



Instructions for
Use

ActiGraph LEAP™

ActiGraph LEAP™ | E.200.6025 | Released: 12/07/2023 | Rev: 0

ActiGraph™

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Instructions for Use

ActiGraph LEAP™



ActiGraph LEAP™ | E.200.6025 | Released: 10/09/2023 | Rev: 0

Overview

ActiGraph LEAP™

The ActiGraph LEAP (LEAP) from ActiGraph captures and records continuous, high resolution acceleration data, which are converted into variety of objective physical activity and sleep measures within the cloud-based CentrePoint software system. This manual provides instructions on how to setup, deploy, and upload data from the LEAP to the CentrePoint software system. The intended user(s) of this LEAP is the participant or end-user.



Technical Specifications

Dimensions	3.85 x 3.9 x 1.225 cm	Dynamic Range	+/- 8G
Weight	24 grams	Communication	USB, Bluetooth® LE 5.3
Sample Rate	32 Hertz (default) - 256 Hertz	Water Resistance	1 meter, 30 minutes
Battery Life	30 days*	Wear Location	Multiple
Data Storage	30 days / 1 GB	Warranty	1 year

*At 32 Hz (default) sample rate.

Intended Use / Indications for Use

The ActiGraph LEAP is a small worn activity monitor designed for documenting physical movement associated with applications in physiological monitoring. The device is intended to monitor the activity associated with movement during sleep. The ActiGraph LEAP can be used to analyze circadian rhythms and assess activity in any instance where quantifiable analysis of physical motion is desirable.

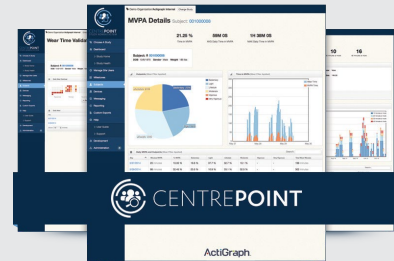
About ActiGraph

ActiGraph is pioneering the digital transformation of clinical research. ActiGraph's medical-grade wearable technology platform has been used to capture real-world, continuous digital measures for nearly 200 industry-sponsored clinical trials and thousands of academic research studies. Appearing in over 22,000 published scientific papers to date, ActiGraph is the most experienced and trusted wearable technology partner in the industry.

Study Package



PC + ActiSync Software



CentrePoint Account



ActiGraph LEAP™



ActiGraph LEAP™ Charger



Wall Plug



CentrePoint Data Hub + Power Cable (optional)

Getting Started

Allow firewall access to the following URLs

Contact your local IT department prior to assigning LEAP(s) to **ensure the following URLs are whitelisted** for open and secure web communication and have access to the ActiGraph services. Please contact support@theactigraph.com for any additional questions or further assistance.

ActiSync Service

<https://studyadmin-actisync-service.actigraphcorp.com>

Connection point for the ActiSync client software order to determine the current assignment status of a device and instruct ActiSync how to proceed

Main Web Portal

<https://studyadmin.actigraphcorp.com>

Site personnel directly accesses this URL to create and monitor participants during the study

Blob Azure Storage

<https://acticlouduploadsprod.blob.core.windows.net>

Allows ActiSync to extract the data from the LEAP and store it on our cloud storage server



Please note: Clicking on the links above does not confirm open access. **URLs must be added to the IT whitelist.** If you are having trouble assigning an LEAP and have not contacted your IT department yet, please do so.

CENTREPOINT® System Requirements

The CentrePoint system is only compatible with **TLS 1.2** or higher security protocols. Contact your local IT department to ensure your systems meet the latest security protocols and have access to the ActiGraph services.

Internet Browsers

- Microsoft Internet Explorer 11 or newer
- Microsoft Edge
- Mozilla Firefox
- Google Chrome

API Integrations

- Java 8(1.8) or higher
- .NET 4.6.2 or newer
- Python 2.7.9 or higher
- Ruby 2.0 or higher
- OpenSSL 1.0.1 or higher
- Mozilla NSS 3.15.1 or higher

Operating Systems

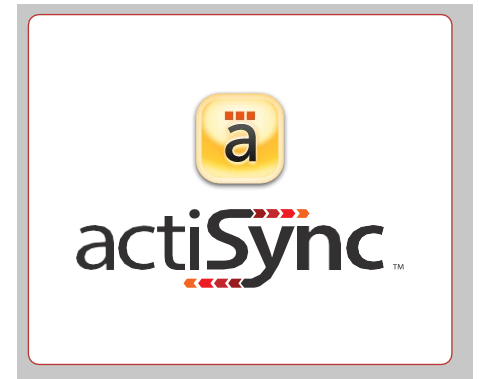
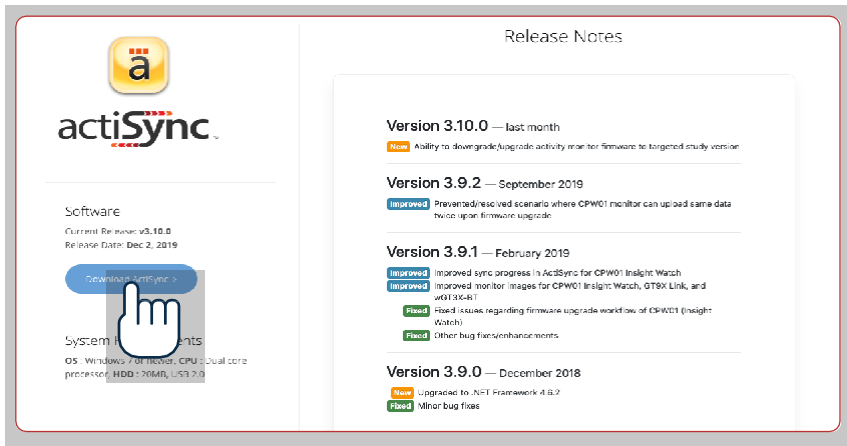
- Windows 10 or newer*

* Sites using operating systems older than Windows 10 (e.g. Windows 7), should contact ActiGraph support for further instructions.

