

Manual 33 Accelerometry Procedures ARIC Visit 12

Version 1.1 10/16/2025



Accelerometry Procedures

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0. MANUAL REVISIONS

| Version Number | Date | Author | Section(s) | Description of Update |
|-------------------|------------|---|------------|---|
| 1.0 | 06/23/2025 | Sydney Schultz | All | Updated information for V12, including exclusion for implanted medical devices, specific instructions for fitting participants with the device and initiating the HR sensor via a button press. |
| 1.1 | 10/16/2025 | Kinue Beugre, Alex Dolwick, Sydney Schultz | 1, 3, 6, 7 | Removed references to sleep monitoring study and sleep devices. Updated to reflect that the actigraph instruction sheet and sleep diary are now combined into one document at V12. Removed references to two-day clinic visits as those do not occur at V12. Added instructions to section 3 to address unreadable serial numbers on old devices. Clarified the duration of the HR sensor collection, and added troubleshooting for step in the event the sensor does not initiate. |

1 OVERVIEW

Physical activity is objectively assessed using the Actigraph LEAP accelerometer, an FDA approved, triaxial, water-resistant, wrist-worn device that can be worn 24 hours a day, continuously measuring intensity, duration, and frequency of physical activity. Participants will be fitted with the device during their clinic visit and asked to continue wearing the device at all times for the subsequent 7 days. The accelerometer data will allow for the detection of differences in physical activity and sedentary behaviors.

2 EXCLUSIONS

- Regular use of a walker (cane is OK)
- Implanted medical device that is battery-operated or electrically active (e.g. Pacemaker or Defibrillator (AICD))

3 EQUIPMENT AND SUPPLIES

• Computer/ Laptop

 The computer/laptop must be a Windows device and USB compatible. Windows is required for the ActiSync software, and the activity watch connects to your computer/laptop via a USB connector cable.

Access to the ARIC CentrePoint Website

- o CentrePoint is Actigraph's cloud-based data capture and management platform.
- O Actigraph admin will grant access to the coordinator at each site. Staff should receive an email invitation to join the study on CentrePoint, which will prompt staff to create a username and password. After the coordinators at each site create their accounts, they will be able to add other staff at their site to CentrePoint. Each staff will have their own login credentials.
- CentrePoint is accessed via the following URL: https://studyadmin.actigraphcorp.com/Account/Login

ActiSync software

o ActiSync is a free software provided by Actigraph that needs to be installed for the Actigraph device to communicate with CentrePoint. Please note that ActiSync is

- only compatible with Windows devices. There is a section below with instructions for installing the software.
- Understand that all steps related to data collection and management will be done on CentrePoint – Actisync is solely a driver software used to sync the device with CentrePoint.

• Actigraph LEAP Watch

- Participants will be asked to wear the watch on their non-dominant wrist continuously for 7 days. Before the visit, the watch must be fully charged and assigned to the subject using CentrePoint.
- o In the event that the serial number/ QR code begins to rub off of the back of the watch, connect the device to CentrePoint to obtain the SN and send the SN to the CC. They will use a label maker to make a new SN label and send it to you. Stick it on the back of the watch, careful not to cover the light sensor, skin temp sensor or charger magnet (circled in the photo on the right).

Actigraph LEAP Charging dock/cable

 You will need to use the watch charging dock to fully charge the device. The dock is also used to connect the watch to the CentrePoint website via your computer/laptop.

• CDART Forms

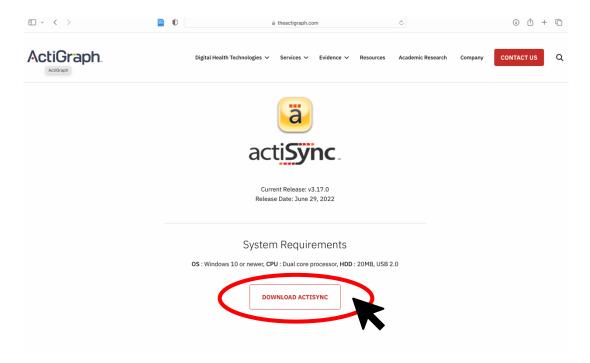
- Accelerometry Form (ACC)
- o Participant Sleep Diary (PSD)
- Paper forms can be found on the ARIC website at the following locations: [Researchers > Cohort Studies > Current and Archived Visit Documents].

