



Manual 33
Accelerometry Procedures
ARIC Visit 11

Version 2.1 2/26/2024



Accelerometry Procedures

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0. MANUAL REVISIONS

Version Number	Date	Author	Section(s)	Description of Update
2.0	12/19/2023	Jennifer Schrack, Kiersten Little	All	Updated information for V11, including new device info, new software procedures, training and certification, device ordering, and results reporting.
2.1	2/23/2024	Sydney Shultz	2.0	Added the pacemaker as an exclusion.
2.1	2/23/2024	Sydney Shultz	6.4	Added that the paper Sleep Diary should be scanned and then uploaded to CDART as an attachment to the PSD Form.
2.1	2/23/2024	Kiersten Little	6.2	Specified that the device should be removed at 8am on Day 8 after initialization. This is the time that should be written in the Actigraph Instruction Sheet.
2.1	2/26/2024	Sydney Schultz	7.4	Added that it is expected that data uploads to CentrePoint may take several hours to display on Subject's details page, and to proceed with subsequent device assignment despite.

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.

If the participant is completing Visit 11 over two days, the accelerometer will be initialized and placed on Day 1. The participant should wear the accelerometer concurrently with the sleep devices, if participating in Sleep Monitoring. Note, the Sleep Diary is shared with the Sleep Monitoring Study.

2 EXCLUSIONS

- Regular use of a walker (cane is OK)
- Pacemaker

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**
 - CentrePoint is Actigraph's cloud-based data capture and management platform. You will no longer need to use the Actilife software for initializing devices and uploading data – all of these steps will now be done through CentrePoint.
 - 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**
 - 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.

- **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.

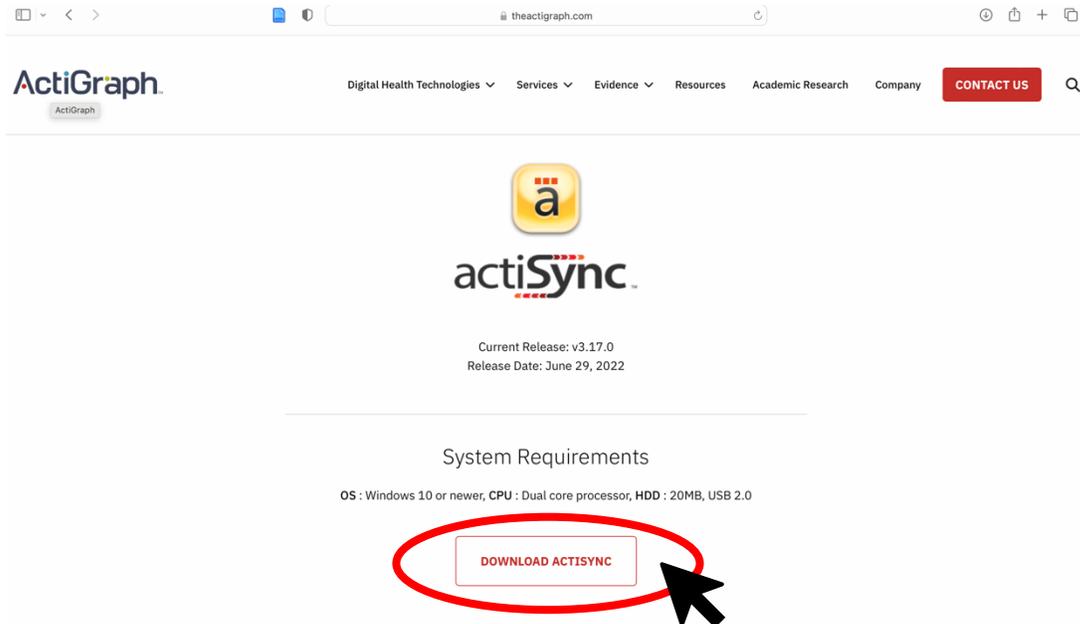
- **CDART Forms**
 - Accelerometry Form (ACC)
 - Participant Sleep Diary (PSD)
 - Paper forms can be found on the ARIC website at the following locations: [Researchers > Cohort Studies > Current and Archived Visit Documents].