Getting Started | Continued

Install ActiSync software

1. Download the ActiSync software from <https://actigraphcorp.com/actisync>



2. Double click the file to open and follow prompts to complete installation.

ActiSync System Requirements

OS Windows 10 or later (ActiSync is not compatible with MacOS)
CPU Dual core processor | **HDD** 20MB, USB 2.0

Charge the LEAP

The LEAP should be fully charged before assignment and deployment. It takes up to 2-3 hours to fully charge an LEAP. Charging temperature range is 0°C to 40°C.

1. Connect the charging dock to a wall outlet using the supplied wall plug.
2. Connect the LEAP to the ActiGraph LEAP™ Charger by placing the LEAP on top of the charger making sure the charging pins are aligned to the correct grooves on the charger. The LEAP will snap into place magnetically.
3. The LEAP is fully charged once a solid battery icon appears on the screen.



Please note: An Internet connection is not required to charge the LEAP(s).

Assignment

LEAP(s) will be assigned to participants at Visit 1. Participants are instructed to bring the LEAP, charging dock, and all accessories back to the Final Visit, during which the LEAP will be unassigned and returned to inventory.

Assigning an LEAP to a new participant

Assigning an LEAP to a new participant will take approximately 3-5 minutes. Make sure the LEAP is fully charged prior to assignment.

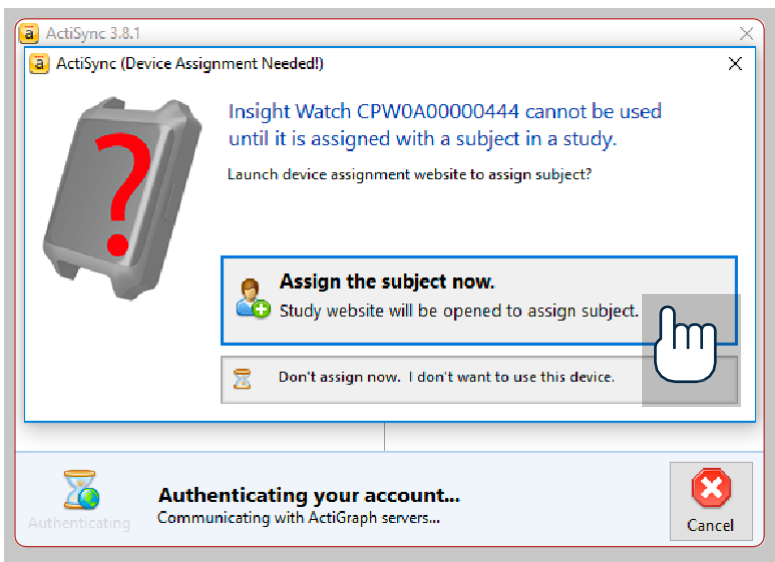
1. Verify that ActiSync is running on the PC by checking for small icon in the taskbar.



2. Connect the charging dock to the computer using the provided USB cable and insert the LEAP into the charging dock.
3. Once connected, the ActiSync icon will turn yellow and a dialog box will open.



4. Select "Assign the subject now."



5. The CentrePoint web portal will open in your web browser.
6. Enter your CentrePoint login information.

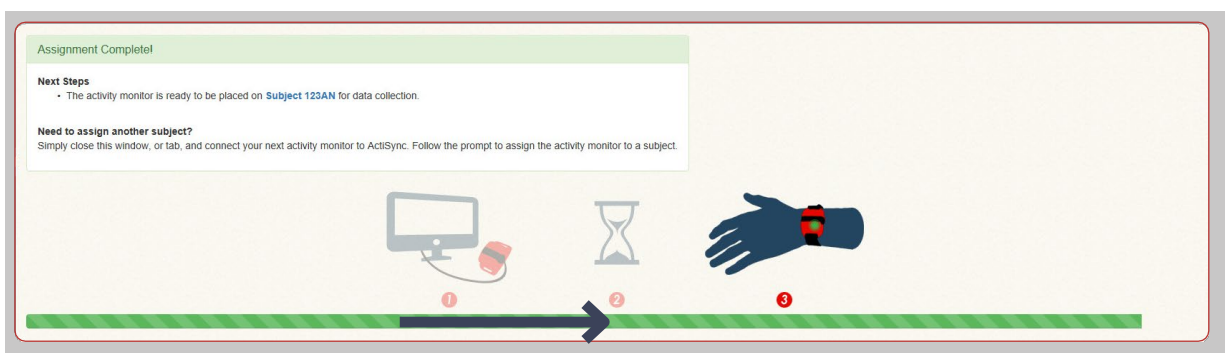
Assignment | Continued

7. Complete **Device Assignment** by entering the following information:

- Site: Select the appropriate site from the dropdown menu. Site coordinators will only have one option available (their site). If you have access to more than one study, select the correct study before you continue with Device Assignment.
- Subject Identifier: This will be six characters long (XXX-XXX), where the first three characters will be prefilled with your site ID and the last three numeric digits are the participant number.
- Date of Birth: (DD-MM-YYYY)
- Weight: (kg or lbs)
- Wear position: Left Non-Dominant Wrist or Right Non-Dominant Wrist.

