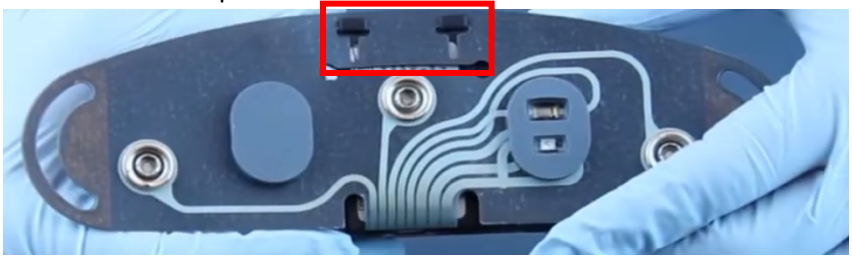
f. Cleaning

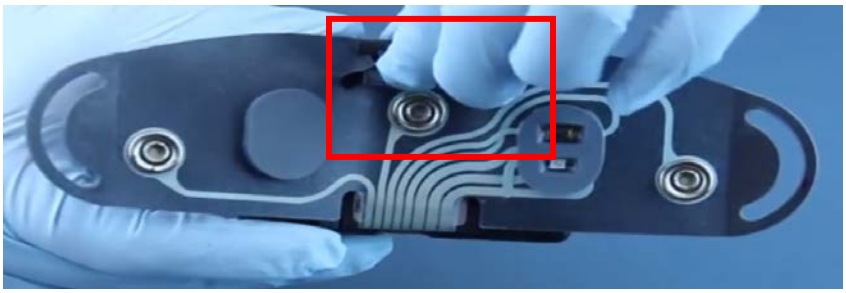
More detailed instructions on cleaning the Sleep Profiler can be found in the Sleep Profiler Hardware Manual and in the video titled “Preparing the Device for Reuse” (see Appendix A).

i. Remove the headband from the device.

ii. Combine 1 teaspoon of dish soap and 1 gallon of water. Submerge the headband and agitate for 1-2 minutes. Rinse with warm water for 1 minute and allow to air-dry.

iii. Use your index finger to pull out and lift up the strip to unhook it from the enclosure snaps and the device.





iv. Use an alcohol pad to thoroughly wipe down the grey rubber pads.
v. Use a new pad to clean the entire surface of the electrode snaps and the SP strip.
vi. Use a new pad to clean the actual device.
vii. Hook the strip back onto the enclosure tabs.

viii. The carrying case should be cleaned inside and out with an alcohol pad.

g. Troubleshooting

The following section describes common issues that may occur with the Sleep Profiler. If the Sleep Processing Center notices consistent poor data quality or other device malfunctions, they will notify the affected site.

i. Common Issues

1. The sensor test failed:
    a) Plastic was not removed from electrodes when placed on forehead.
    b) There was poor electrode contact with the skin (e.g., the sensors were not attached securely, or there was hair between the sensor and the forehead).

c) The forehead was not prepared according to the instructions (e.g., lotion was applied to the forehead, or the face was not clean and dry).

2. There is consistent poor data quality.
    a) Replace the SP strip.
3. The device fell off during the night.
    a) The electrodes came loose from the strip. Participants should hear the electrode snap into place.
    b) The electrodes fell off of the forehead. Encourage participants to avoid wearing lotion. Electrodes should be applied firmly to skin to ensure good contact.

h. SP Strip Replacement

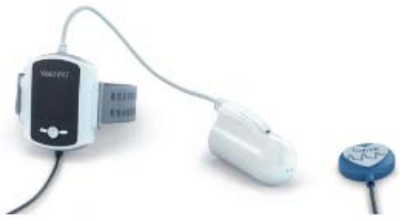
The strip on the Sleep Profiler needs to be changed to ensure good study quality. Instructions to change the strip are in Section IV of the Sleep Profile Hardware Manual (see Appendix A). There is also a video available within the Hardware Manual.

i. The strip should be replaced when:
    1. The device has been used 50 times with that strip. The Sleep Processing Center will keep track of this number and will notify the site when the strip needs replaced.
    2. If there is any damage to the strip, such as a tear or if the gray pads shifted or fell off.
    3. The Sleep Processing Center notes poor quality data.

ii. Document the date the SP strip was replaced. There is an SP Strip Replacement Excel sheet available at the Equipment Tracker Template link in Appendix B.

iii. Send the Sleep Processing Core the date and device serial number when a SP strip is replaced.