- **Participant Instructions and Handouts**
 - Actigraph Instruction Sheet
 - Note, if the participant is also completing Sleep Monitoring, they should receive the Actigraph/Sleep Combined Instruction Sheet instead.
 - Sleep Diary
 - The paper Sleep Diary is shared with the Sleep Monitoring study. Participants will document the time they went to bed and the time they got out of bed. They should also document the days they wore the Actigraph device.
 - Participant instructions and handouts can be found on the ARIC website at the following location: [Researchers > Cohort Studies > Supporting Documents > Visit 11].

4 DOWNLOADING ACTISYNC

** Please note that ActiSync is only compatible with Windows devices.

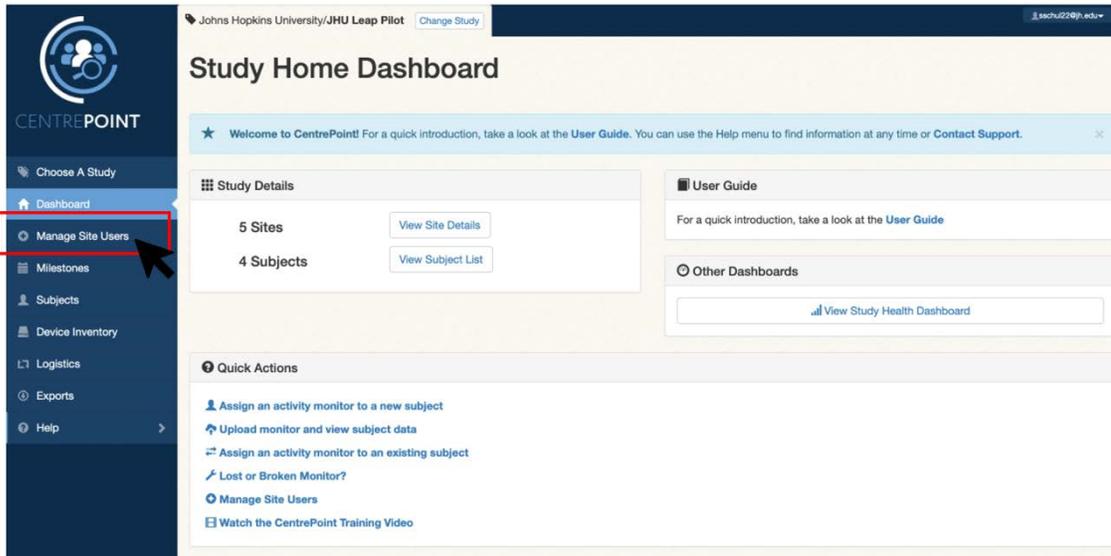
1. Navigate to the Actigraph website: <https://theactigraph.com/actisync>
2. On the ActiSync homepage select the **“Download ActiSync”** button