• Participant Instructions and Handouts

- Actigraph Instruction Sheet and Sleep Diary
 - Participants will document the time they went to bed and the time they got out of bed.
- Participant instructions and handouts can be found on the ARIC website at the following location: [Researchers > Cohort Studies > Supporting Documents > Visit 12].

4 DOWNLOADING ACTISYNC

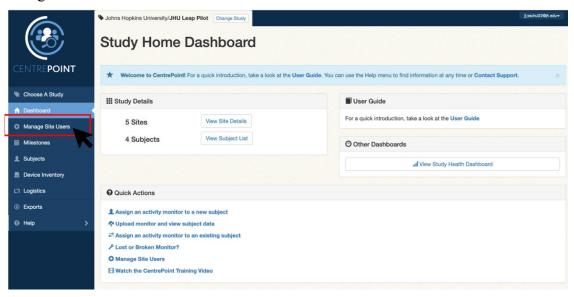
- ** Please note that ActiSync is only compatible with Windows devices.
 - 1. Navigate to the Actigraph website: https://theactigraph.com/actisync
 - 2. On the ActiSync homepage select the "Download ActiSync" button



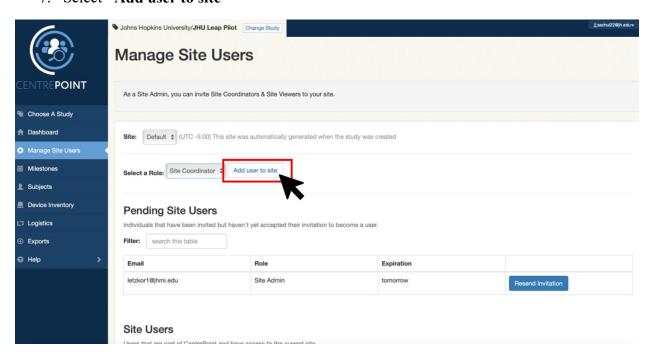
- 3. Open the download and follow the download instructions provided in the pop-up windows.
- 4. Once the software is installed, it will automatically run/open when the LEAP device is connected to your computer/laptop via the USB cable.

5 INVITING USERS TO CENTREPOINT

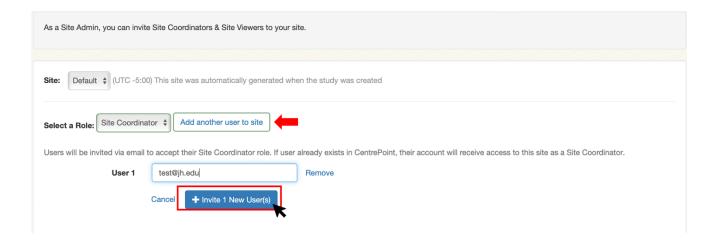
- 1. After the coordinators at each site create their accounts, they will be able to add other staff at their site to CentrePoint. Each staff will have their own login credentials.
- 2. Navigate to the "Study Home Dashboard" in CentrePoint
- 3. From the Study Home Dashboard, navigate to the "Manage Site Users" tab on the left navigation menu.



- 4. To invite staff to the CentrePoint study, first double check the correct site is selected.
- 5. Coordinator's should only have access to their assigned site.
- 6. Select the role for the staff you are inviting
- 7. Select "Add user to site"



- 8. You can invite multiple people at a time. If you'd like to invite another individual, select "Add another user to site"
- 9. Enter the individuals' email and select "Invite New User(s)"
 - Invited users will receive an email from CentrePoint to join the study.
 - Staff should follow all steps in the email to complete the set-up of their CentrePoint login.



6 ADMINISTRATION

6.1 BEFORE THE VISIT

- Ensure that Actigraph is **fully** charged (100% battery life) please note: charging the device may take up to two hours.
- Plug the charging dock into a USB compatible power source (e.g., laptop/computer).

6.2 DURING THE VISIT

- Initialize the Actigraph using ActiSync and CentrePoint. See Section 6.2 for more details.
- Place the Actigraph on the participant's **non-dominant wrist**. Let the participant know that the watch will only display the time and date when the button on the side is pushed.