3. WatchPAT and CloudPAT



The WatchPAT is worn for one night by participants on Night 2. If the participant opts to not wear the Sleep Profiler, the WatchPAT will be worn on Night 1. If the participant repeats their Sleep Profiler night, the WatchPAT will be moved to Night 3. It is generally recommended that participants wear the devices on separate nights as outlined above, however participants are allowed to wear the devices on the same night if preferred.

a. Software

The web software used to initialize and upload the WatchPAT devices is called CloudPAT. Details on getting access to the software are below.

i. Software Download

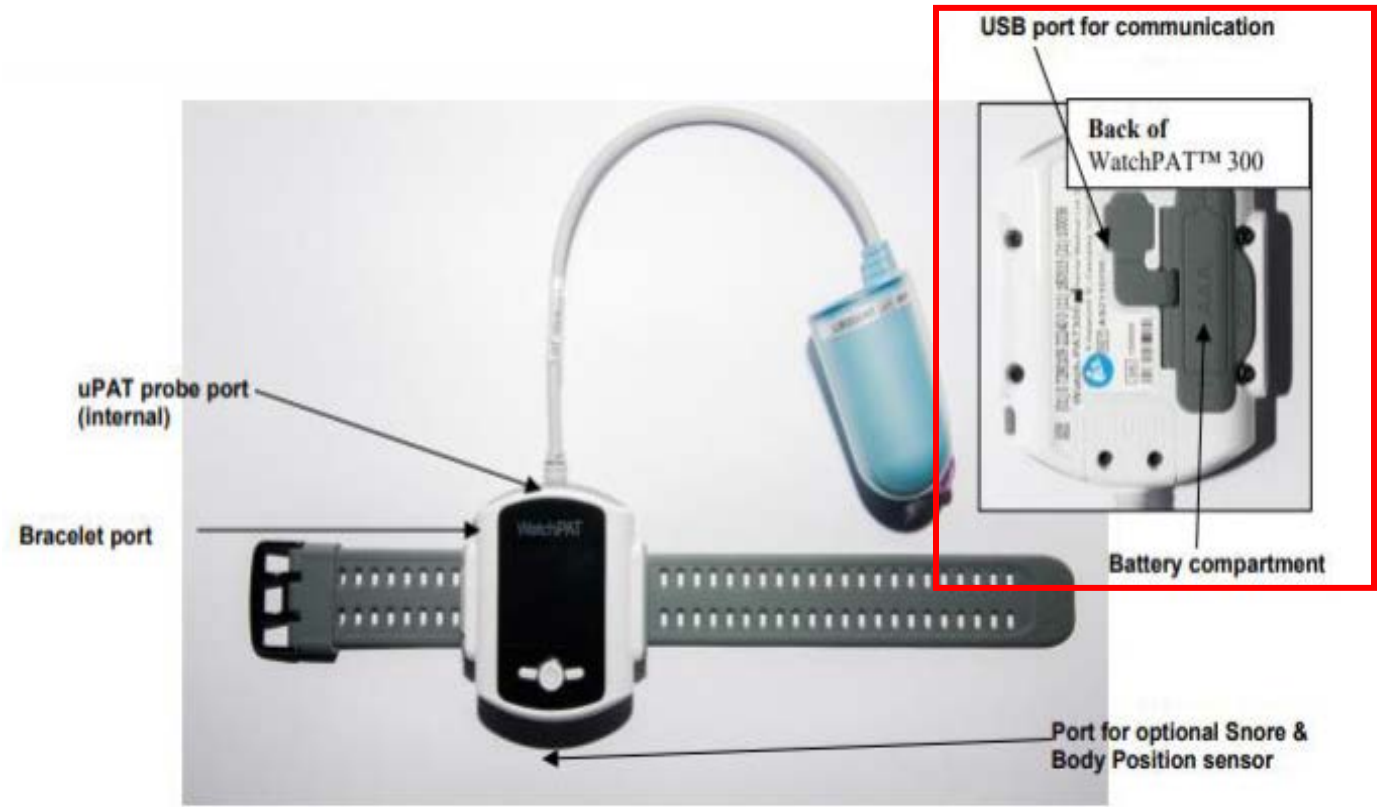
1. To set up CloudPAT, please follow the instructions in Section 2 of the CloudPAT Web Software Operation Manual or the CloudPAT video guide (see Appendix A).
2. To receive an email and password, email CloudSupport@itamar-medical.com.
3. You should be connected through your SSO portal.
4. Log on to the server at https://cloudpat.itamar-medical.com/
5. You will be prompted to set a new password.

b. Initialization

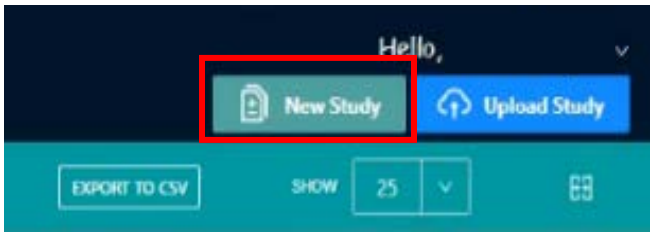
Devices should be initialized prior to recording sleep data. A synopsis of the steps to initialize the WatchPAT is below. A more detailed description of the initialization process for the WatchPAT can be found in Section 3.7 of the CloudPAT Web Software Operation Manual. There are also video guides available at the CloudPAT video link. See Appendix A for both links.