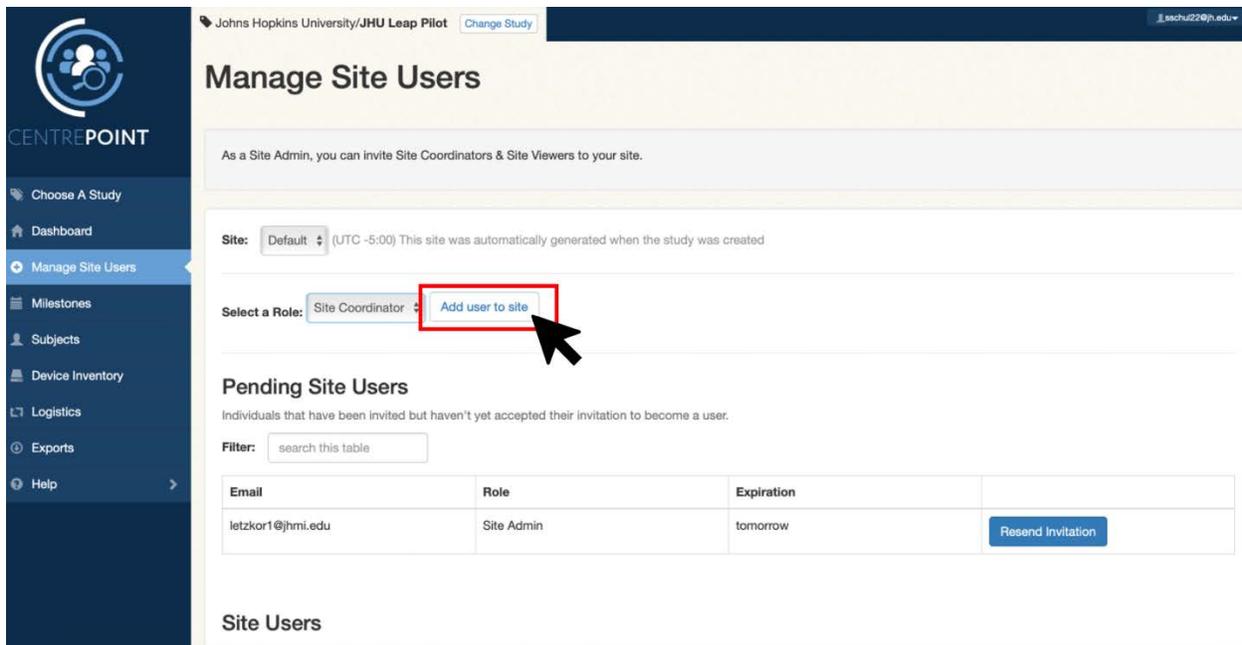
3. Open the download and follow the download instructions provided in the pop-up windows.
4. Once the software is installed, it will automatically run/open when the LEAP device is connected to your computer/laptop via the USB cable.

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 email to complete the set-up of their CentrePoint login.

As a Site Admin, you can invite Site Coordinators & Site Viewers to your site.

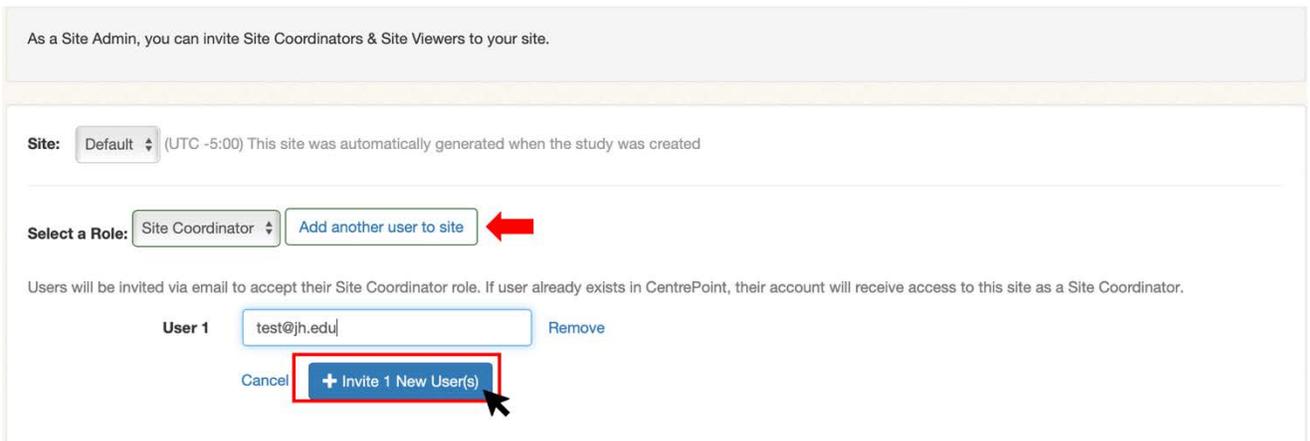
Site: Default (UTC -5:00) This site was automatically generated when the study was created

Select a Role: Site Coordinator Add another user to site

Users will be invited via email to accept their Site Coordinator role. If user already exists in CentrePoint, their account will receive access to this site as a Site Coordinator.

User 1 test@jh.edu Remove

Cancel + Invite 1 New User(s)



6 ADMINISTRATION

6.1 BEFORE THE VISIT

- Ensure that Actigraph is charged – note: the device must be at least 80% charged to initialize and charging 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

If the participant is completing Visit 11 over two days, the Actigraph should be placed on **Day 1**.