- Also let the participant know that it is ok to wear the Actigraph while showering it should only be removed if bathing, soaking, or swimming for longer periods of time.
- Go over the Actigraph Instruction sheet and sleep diary with the participant and answer any questions. Let them know that this should be returned with the device.
- On the last page of the Actigraph Instructions sheet, there is place for the technician to write in the date and time for "Your device should be removed from your wrist no earlier than:

 ." The device should be removed at 8am on Day 8 after initialization.

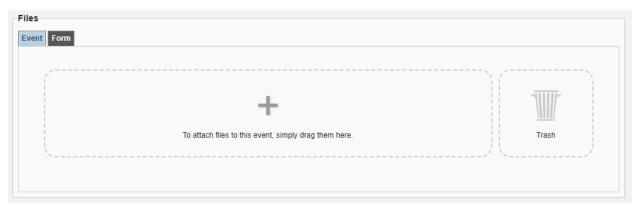
• Complete items 1, 2, 3, 4 (Section A) on the ACC form.

6.3 AT THE END OF VISIT

• Give the participant the Actigraph Instruction sheet and Sleep Diary, as well as the postage-paid padded mailer, and remind him/her of the instructions (wear 24/7, mail the completed Instruction Sheet and Sleep Diary back with the accelerometer in the mailer).

6.4 AFTER THE VISIT – RECEIPT AND UPLOAD

- If the accelerometer has not been returned to the clinic within 2 weeks of the visit, call the participant and remind him/her to mail it back, along with the Sleep Diary.
- Once the accelerometer has been received, upload the data. Complete Section B of the ACC form in CDART.
- Complete the Participant Sleep Diary (PSD) in CDART using the information included in the returned paper Sleep Diary.
- Upload a scanned copy of the paper Sleep Diary to the PSD form in CDART. The file can be attached by dragging and dropping it into the file attachment field at the bottom of the form, or by clicking the plus (+) icon to open up the file explorer.



o If the scanned document contains any PHI, redact any PHI using Adobe.

 Name the uploaded scanned Sleep Diary following this naming convention: ARICID VISIT11 (e.g., X123456_VISIT11)

7 PHYSICAL ACTIVITY MONITORING – ACTIGRAPH

This section describes how to charge the Actigraph LEAP, prepare it for data collection (initialize it), and download the data collected.

The Actigraph LEAP (Actigraph Corp, Pensacola, FL) is an FDA-approved medical device (FDA 510(K): K231532) that we will use as a measure of physical activity, rest/activity rhythms, sleep, oxygen saturation, and heart rate.

Please note that the software for initialization, downloading, and processing the data is called CentrePoint. It is accessible via your internet browser and does not need to be downloaded. The ActiSync software is required to use CentrePoint and must be downloaded and installed to assign the LEAP device to participants and download data through CentrePoint. ActiSync should be installed on one computer at each site. See procedures for installing ActiSync in section 4.

7.1 CHARGING THE BATTERIES

Fully charge the device

Before the visit, make sure that the watch is **fully charged.** Fully charging the watch can take time (1-2 hours), so it's very important that this step is done **prior to the start** of the visit.

• To charge:

- Insert watch onto the LEAP charging dock: the face of the device should magnetically snap into place on the dock.
- Use the charger's USB cable to connect the dock to a USB compatible charging block.

Always use a USB compatible charging block (e.g. phone charging block) to charge the watch. It is possible to charge the watch by plugging into the laptop, but this method takes much longer to complete the charge.

- The watch is fully charged when a solid green battery icon appears on the screen.
- When watch is fully charged, proceed with device initialization (Section 6.2).

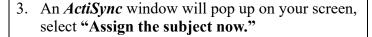




7.2 PREPARING THE DEVICE FOR DATA COLLECTION: INITIALIZATION

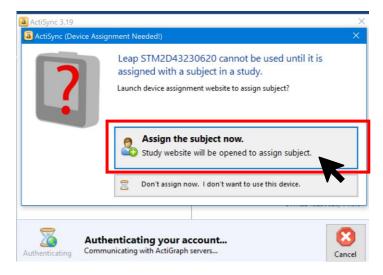
Note: Actigraph LEAP must be fully charged to initialize.