Note: CloudPAT will prompt you to install an app when initializing the first device. Instructions are in Section 3.6 of the CloudPAT Web Software Manual (see Appendix A).

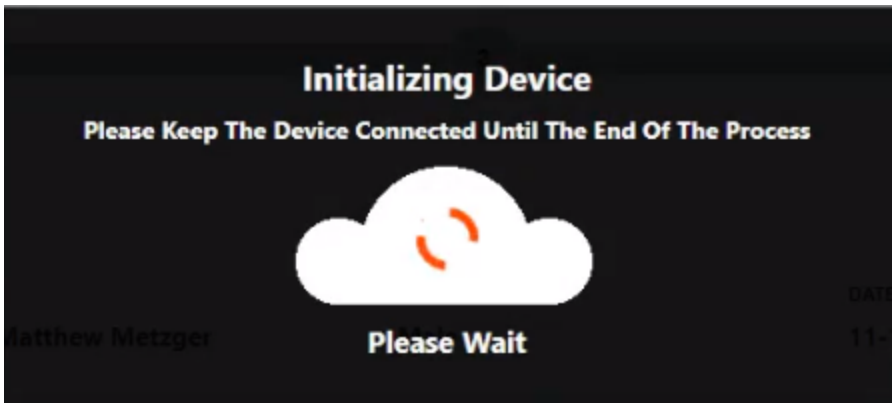
i. Remove the wrist strap from the WatchPAT
ii. Place a new AAA battery in the WatchPAT.
iii. Connect WatchPAT to the computer using the provided USB cable.



iv. Log on to the CloudPAT server at https://cloudpat.itamar-medical.com/ using your username and password.
v. Select "New Study" in the top right-hand corner.

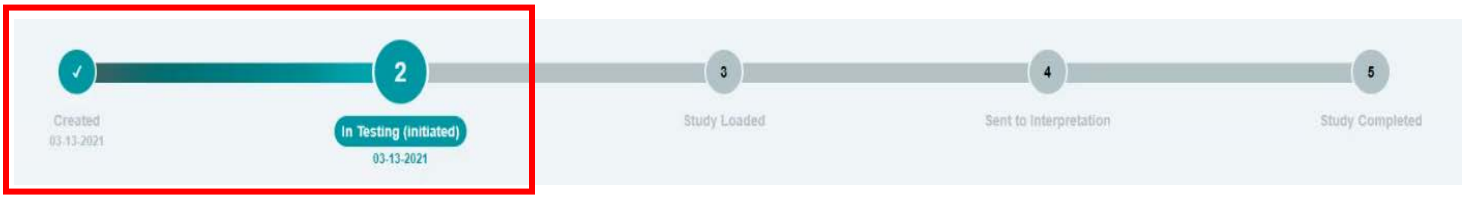


vi. Enter the participant's Study ID #. Leave the remaining fields blank.
vii. Select "Save and Initialize" in the bottom right-hand corner.
viii. Another window will populate, select WatchPAT 200U/300.
ix. Select "Lucey Lab" as the interpreter.
x. Document any implantable devices under the "Diseases & Medications" tab in the "Clinical Comments" box.
xi. Number of Nights: 1
xii. Select "Initialize."
xiii. A window will populate to show that the device is being initialized.



xiv. The window will disappear and you will see a notification on the top of the screen that says “Initialization was successful.”

xv. Once the device is initialized, at the top of your screen, the tracker should move to “In Testing (initiated).”



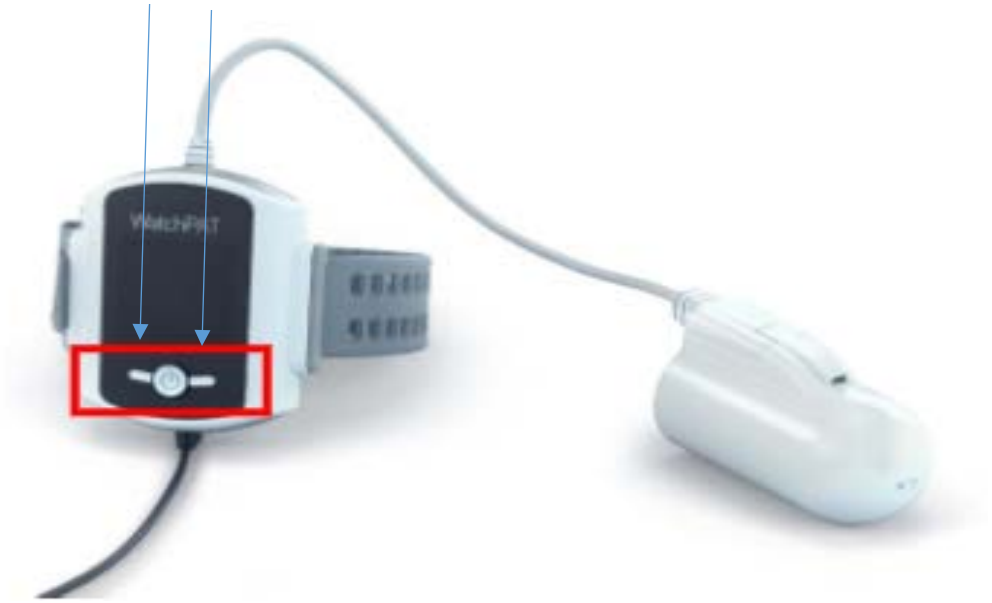
xvi. If you click on the tab “Studies and Initializations,” under the tracker and the patient information, it will display the initialization date and serial number.