- Initialize the Actigraph using ActiSync and CentrePoint. See Section 6.2 for more details.
- Place the Actigraph on the participant **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.

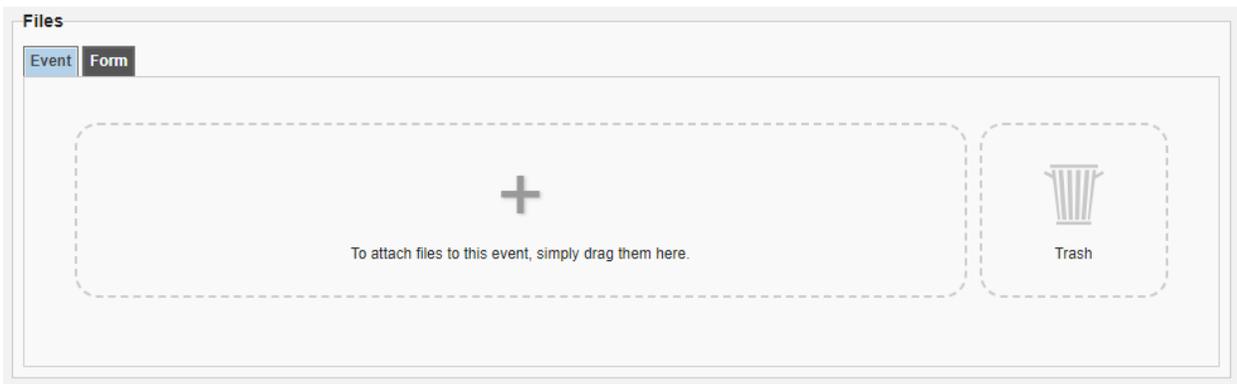
- Go over the Actigraph Instruction sheet with the participant and answer any questions.
 - If the participant is also completing Sleep Monitoring, provide the participant with the Actigraph/Sleep Combined Instruction sheet instead.
- On the last page of the Actigraph Instructions sheet, there is place 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.
- Go over the Sleep Diary with the participant and answer any questions. Let them know that this should be returned with the device.
- 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, Sleep Diary, and the postage-paid padded mailer and remind him/her of the instructions (wear 24/7, mail the completed 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.



- 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.

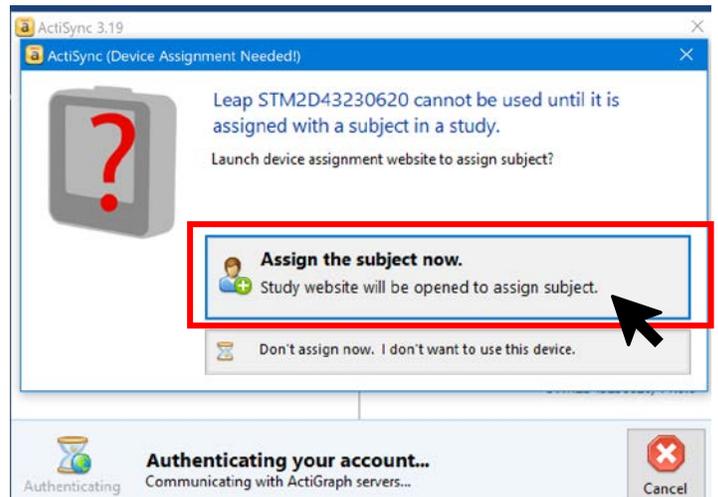
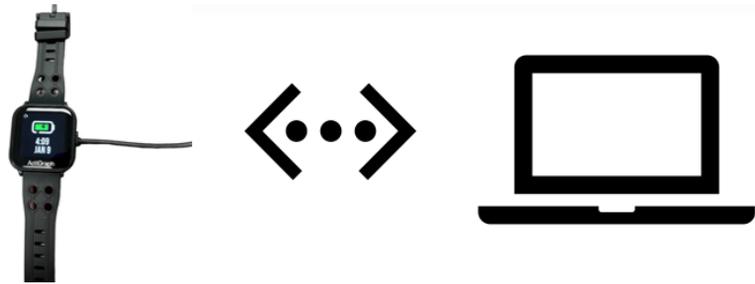
Always use a USB compatible charging block (e.g. phone charging block) to charge the watch. It is possible to charge the watch by plugging into the laptop, but this method takes much longer to complete the charge.
 - The watch is fully charged when a solid green battery icon appears on the screen.
- 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.