- 1. Obtain a watch that has been fully charged
 - Scan the watch's serial number into field 2 of the ACC form, using the QR code on the back of the LEAP device. The QR code can be scanned directly into CDART using the site's scanner.
- 2. Connect the LEAP device to the charging dock and plug the cable into your computer's USB port.





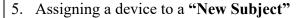




4. Login to CentrePoint

https://studyadmin.actigraphcorp.com/Account/Login

- The CentrePoint login screen will appear automatically.
- Use your assigned CentrePoint username and password.

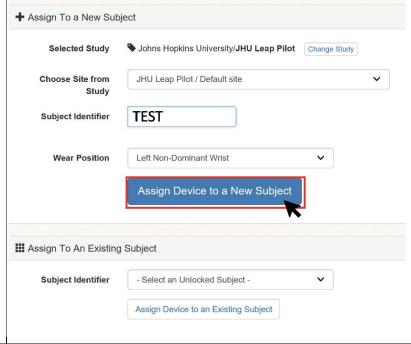


Once logged in, the "**Device Assignment**" screen of the CentrePoint portal appears automatically.

Under the section titled "Assign To a New Subject" fill out the fields as described below:

- **Selected Study:** make sure "ARIC V12" is chosen
- Choose Study Site: Forsyth, Jackson, Minnesota, or Washington
- Subject Identifier: Scan the barcode with the participant's ARIC ID directly into this field in CentrePoint.
- Wear Position: Select non-dominant wrist for ALL.
- 6. Then click on the blue **Assign Device to New Subject** button at the bottom of the page.





7. After the device has been assigned to a subject, allow the progress bar on the "Activity Monitor Assignment" page to reach step 3 and confirm the screen to the right displays with the message "Activity Monitor Configured"

8. The device has been assigned to the subject and can be disconnected from the dock.

9. Once you remove the device from the dock, lay the activity monitor down with the screen facing up. Allow 2 minutes for the device to go from "Halt mode" to "Active mode."

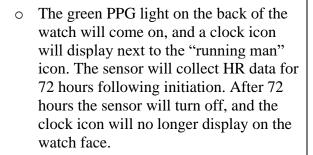


- 10. Confirm that the watch displays a "running" icon in the top left corner. This indicates that the device is in *Active mode* and has begun collecting data.
 - If the device is displaying a syncing icon, this means it is still in Halt mode, and that initialization was not completed.
 - If this happens, it's most likely that the device was disconnected from the dock before the watch was finished configuring.
 - Return the device to the dock and allow the device to finish configuring until the progress bar on the Activity Monitor Assignment page reaches step 3 and displays the green confirmation message.
- 11. Disconnect the device from the charging dock and disconnect the cable from your computer.
- 12. Check that the watch displays the correct time for the subjects' time zone.
 - If the watch does not display the correct time for the subject's time zone reach out to the JHU Accelerometry team (Sydney Schultz sschul22@jh.edu)
- 13. Once the test upload was completed successfully, log out of CentrePoint.

Once you have confirmed that the device is in collection mode, initiate the Heart Rate sensor.

14. Press and hold the event maker button on the right side of the watch face for 4-5 seconds.

The watch will display a blue icon.
 Ensure that all four quadrants of the icon appear, so that an arrow with a clock icon in the middle displays. This will initiate the heart rate sensor.



If the sensor does not initiate following the button press, check that you have created the participant under the right







CentrePoint study. The selected study should be "ARIC V12".

- 15. The watch is ready to be fitted to the participant. To place the device:
 - Fit the device on the participant's nondominant wrist. Adjust the strap so it is snug—tight enough to allow only a pinky finger underneath, but not so loose that it shifts on the wrist.
 - *Please note the device must be fitted properly to the wrist to ensure the heart rate sensor captures accurate readings.



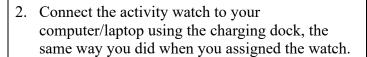
7.3 CLEANING THE ACTIGRAPH LEAP

The Actigraph LEAP should be cleaned between participants. When a participant has returned the LEAP after data collection is complete, clean the LEAP and its wristband thoroughly with an isopropyl alcohol wipe, use a soft toothbrush to loosen debris as needed, then rinse and dry.