xvii. If the participant is wearing PAP, document in the clinical comments section under the Diseases and Medications tab.

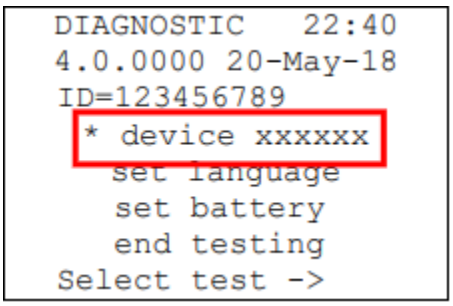
xviii. If there is data stored on the watch, it will not let you initialize it until the study has been uploaded. If you get the prompt “Previous study found,” upload that study and initialize for the current participant.

xix. The device should be tested before sent out.

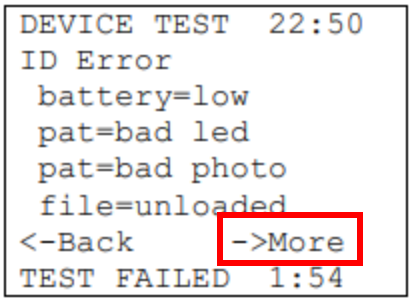
1. To test, first unplug the watch from the computer.
2. Turn the watch on by pressing the power button for 2 seconds.
3. When the watch turns on, you will see a person with a “zzz” by their head. While on this screen or the screen that populates next (Patient Testing), press both buttons on either side of the power button simultaneously to take you to the testing screen.



4. “Device xxxxxx” will have an asterisk by it on the WatchPAT device screen. Select “device xxxxxx” by pressing the power button and the test will begin.



5. Use the left button to go back.
6. If test passes:
    a) Use the left button to go back to the previous screen.
    b) Use the right button to go down to “end testing” and select with the power button.
7. If the test fails:
    a) Check the error code(s) and look in Section 9 of the WatchPAT 300 Operation Manual (see Appendix A).
    b) If at the bottom of the screen, there is a “->More” choice, use the right button to see the additional codes.



c) Once the problem has been fixed, redo steps 1-5.

8. Once the device has passed testing, it is ready for use.

c. Demonstration

During the study visit, thoroughly explain the items below. Demonstrate to the participant how to apply the device by reviewing the steps below. When demonstrating the wrist band, do not turn on the device or apply the finger probe as it is single use only and can be damaged.

When possible, the WatchPAT should be worn on the non-dominant wrist, but it may be worn on the dominant wrist in special circumstances (e.g., due to wrist injury). The participant should document the wrist the WatchPAT is worn on in their Sleep Diary, and staff will then document this on the Sleep Equipment Form in CDART.

Provide the participant with the WatchPAT Participant Instructions, found on the ARIC website at the following location: [Researchers > Cohort Studies > Supporting Documents > Visit 11].

Update the Sleep Equipment Form with the serial number of the WatchPAT and other information to reflect that the device has been sent out. The serial number can be found on the back of the device as shown below.

i. Trim thick chest hair, if needed.
ii. Run the RESBP sensor through the sleeve of the shirt of the non-dominant hand to the neck opening.
iii. Remove the white paper from the back of the sensor. Leave the blue tab in place.
iv. Stick the sensor to the center of the upper sternum, just below the notch in the front of the neck.
v. Secure with tape
vi. The wrist strap should be snug, but not uncomfortable.
vii. The finger probe can be placed on any finger, except the thumb. If the participant has large fingers, the pinky is recommended.
viii. When inserting finger into the probe, the sticker marked "TOP" should be facing up and on top of the finger.
ix. Insert finger completely into the probe until the end/or bottom can be felt.
x. Press the tip of the probe against a hard surface and pull the "TOP" tab out of the probe.
xi. Press the power button and the device will begin to test. Do not power the device on until all sensors are connected.
    1. If it passes, "GOOD NIGHT!!!" and a checkmark will appear and it will begin recording. The display will power off.
    2. If it fails, contact the number on the participant instructions sheet.
xii. Once the study has started, do not remove any of the sensors or press any buttons on the device.
xiii. In the morning, remove the device. The device will automatically power off.
xiv. If you need to use the restroom or get up in the night, leave the device on and in place while performing these tasks.
The device should not get wet.