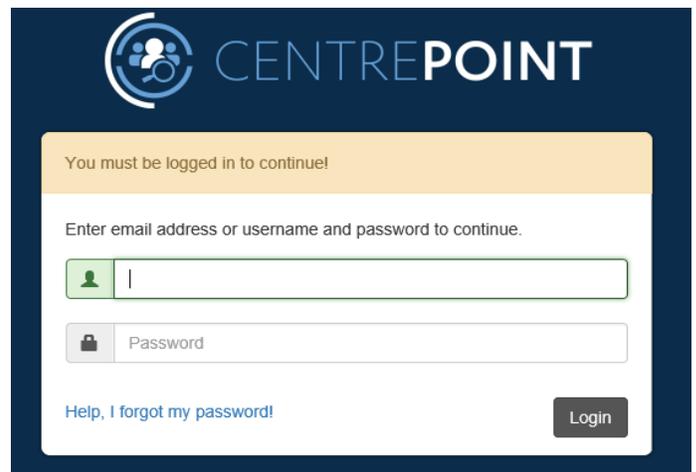
1. Obtain a watch that has been fully charged
 - o Scan the watch's serial number into field 2 of the ACC form, using the QR code on the back of the LEAP device. The QR code can be scanned directly into CDART using the site's scanner.
2. Connect the LEAP device to the charging dock and plug the cable into your computer's USB port.
3. An *ActiSync* window will pop up on your screen, select **"Assign the subject now."**



4. Login to CentrePoint

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

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



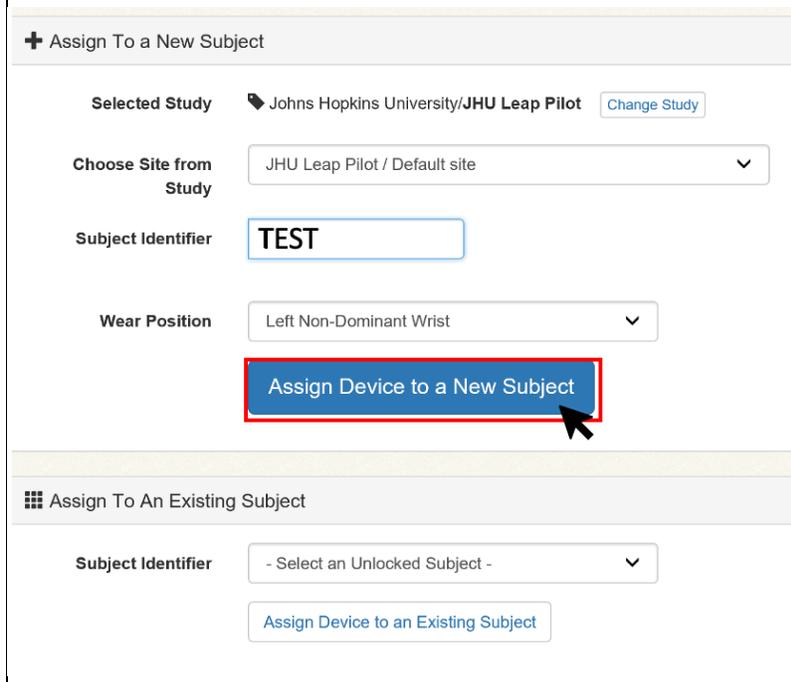
5. Assigning a device to a “New Subject”