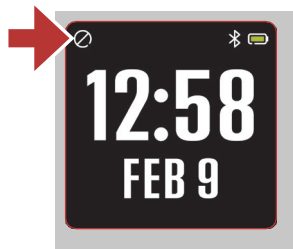
The screenshot shows the CENTREPOINT web interface for Device Assignment. The left sidebar contains navigation links: Choose A Study, Dashboard, Manage Site Users, Milestones, Subjects, Devices (highlighted), Logistics, Exports, Help, Internal Systems, and Administration. The main content area is titled 'Device Assignment' and shows a 'Demo Organization/Demo Study' header with a 'Change Study' button. A green progress bar indicates 99% battery for the connected activity monitor (CPW1A37180213). Below this, a section titled '+ Assign To a New Subject' contains the following fields: 'Selected Study' (Demo Organization/Demo Study), 'Choose Site from Study' (Demo Study / Site 1), 'Subject Identifier' (101-101), 'DOB' (02/09/1980), 'Weight' (155.0 lbs), and 'Wear Position' (Left Non-Dominant Wrist). A blue button labeled 'Assign Device to a New Subject' is at the bottom, with a hand cursor icon pointing to it.

8. Select “Assign Device to a New Subject.” Wait for progress bar to indicate that assignment is complete.



Assignment | Continued

9. Remove the LEAP from the charging dock. Wait for the LEAP to go from halt mode into active mode, as indicated by the running person icon in the upper left corner of the screen. This takes approximately 90 seconds.



Halt Mode

Stop icon will be displayed if the LEAP is not collecting data.



Active Mode

A running person icon will be displayed if the LEAP is collecting data.

10. Pair the CP Data Hub with the LEAP

(If you're not using a CentrePoint Data Hub, skip ahead to **Information for Participants**)

- Connect the adapter end of the power cable into the back of the CP Data Hub and plug the other end into a wall outlet.



- The blue LED status light on the back of the CP Data Hub will flash during startup. It may take up to 20 seconds for the light to begin to flash. Once the CP Data Hub connects to the cellular network, the blue LED light will stay on solid.



- Connect the charger to the USB port on the CP Data Hub using the USB cable.

Assignment | Continued

- Place the LEAP on the charger. Once connected, a progress wheel will appear on the screen indicating that an upload has begun. When the upload is complete, a check-mark will appear on the screen.



Please note: If you see a warning sign on the screen of the LEAP, pull it from the charger and place again. Make sure you see a check-mark on the screen before proceeding to the next step.

11. Verify connection and test upload status in

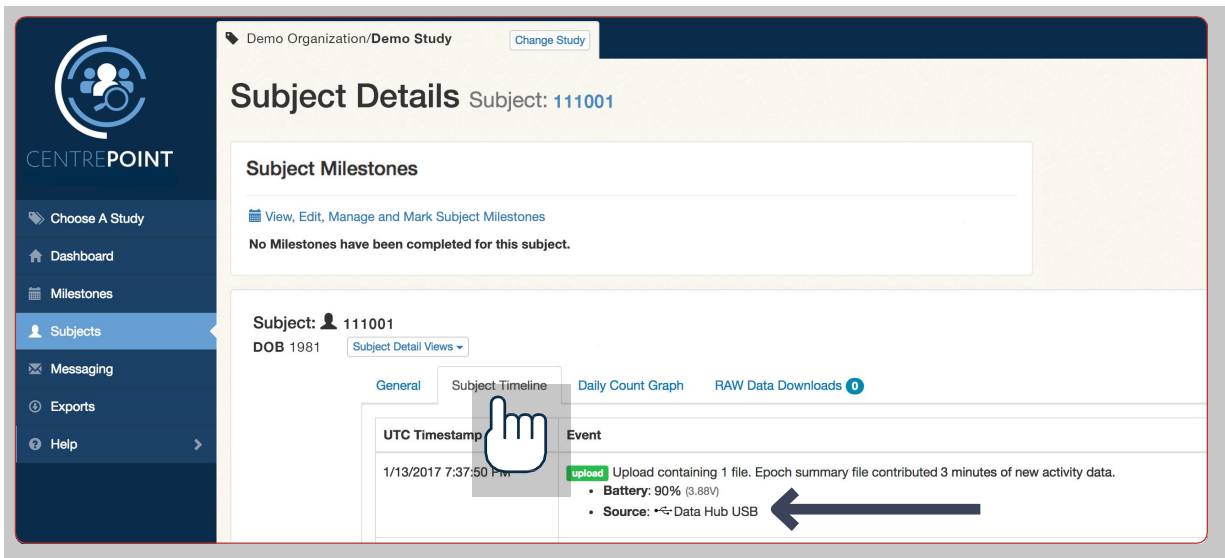
- Login to the CentrePoint web portal. Select the **"Subjects"** tab from the left hand menu, and select the desired subject from the list.

The screenshot shows the CentrePoint web portal interface. The left sidebar contains a menu with options: 'Choose A Study', 'Dashboard', 'Manage Site Users', 'Milestones', 'Subjects' (selected), 'Devices', and 'Messaging'. The main content area is titled 'Study Subjects' and includes a '+ Add New Subject' button, a '- Show All Sites -' dropdown, and a 'Filter By Site' button. Below these are two tabs: 'Quick Reference Subjects' (selected) and 'Detailed Reference Subjects'. A search bar is located to the right of the table. The table has three columns: 'Subject', 'Site', and 'Days Of Data'. The first subject is highlighted with a hand cursor.

Subject	Site	Days Of Data
01017 Female 8/29/197	Site 01	20 days
01018 Female 9/9/1959	Site 01	35 days
01101 Female	Site 01	12 days

Assignment | Continued

- You will be directed to the **"Subject Details"** page. Select the **"Subject Timeline"** tab, and verify that an upload has occurred via Data Hub USB. The LEAP and the CP Data Hub are now paired.



12. Remove the LEAP from the charger by pulling the LEAP away from the charger.



Assignment Completed

Give the LEAP, charger, and all accessories to the participant and provide the following

Wear the LEAP securely on your non-dominant wrist for 24 hours a day for the duration of the study. There is no need to remove the LEAP for bathing or other water activities. There is no need to remove the LEAP at night or during sleep periods.