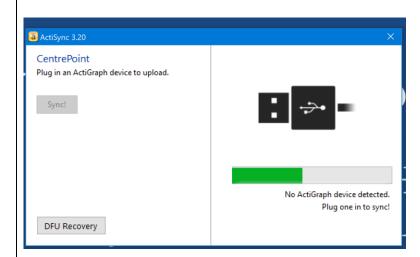
7.4 DOWNLOADING THE LEAP DATA

Once data collection has completed, and the subject has returned the device, data from the LEAP watch will be uploaded to CentrePoint using your Laptop/Computer.

- 1. Before connecting the device to your computer make sure the Actisync software is running on your computer, by checking for the Icon on your task bar
 - If it's not running, open the software. The pop-up to the right should display:



- 3. Once connected, a pop-up screen from ActiSync (shown on the right) will be displayed, and the data will automatically download to the system. This may take a few minutes.
 - If any errors are encountered at this step, please see section 7.5 for troubleshooting steps.





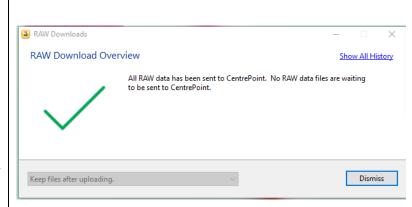


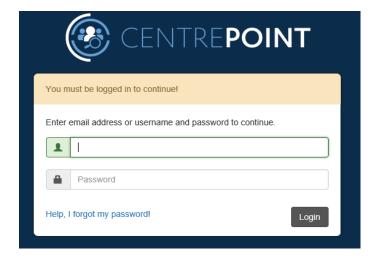
- When the upload is complete, the pop-up screen to the right will be displayed, and you'll be redirected to CentrePoint.
- If the confirmation message does not display or there is any error in the download process, contact the JHU accelerometry team for assistance (Sydney Schultz sschul22@jh.edu).



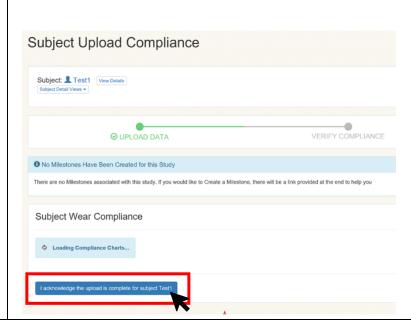
https://studyadmin.actigraphcorp.com/Account/Login

- The CentrePoint login screen will appear automatically.
- Use your assigned CentrePoint username and password.





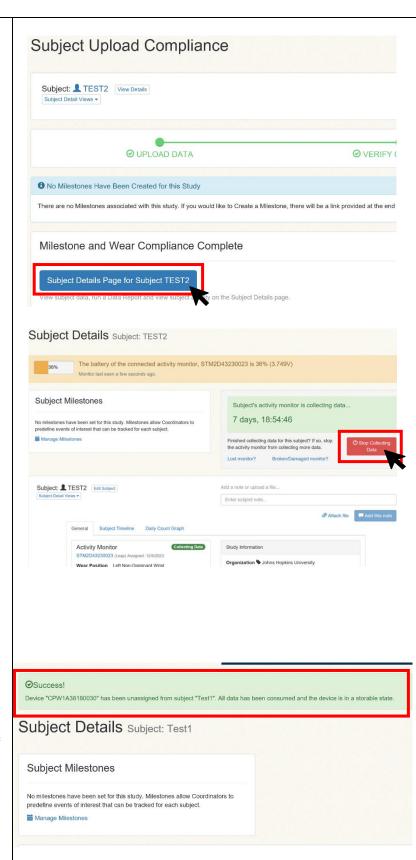
5. Once you've logged in, you'll be taken to the Subject page. Confirm the subject ID displayed at the top of the page matches the ID that is expected for that accelerometer. Click the box that says: "I acknowledge the upload is complete for subject X"



6. Then select the "Subject Details Page for Subject X" button below the "Milestone and Wear Compliance Complete" section.