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

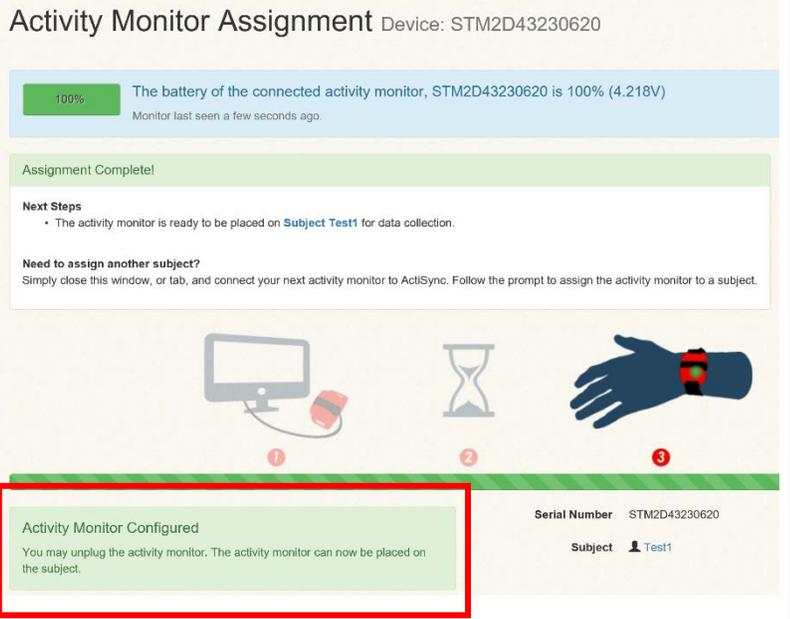
Under the section titled “**Assign To a New Subject**” fill out the fields as described below:

- **Selected Study:** make sure “ARIC V11” 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.

14. **The watch is ready to be fitted to the participant.**

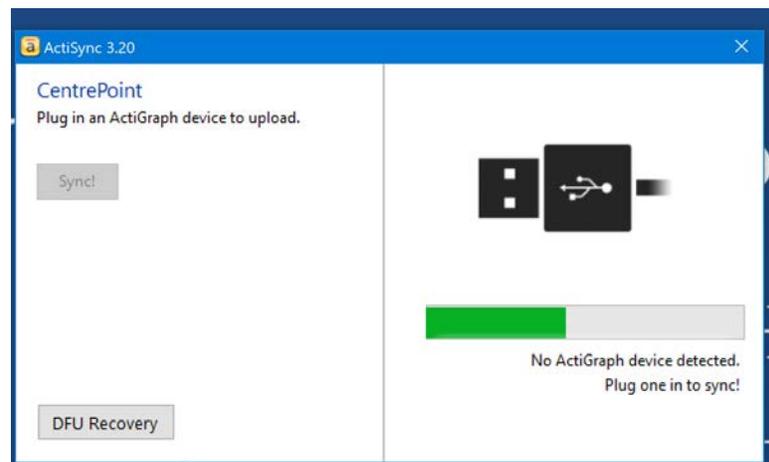
7.3 CLEANING THE ACTIGRAPH LEAP

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.

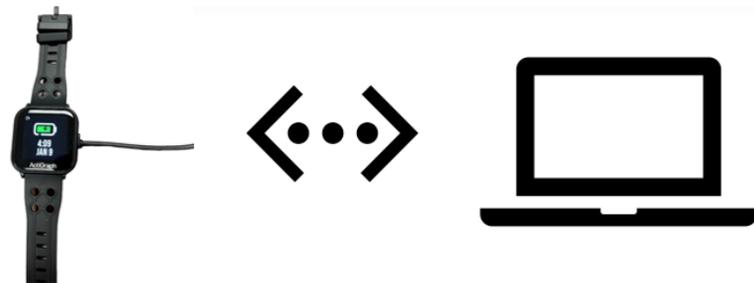
7.4 DOWNLOADING THE LEAP DATA

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:



2. Connect the activity watch to your computer/laptop using the charging dock, the same way you did when you assigned the watch.