d. Device Return

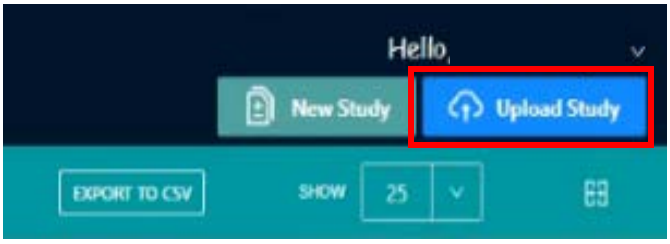
Participants will mail both sleep devices back to the clinic as soon as possible after completing the wear period using the pre-paid shipping materials. The Sleep Equipment Form should be updated to include the date of device return and date of data download.

e. Uploading

Data from each device should be uploaded as soon as possible after the device is returned. A synopsis of the steps to upload the WatchPAT is below. A more detailed description of the uploading process for the WatchPAT can be found in Section 3.11 of the CloudPAT Web Software Operation Manual. There are also video guides available at the CloudPAT video link. See Appendix A for both links.

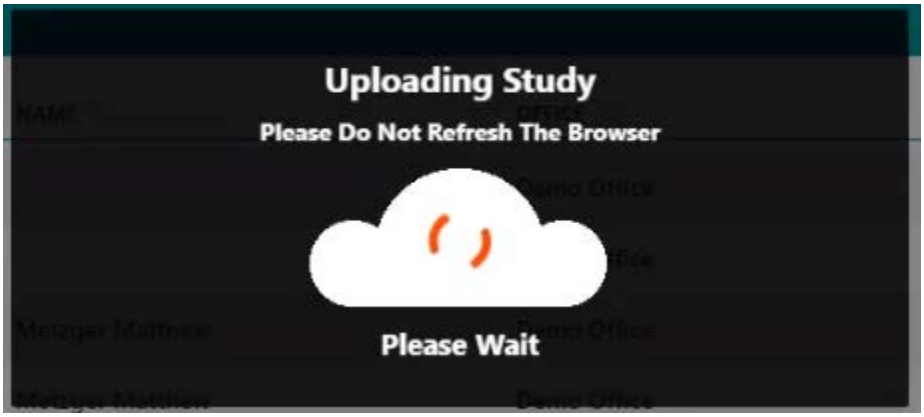
i. Clean the device.

ii. Remove the WatchPAT from the wrist strap.
iii. Connect the WatchPAT to the computer using the provided USB cable.
iv. Log on to the WatchPAT server at https://cloudpat.itamar-medical.com/ using your username and password.
v. Select “Upload Study” in the top right-hand corner.

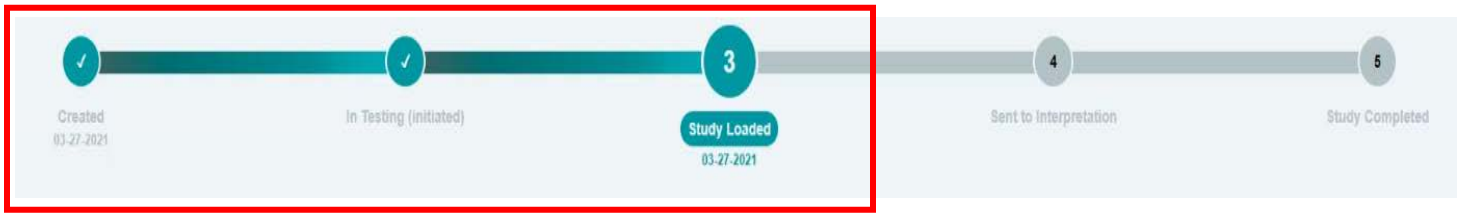


Note: If you get a pop-up for running the command line, click the checkbox to not receive this message again and click the button to allow.

vi. A new window will appear, select “Proceed with Upload.”
vii. Another window will appear saying “Uploading Study” and will continue updating to show what step in the upload process the study is in.