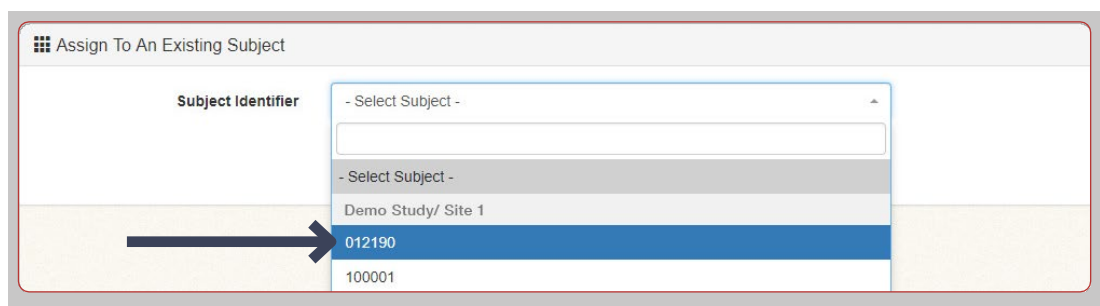
Use the charging dock to fully charge the LEAP once every 3 weeks. Be sure to bring the LEAP, charger, and all accessories back to the Final Visit for a final upload and completion of the assessment.

Assignment | Continued

Assigning an LEAP to an existing participant

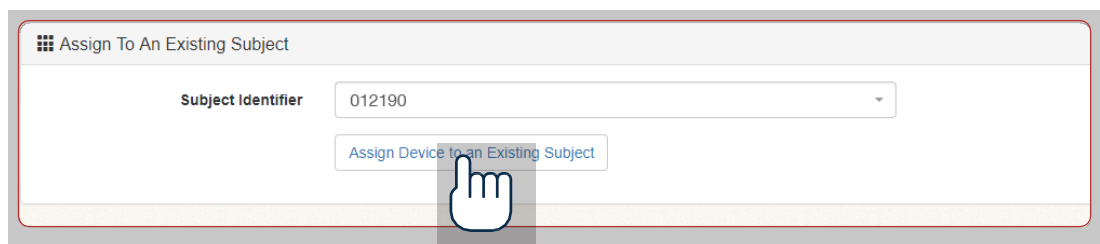
To assign a LEAP to an existing participant (such as in the case of a lost or broken device) or if the visit schedule requires collection and reassignment. Follow these steps to assign a LEAP to an existing participant (such as, in the case of a lost or broken device) or if the visit schedule requires collection and reassignment:

- Complete steps 1- 6 above on page 8.
- Scroll to the bottom of the page and select the corresponding subject identifier from the list.



The screenshot shows a web form titled "Assign To An Existing Subject". It contains a label "Subject Identifier" and a dropdown menu. The dropdown menu is open, showing a list of options: "- Select Subject -", "Demo Study/ Site 1", "012190", and "100001". A blue arrow points to the "012190" option, which is highlighted in blue.

- Select **"Assign Device to an Existing Subject."** Wait for the progress bar to indicate that assignment is



The screenshot shows the same web form, but now the "Subject Identifier" dropdown menu is closed and displays "012190". Below the dropdown menu is a button labeled "Assign Device to an Existing Subject". A hand icon is pointing at the button.



Please note: We encourage the reuse of the previously assigned LEAP that the participant used during the first monitoring period. Otherwise, a new LEAP and watch band should be used.

Information for Participants



How do I wear the LEAP?

Fasten the LEAP to your non-dominant wrist, so the numbers on the screen are not upside down when viewed like a wristwatch. The non-dominant wrist is the one that is not used to write. The LEAP should only be worn by the study participant.

- Wear the LEAP device on your wrist, at least one finger width from the wrist bone.
- Tighten the strap around your wrist.
 - Put the strap into the buckle, tighten until it's applied, without force on the wrist (no move, no space between wrist/strap/device)
 - Tighten one more hole in bracelet
- When you push the wristband upwards, you shouldn't be able to see the sensor's LED
- For the most accurate heart rate measurement
 - We recommend that you put on your device a few minutes before starting the heart rate measurement.
 - It's also advisable to warm up your skin if your hand and wrist get cold easily. Activate your blood circulation before starting your session.

When do I wear the LEAP?

- The LEAP should be worn 24 hours a day according to the schedule below. There's no need to remove the LEAP at night or during sleep periods.
- Be sure to bring the LEAP with you to every site visit. Bring the CP Data Hub, charger, and all other accessories to your final site visit.

Strap Instructions

Pull the strap through the buckle so that it is comfortably taught with no gaps between the strap and your skin but does not compress the skin. Then pull strap to tighten to one more hole past that and insert buckle tongue to secure. The strap should feel secure but comfortable on your wrist.



Please note:

- You may wear the LEAP while bathing or showering. However, remove the LEAP for any water activity that exceeds 1 meter of depth for more than 30 minutes.
- Data will not be negatively affected by lint, dust, or direct sunlight.
- Pets have the potential to destroy a device. Keep devices away from pets and other animals that may chew, bite, urinate on, swallow, and/or destroy a device in any other method imaginable.

Information for Participants | Continued

Charging the LEAP

You will be required to fully charge the LEAP once every 3 weeks, preferably at night time (e.g. before you go to bed). This takes approximately 2-3 hours. Data will be uploaded each time the LEAP is connected to the CP Data Hub.

1. Place the LEAP on the charger by placing the LEAP on top of the charger. The LEAP will snap into place magnetically. A progress wheel will appear on the screen indicating that an upload has begun. When the upload is complete, a check-mark will appear on the screen.



Uploading

Upload Complete



2. While the LEAP is connected to the charger, an animated battery icon will appear on the screen to indicate charging. The LEAP is fully charged once a solid battery icon appears on the screen.