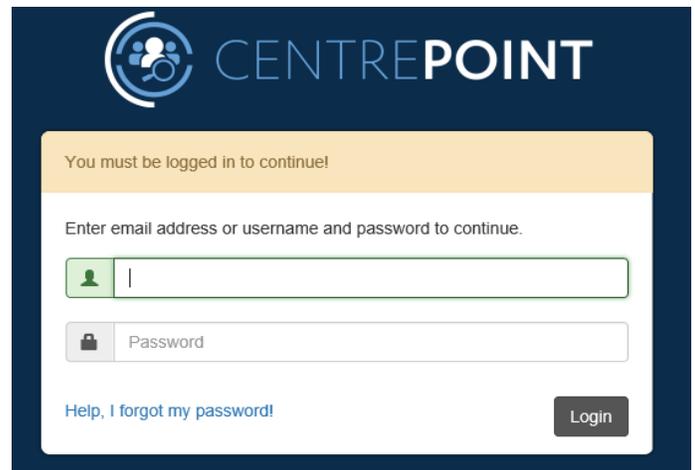
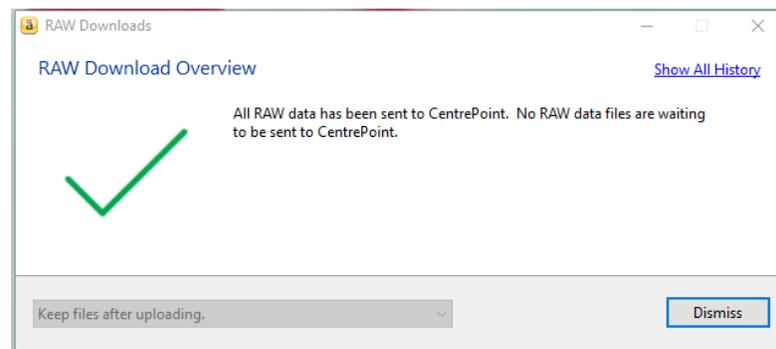
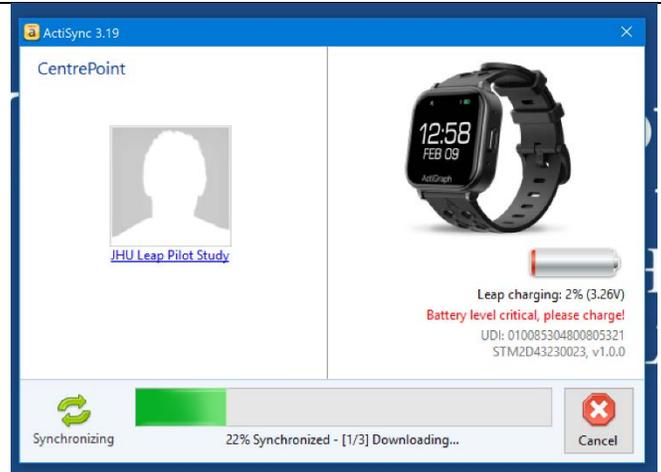
3. Once connected, a pop-up screen from ActiSync (shown on the right) will be displayed, and the data will automatically download to the system. This may take a few minutes.

- 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 ssschul22@jh.edu).

4. Login to CentrePoint

<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.

Subject Upload Compliance

Subject: Test1 [View Details](#)
[Subject Detail Views](#)

● **UPLOAD DATA** ● VERIFY COMPLIANCE

No Milestones Have Been Created for this Study
There are no Milestones associated with this study. If you would like to Create a Milestone, there will be a link provided at the end to help you

Subject Wear Compliance

Loading Compliance Charts...

I acknowledge the upload is complete for subject Test1

Subject Upload Compliance

Subject: TEST2 [View Details](#)
[Subject Detail Views](#)

● **UPLOAD DATA** ● VERIFY COMPLIANCE

No Milestones Have Been Created for this Study
There are no Milestones associated with this study. If you would like to Create a Milestone, there will be a link provided at the end

Milestone and Wear Compliance Complete

Subject Details Page for Subject TEST2

View subject data, run a Data Report and view subject compliance on the Subject Details page.

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.

Subject Details Subject: TEST2

36% The battery of the connected activity monitor, STM2D43230023 is 36% (3.749V)
Monitor last seen a few seconds ago.

Subject Milestones

No milestones have been set for this study. Milestones allow Coordinators to predefine events of interest that can be tracked for each subject.

[Manage Milestones](#)

Subject's activity monitor is collecting data...

7 days, 18:54:46

Finished collecting data for this subject? If so, stop the activity monitor from collecting more data.

[Lost monitor?](#) [Broken/Damaged monitor?](#)

[Stop Collecting Data](#)

Subject: TEST2 [Edit Subject](#)

[Subject Detail Views](#)

Add a note or upload a file...

Enter subject note...