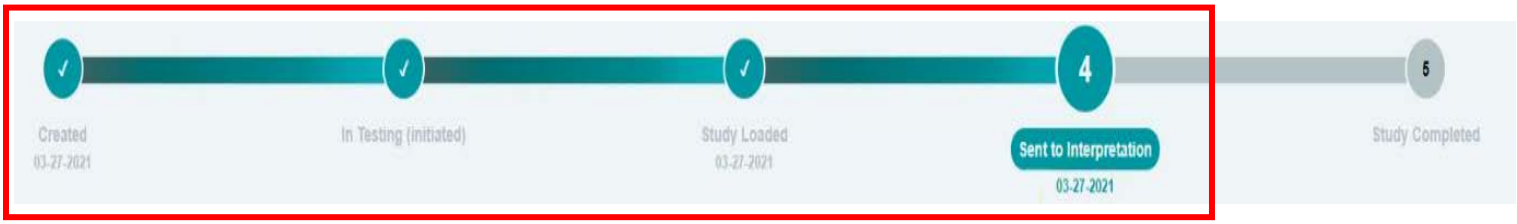


viii. You will see the tracker at the top of the screen move to “Study Loaded.”



ix. If the study was uploaded successfully, the study information will be under the Studies & Initializations tab.
x. Click on the pencil next to the study and select “Lucey Lab” as an interpreter and hit the checkmark.

xi. The tracker will now move to "Sent to Interpretation."



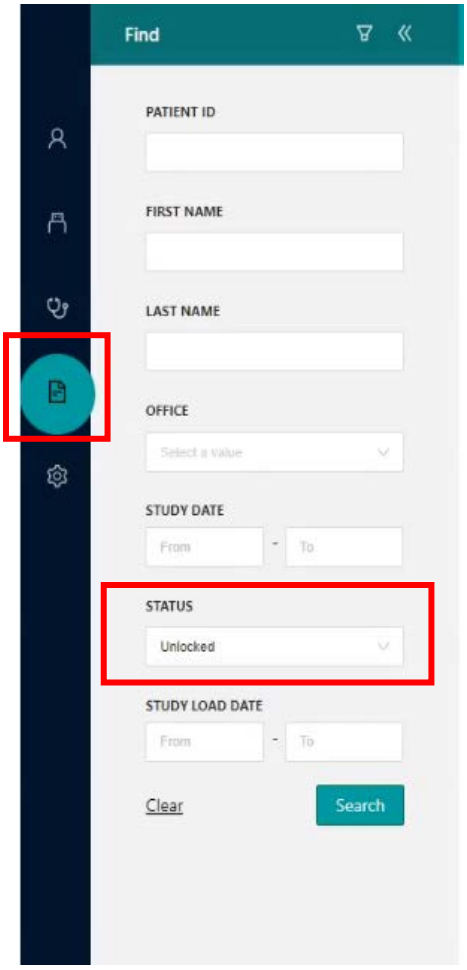
xii. Document the device was returned/uploaded on the Sleep Equipment Form.

xiii. Once the Sleep Processing Center has scored the study and it has been reviewed and locked by the PI, the tracker will move to "Study Completed".

xiv. At that point, the site user that sent the study originally will receive a notification that the study has been completed.

xv. Under the "List of Studies" tab, completed studies will have a lock icon to the left of the Patient ID. That is what indicates that the study has been scored and the report has been finalized. At that point, the report may be printed.

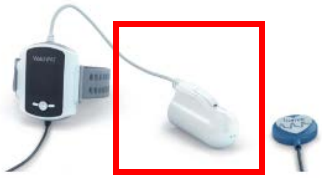
xvi. Under the "List of Studies" tab, you can also search for a specific participant to see if the report is ready. You can also filter to view all of the locked studies so you can see which reports have been finalized and are ready for download.

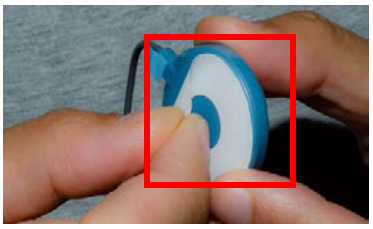


f. Cleaning

More detailed instructions on cleaning the WatchPAT can be found in Section 6.1 of the WatchPAT Operations Manual (see Appendix A). A list of approved products to clean the WatchPAT can be found at https://www.itamar-medical.com/articles/approved-cleaning-products-for-watchpat-devices/.

i. To clean the device and the snore and body position sensor, remove the device from the wrist strap.
ii. Wipe the device, wrist strap, and sensor down.
iii. If the wrist band is visibly soiled, disinfect by immersing the wrist strap in 70% ethyl alcohol or isopropyl alcohol (IPA).
iv. The uPAT finger probe and the RESBP sticker on the back of the sensor need to be discarded after being used.



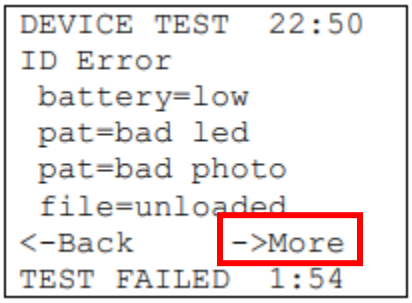


v. The carrying case should be wiped inside and out.

g. Troubleshooting

i. An error code is displayed on the WatchPAT screen during device testing at the Site (see Section 3b for device testing instructions).

1. Check the error code(s) and look in Section 9 of the WatchPAT 300 Operation Manual (see Appendix A).
2. If at the bottom of the screen, there is a "->More" choice, use the right button to see the additional codes.