Charging

Fully Charged

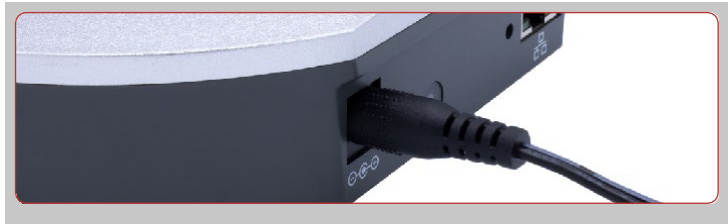


3. Remove the LEAP from the charger by pulling the LEAP away from the charger. Continue wearing the LEAP according to instructions.

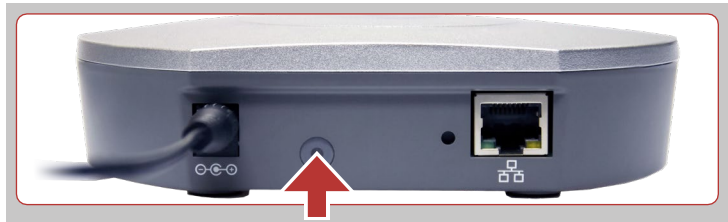
Information for Participants | Continued

Setting up the CentrePoint Data Hub

1. The CP Data Hub should be placed at home in a location where you spend most of your time.
2. Connect the adapter end of the power cable to the back of the CP Data Hub, and plug the other end into a wall outlet.



3. The blue LED on the back of the CP Data Hub will begin to flash during startup. Once the CP Data Hub connects to the cellular network, the blue LED will stay on solid.



4. Once the CP Data Hub is successfully connected, plug the USB cable into the USB port on the side of the Hub, and plug the other end into the charger.



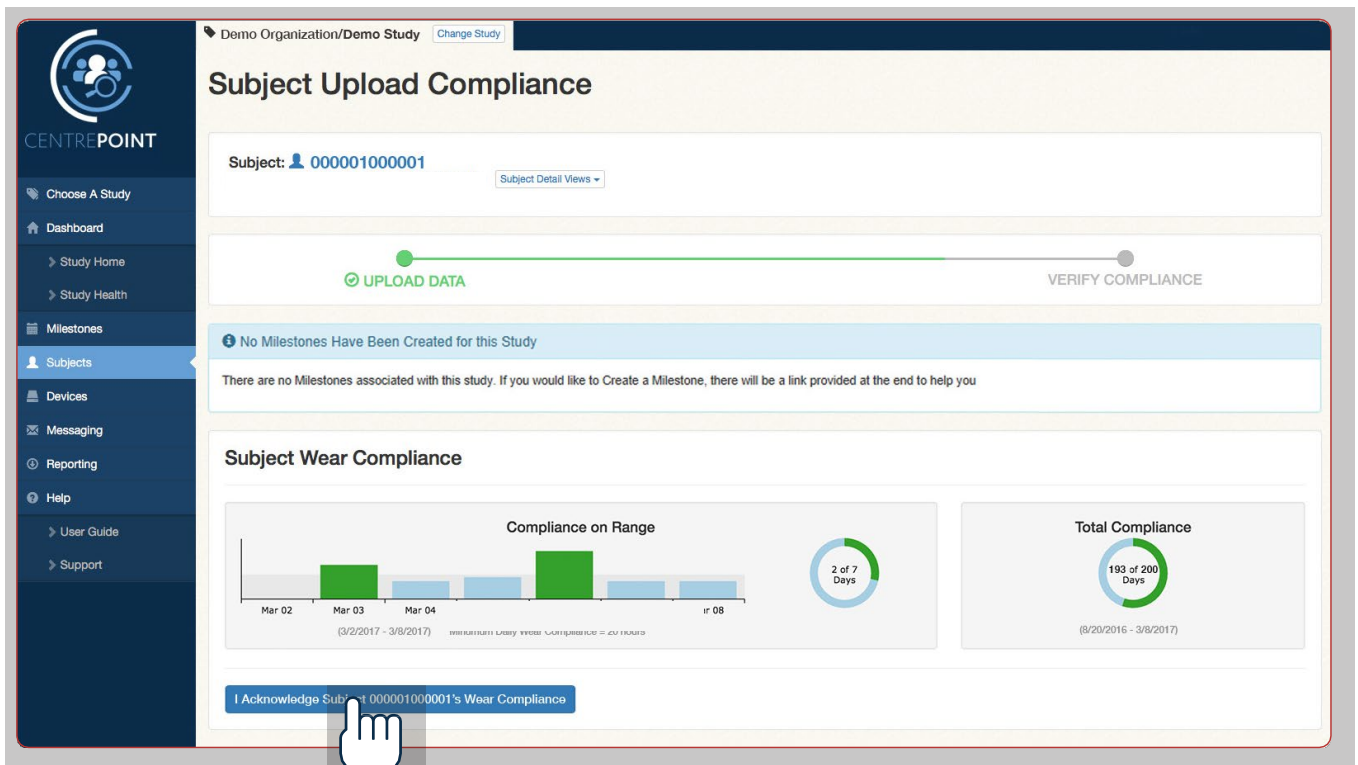
Uploading

Upload LEAP(s)

Participants are instructed to bring the LEAP with them to every site visit, during which sites can upload activity data and review wear compliance.

1. Verify that ActiSync is running on the PC by checking for small icon in the taskbar.
2. Connect the charger to the computer using the provided USB cable and place the LEAP on the charger. The ActiSync icon will turn yellow and the data will begin to upload automatically to the system.
3. Once the upload is complete, a browser window will open to display the **"Subject Upload Compliance"** page.
4. Enter your CentrePoint login information.
5. **Subject Wear Compliance**

Following an ActiSync upload, you will be prompted to acknowledge wear compliance. Please note wear compliance results may take up to 1-2 hours to be processed by CentrePoint. For this study, a day is consider compliant if the LEAP was worn for at least **80% of the time in a 24 hour period**. If the wear compliance summary does not appear, we ask that you still select **"I Acknowledge Wear Compliance."**



6. Remove the LEAP from the charger, and return it to the participant for continued monitoring.

Viewing Participant Data

Go to the CentrePoint Main Portal at <https://centrepoin.actigraphcorp.com> and login using your username and password.