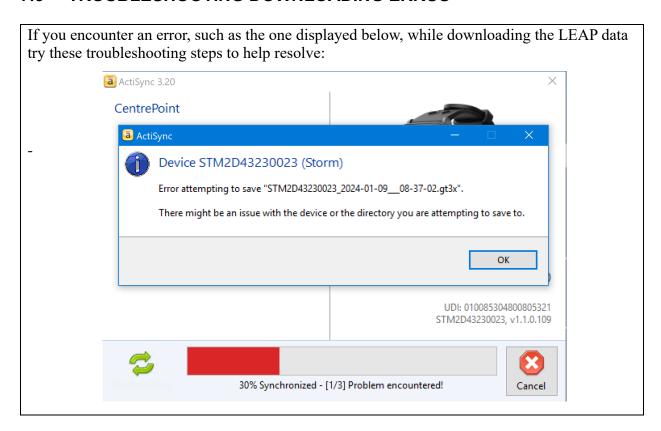
7. Select the "Stop Collecting Data" button on the right-hand side of the page, to stop data collection on the device, and to unassign the device from the participant.

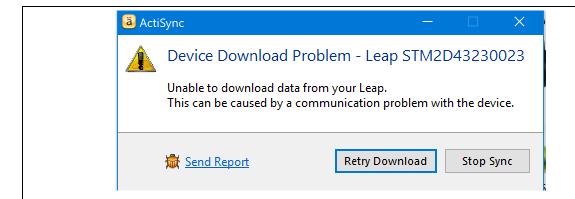
- 8. You will see a green box at the top of the Subject details page confirming that the device has been unassigned from the subject, and that all the data has been consumed from the device.
 - a. **Please note:** it may take several hours for the data to display on the Subject's Details page for the Participant. Once the data has been downloaded from the device and uploaded to the cloud, backend processing of the data in CentrePoint can take a few hours, due to the large size of the data files. For this reason, do



- not be alarmed if data does not display for a subject right away.
- b. If you have received the green "Success!" message (pictured to the right) then at this point, all collected data for this subject has been consumed from the device, and uploaded to the cloud and the device can be assigned to the next subject.
- 9. Data upload for the subject is complete. Sanitize the activity watch and store in a safe place or assign to the next subject.

7.5 TROUBLESHOOTING DOWNLOADING ERROS





First try "Retry Download".

If this fails, and the same error occurs, select "Stop sync". This will stop the syncing process. The watch will still be in *Active mode* (as indicated by the running icon in the top left corner of the watch). Try these troubleshooting steps:

- If you have an extra dock/USB cable, try swapping out the dock/USB cable.
- Try moving the cable to a different USB port on the computer.
- Leave the device plugged in for about 5 to 10 minutes to see if there is any activity or if it goes further than 30%.
- Try plugging the device into a different computer and see if it fully uploads there.
- Try closing the Actisync software, reopening it, and then performing an upload.
- Try fully powering off the computer and then turning it back on and attempting an upload.

If you try these steps, and continue to get the same error, reach out to the JHU Accelerometry team (Sydney Schultz sschultz <a href="s

8 DATA TRANSFER AND RESULTS REPORTING

Data will be sent to the Coordinating Center monthly via electronic data transfer. Data will be reviewed by the JHU team as it is processed.

Accelerometry results will be included in the Visit 11 Summary of Results Report. Participants will receive a printed report that includes the average time spent physically active per day, average sleep duration, and sleep efficiency. Note, average amount of time spent engaged in moderate-to-vigorous physical activity per day is no longer reported at Visit 11. There are no ARIC alerts associated with the accelerometry protocol.

The results template is included as a separate document with this manual on the ARIC website [Researchers > Cohort Studies > Current and Archived Visit Documents > Manuals].

9 TRAINING AND CERTIFICATION

Training will take place over Zoom in 2025. All staff should attend the training or view the training recording.

The examiner requires no special qualifications or experience to perform this assessment. Training will include:

- Read and study the manual
- Practice on other staff or volunteers
- Discuss problems and questions with JHU accelerometry team (Sydney Schultz sschul22@jh.edu)

Certification will include:

- Complete training requirements
- Recite exclusions
- Conduct exam on two volunteers according to protocol, as outlined in this manual

10 DEVICE ORDERING

Sites should contact the JHU accelerometry team (Sydney Schultz sschul22@jh.edu) about ordering additional LEAP watches and wristbands as needed.