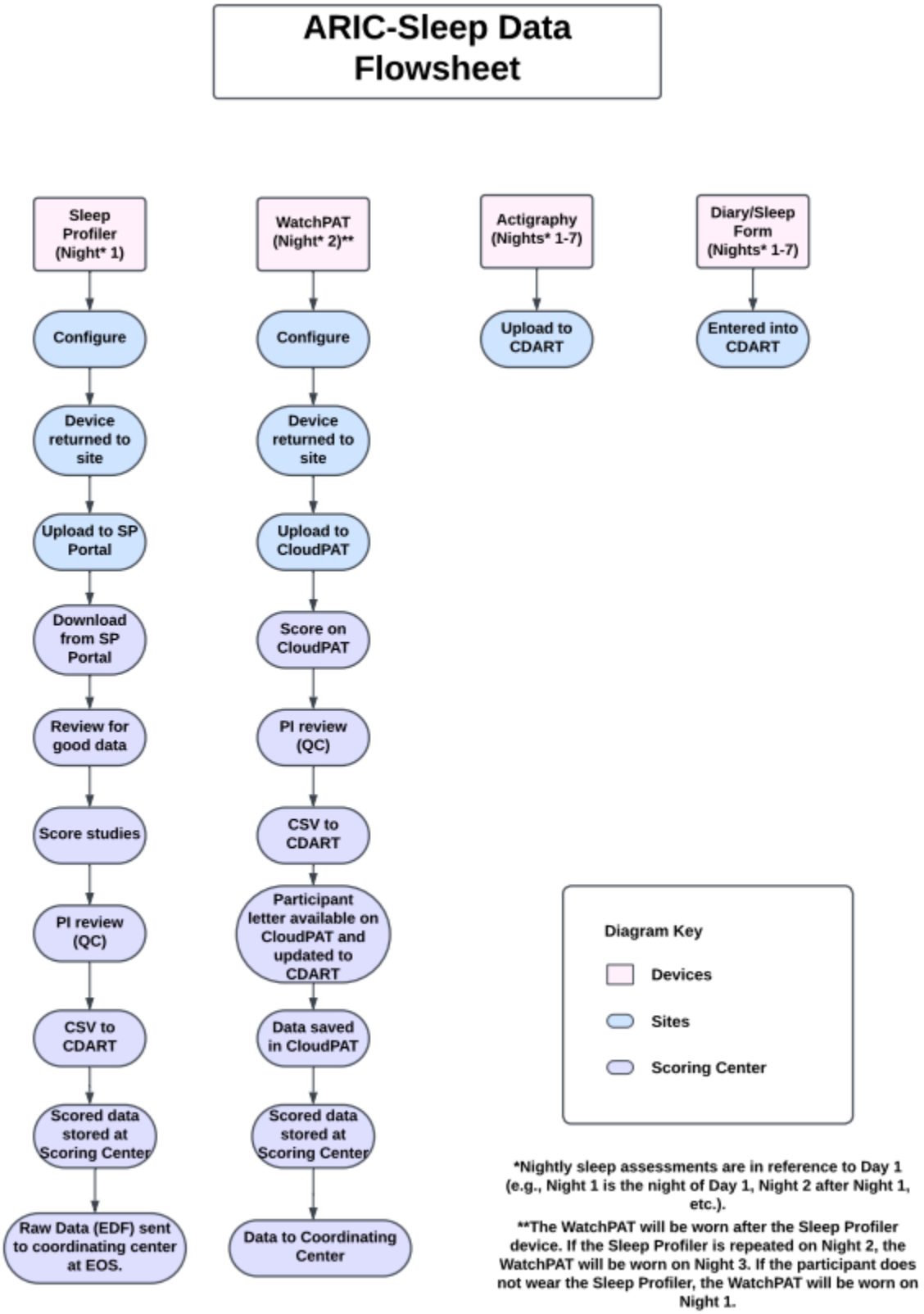
ii. An error code for the finger sensor is displayed on the WatchPAT screen during device testing at the Site.

1. Disconnect the probe and reconnect – if this doesn't fix the problem, the finger probe sensor is bad and needs replaced.

iii. An error for the finger probe is displayed on the WatchPAT screen during device testing while at home with the participant (see Section 3c).