Once logged in, you will be directed to the “Study Home Dashboard” page. All uploads are instantly logged in the “Activity Feed” on the “Study Home Dashboard.”

The screenshot shows the 'Study Home Dashboard' for a 'Demo Organization/Demo Study'. The left sidebar contains navigation links: Choose A Study, Dashboard, Milestones, Subjects, Messaging, Exports, and Help. The main content area includes a 'Study Details' section with '1 Site' and '1 Subject', a 'User Guide' section, and a 'Quick Actions' section. The 'Activity Feed' is highlighted with a red arrow, showing two data uploads for Subject 111 on 3/25/2017.

Activity Feed	
3/25/2017 about a month ago	upload Uploaded data for Subject 111
3/25/2017 about a month ago	upload Uploaded data for Subject 111

To view detailed upload information for a participant, select the “Subjects” tab from the left hand menu, and select the desired subject ID from the list.

The screenshot shows the 'Study Subjects' page for a 'Demo Organization/Demo Study'. The left sidebar contains navigation links: Choose A Study, Dashboard, Manage Site Users, Milestones, Subjects, and Devices. The main content area includes a 'Quick Reference Subjects' section and a 'Detailed Reference Subjects' section. The 'Subjects' list is highlighted with a red arrow, showing two subjects: 111001 and 111002.

Subject	Site	Days Of Data
111001 Female 11/15/1982	RH Demo	1 day
111002 Female 11/30/1982	RH Demo	1 day

Viewing Participant Data | Continued

Go to the “**Subject Details**” page and select “**Subject Timeline.**” Each timestamped data upload is logged and the amount of new data, LEAP battery level, and upload source are provided.

The screenshot shows the CENTREPOINT interface for "Subject Details". The left sidebar contains navigation options: Choose A Study, Dashboard, Milestones, Subjects (selected), Messaging, Exports, and Help. The main content area is titled "Subject Details" and includes a "Subject Milestones" section with a "Manage Milestones" link. A green box indicates "Subject's activity monitor is collecting data..." with a timer at "109 days, 00:35:15" and a "Stop Collecting Data" button. Below this, there's a section for "Subject: 111" with an "Edit Subject" link and a "Subject Detail Views" dropdown menu. The "Subject Timeline" tab is selected, showing a table with columns "UTC Timestamp" and "Event". The table contains one entry for "3/25/2017 5:49:46 PM" with an "upload" event, indicating "Upload containing 1 file. Epoch summary file contributed 11 minutes of new activity data." and listing "Battery: 11% (3.66V)" and "Source: **ActiSync". A blue arrow points to the "Subject Timeline" tab, and a "downloads 0" indicator is visible.

Reviewing wear compliance

To review a participant’s wear compliance, go to the “**Subject Details**” page and select “**Wear Details**” from the drop down menu labeled “**Subject Detail Views.**” The “**Wear Details**” section displays daily details on subject wear time compliance. For this study, a participant is considered wear compliant for the day if the LEAP was worn for **80% of the time in a 24 hour period.** You should review “**Wear Details**” regularly to verify that participants’ wear compliance meets minimum requirements

The screenshot shows the "Wear Time Validation Details" page. The left sidebar is the same as the previous screenshot. The main content area is titled "Wear Time Validation Details" and includes a "Subject: 000014000003" with a "Subject Detail Views" dropdown menu. The "Wear Details" section displays "Algorithm Used: Troiano (2007)" and "Compliant with at least 10 hours Wear: 15 of 35 days". Below this is a "Daily Wear Heatmap" showing a calendar view from April (04/2018) to September (09/2018). The heatmap uses a color scale from 01 to 30 to represent wear time. A blue arrow points to the "Subject Detail Views" dropdown menu, and a hand icon points to the "Wear Details" option.

Unassignment

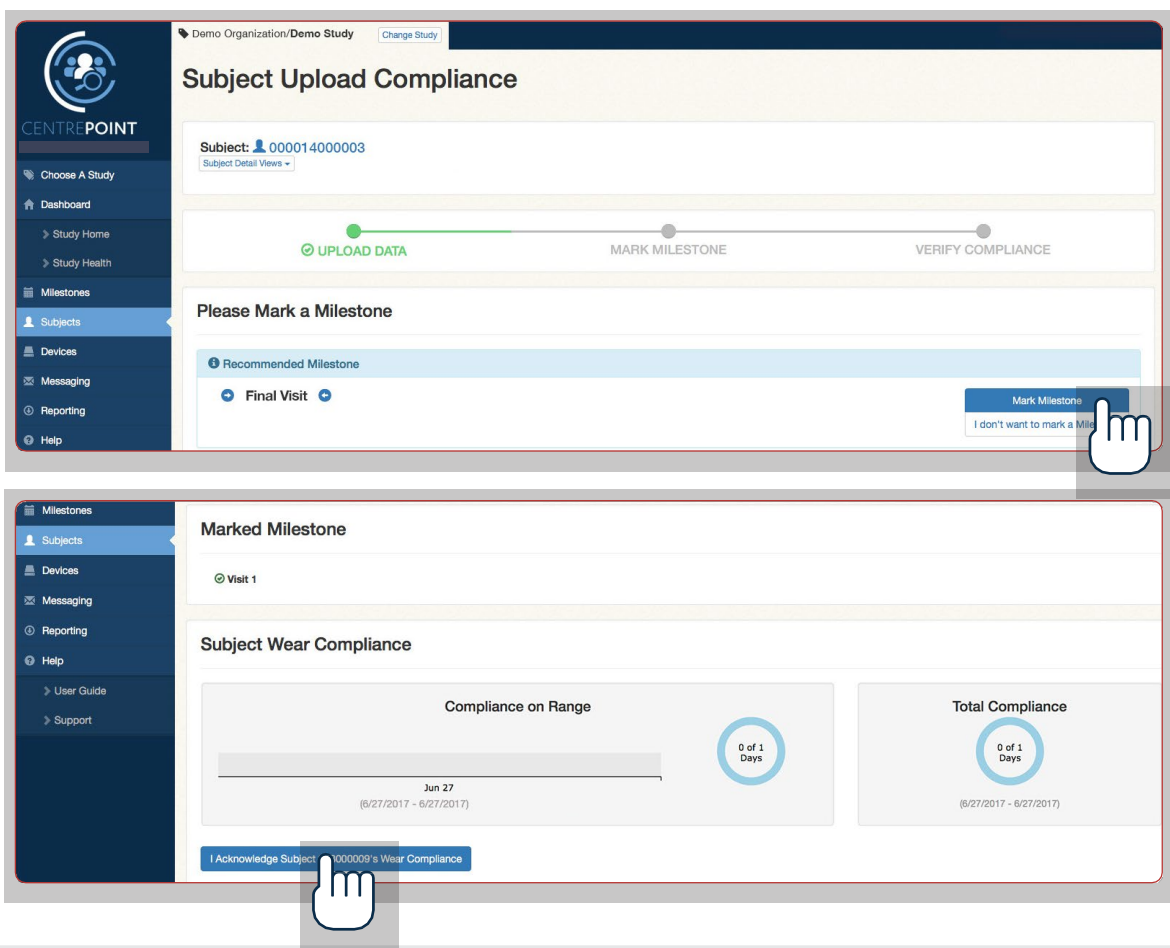
At the Final Visit, the LEAP will be uploaded and unassigned from the participant. Sites will then collect the LEAP(s), charging docks, and all accessories and return them to inventory.