[Attach file](#) [Add this note](#)

General Subject Timeline Daily Count Graph

Activity Monitor

STM2D43230023 (Leap) Assigned: 12/6/2023

Wear Position 1 left Non-Dominant Wrist

Collecting Data

Study Information

Organization Johns Hopkins University

Success!

Device "CPW1A38180030" has been unassigned from subject "Test1". All data has been consumed and the device is in a storable state.

Subject Details Subject: Test1

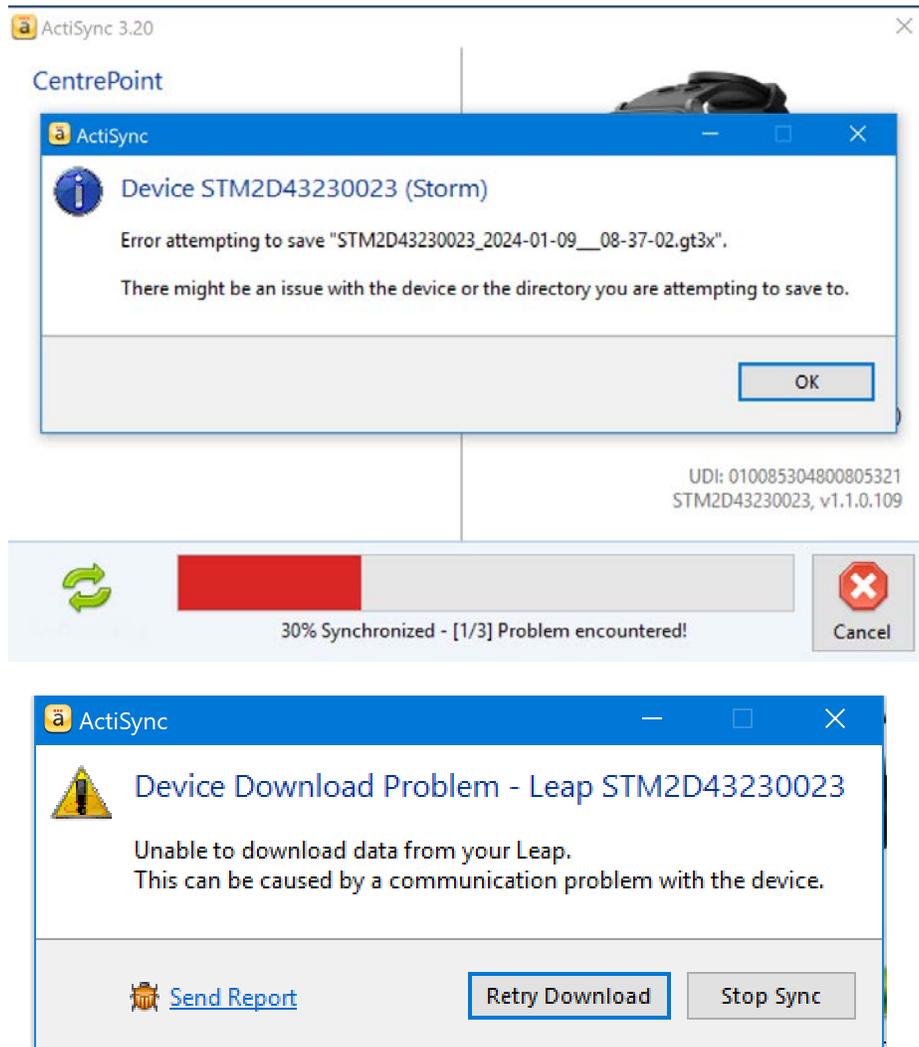
Subject Milestones

No milestones have been set for this study. Milestones allow Coordinators to predefine events of interest that can be tracked for each subject.

[Manage Milestones](#)

7.5 TROUBLESHOOTING DOWNLOADING ERRORS

If you encounter an error, such as the one displayed below, while downloading the LEAP data try these troubleshooting steps to help resolve:



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.^[SEP]
- Try moving the cable to a different USB port on the computer.^[SEP]

- 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 sschul22@jh.edu).

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 January 2024. 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 ssschul22@jh.edu) about ordering additional LEAP watches and wristbands as needed.