1. Follow on-screen instructions.

4. Data Management



a. Site

i. Complete Epworth Sleepiness Scale and Jenkins Sleep Evaluation Questionnaire in CDART with **all** ARIC participants at clinic visit.
ii. Initialize devices and complete sections A-C in Sleep Equipment Form in CDART at the clinic visit.
iii. Upon device return, upload studies from equipment to the Sleep Profiler portal and to CloudPAT.
iv. Update the Sleep Equipment Form (Sections D-F) with device return information and complete the Participant Sleep Diary in CDART using the information the participant recorded in the paper Sleep Diary.
v. Mail WatchPAT report and corresponding cover letter to participant when available in CDART (see Sleep Processing Center section below).

b. Sleep Processing Center

i. Scored Studies

1. Once studies have been scored and reviewed by the PI, the WatchPAT study will be marked as complete in CloudPAT.
2. The Sleep Processing Center will store the data.
3. At the end of the study, the Sleep Processing Center will send the Sleep Profiler raw data to the Coordinating Center. The WatchPAT data will be stored on CloudPAT and sent to the Coordinating Center.

ii. Reports

1. Once the Sleep Profiler and WatchPAT studies are scored and reviewed by the PI, the CSV reports will be uploaded to CDART. The WatchPAT report will be attached to the WPR CDART form, which will have a dropbox for the report file to be put in.
2. When the WatchPAT report is available in CDART, sites will print out the report as well as the corresponding cover letter (either “normal” or “with respiratory events”). Staff will then mail these to the participant.

5. Device Return Information

Participants should be provided with pre-paid return envelopes/boxes to send the sleep devices and the paper Sleep Diary back to the field centers. It is generally recommended that participants return the sleep devices as soon as possible after completing the wear period. Sites may allow participants to mail back the sleep devices with the Actigraph at the end of the 7-day Actigraph wear period on a case-by-case basis. This will be determined by availability of devices at the field center and assessed participant burden.
The Sleep Profiler and WatchPAT cases can fit in a 9x6x4 box.

If the devices are returned with the Actigraph, the actigraph can be placed in the Sleep Profiler case and the devices can be shipped back together.

If completing Visit 11 over two days, participants may also return the sleep devices to the field center in person at Day 2 of the visit.

6. Ordering Supplies

a. Sleep Profiler

i. The Sleep Profiler kits contain a 50 night supply.
ii. Please contact the Sleep Processing Core to order more kits when you open the last kit box.

b. WatchPAT

i. You will receive 2 shipments of study supplies. The first shipment will occur at the start of the study, and the second shipment will be approximately 6 months later.

c. Expiration dates

i. Study supplies will have an expiration date. When possible, please use the older supplies first to prevent them from expiring.
ii. Please alert the Sleep Processing Core a month before study supplies expire to allow time for new supplies to be delivered to your site.

7. Contact Information

a. Sleep Processing Core Contacts

i. Cristina Toedebusch – toedebuschc@wustl.edu
ii. Rachel Richardson – rachel.dedert@wustl.edu
iii. Allyson Quigley – allysonwuest@wustl.edu
iv. Ashley Hess – hessa@wustl.edu

b. Sleep Equipment Technical Support

i. Sleep Profiler (ABM)

1. Phone support: (760) 720-0099 ext 6032.
2. Email: support@advanced-sleep.com
3. You may also create a ticket on the SP portal by selecting "Tech Support" on the upper right-hand side of the page.

ii. WatchPAT and CloudPAT

1. Phone support: 1 (888) 748-2627
2. Contact request form: https://www.itamar-medical.com/contact-us/

8. Training and Certification

Before implementing the sleep equipment protocol, site staff will undergo certification training by completing the steps listed in the certification checklist below.

Certification checklist:

a. Review this user manual.
b. Review device video tutorials (see Appendix A)

c. Attend in-person training from the Sleep Processing Center. They will provide training on device use and participant education. In-person training will occur in December 2023 and January 2024.
d. Attend virtual WatchPAT training provided by the Sleep Processing Center.

Site staff hired after implementation of the protocol will be trained by a certified member of the site study team.

9. Appendix

a. Sleep Equipment Links

Videos and manuals for the sleep equipment devices can be accessed online.

i. Sleep Profiler

1. Manuals and video assistance: https://cportal.b-alert.com

ii. WatchPAT 300

Ensure when following these links, you refer to the manuals/videos for the WatchPAT 300.

1. Operations Manual: https://www.itamar-medical.com/support/manuals/.
2. Equipment application video: https://www.itamar-medical.com/support/tutorial-videos/
3. Equipment application written instructions: https://www.itamar-medical.com/wp-content/uploads/2023/03/OM2193380-Ed.5-Step-By-Step-Guide-WP300-PQ.pdf

iii. CloudPAT

1. Web Software Operation Manual: https://www.itamar-medical.com/wp-content/uploads/2023/04/OM2200005-edition5.pdf
2. Video tutorials: https://www.itamar-medical.com/cloudpat-tutorials/

b. Site Instructions and Templates

i. Equipment Tracker Template

In the template, there are pages for SP and WatchPAT Device Trackers, SP and WatchPAT Troubleshooting Trackers, and an SP Strip Replacement Tracker. These are optional templates the sites may choose to use to keep track of the study equipment.

1. https://wustl.box.com/s/6164tqpzjgxxmff76sgu1i8dvlr7e3ap