Final data upload and LEAP unassignment

1. Verify that ActiSync is running on the PC by checking for small icon in the taskbar.



2. Connect the charger to the computer using the provided USB cable and place the LEAP on the charger. The ActiSync icon will turn yellow and the data will upload automatically to the system.
3. Once the upload is complete, a browser window will open to display the **"Subject Upload Compliance"** page. Mark the corresponding milestone and select **"I Acknowledge Subject's Wear Compliance."**

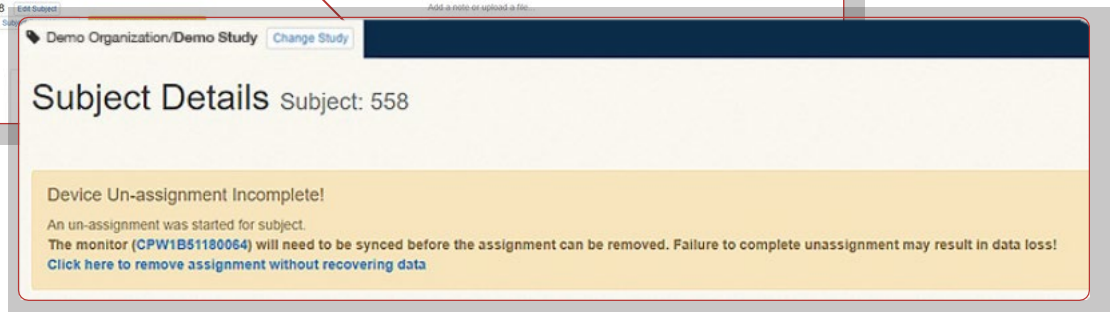
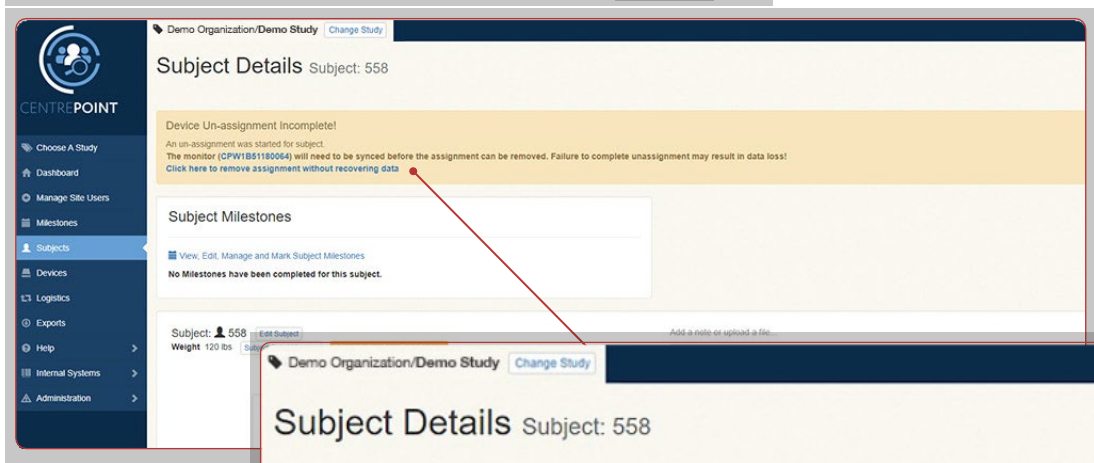
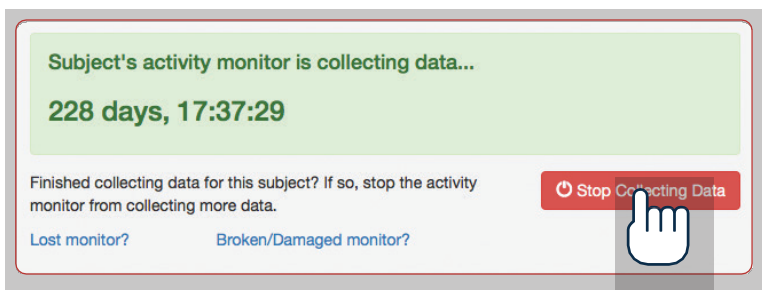


Unassignment | Continued

4. Remove the LEAP from the charger by pulling the LEAP away from the charger.



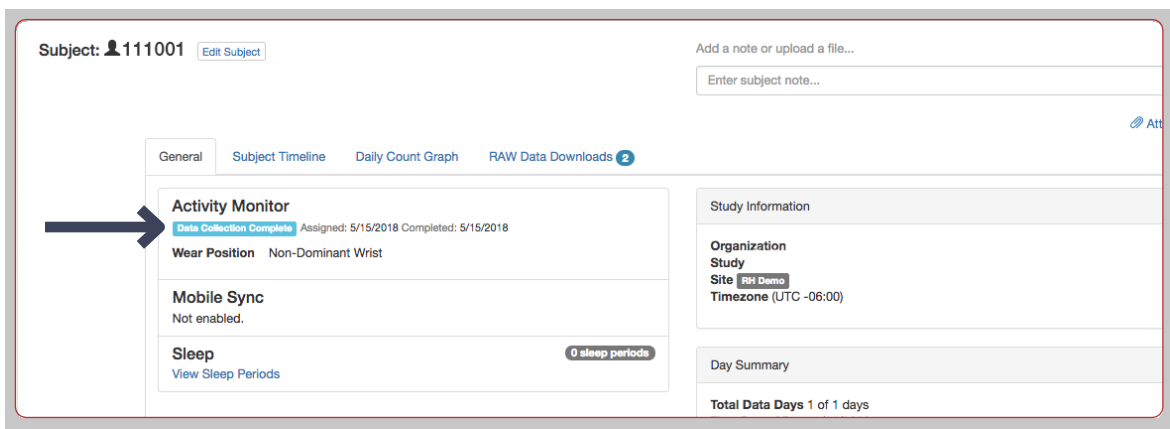
5. From the “Subject Details” page, select “Stop Collecting Data” to remove the participant assignment from the LEAP.



6. Place the LEAP back onto the charger to perform the final upload and complete the unassignment.

Unassignment | Continued

7. A **"Data Collection Complete"** tag will appear in the general tab under the **"Subject Details"**



Subject: 111001 [Edit Subject](#)

Add a note or upload a file...
Enter subject note...

General Subject Timeline Daily Count Graph RAW Data Downloads 2

Activity Monitor
Data Collection Complete Assigned: 5/15/2018 Completed: 5/15/2018
Wear Position Non-Dominant Wrist

Mobile Sync
Not enabled.

Sleep 0 sleep periods
[View Sleep Periods](#)

Study Information
Organization
Study
Site RH Demo
Timezone (UTC -06:00)

Day Summary
Total Data Days 1 of 1 days

8. Collect the LEAP, charger, and all accessories. Clean the LEAP with an alcohol-based solution (wipes or swabs) and store all equipment until the end of the study.

LEAP devices from ActiGraph are approved to be cleaned with a non-abrasive cloth and any alcohol-based solution. For optimal results, apply isopropyl alcohol to the cloth, clean the device for 15-20 seconds, and let air dry. The ActiGraph LEAP devices are not to be sterilized because damage may occur. Although the LEAP devices from ActiGraph are not required to be cleaned on any predetermined schedule, it is advised that the devices be cleaned after each use by a user.

Cleaning the LEAP multiple times during its expected service life will not cause a loss of basic safety or essential performance.



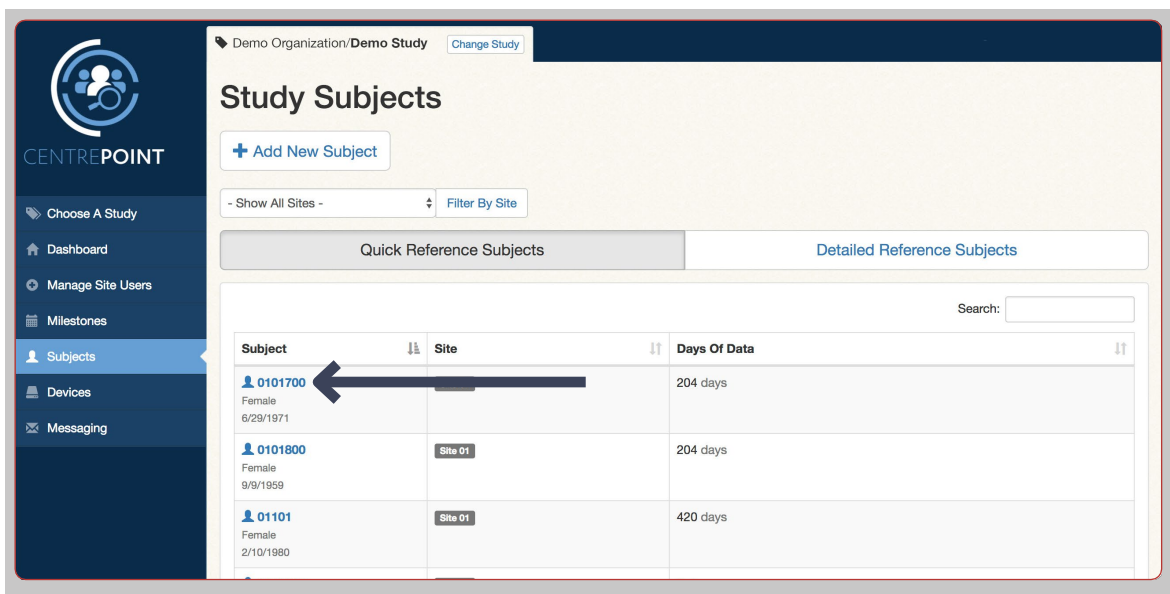
Please note: The ActiGraph LEAP™ (LEAP) and accessories should be cleaned with 70% Isopropyl alcohol between each use. Allow 10 minutes to air dry prior to re-use.

Lost or Broken LEAP(s)

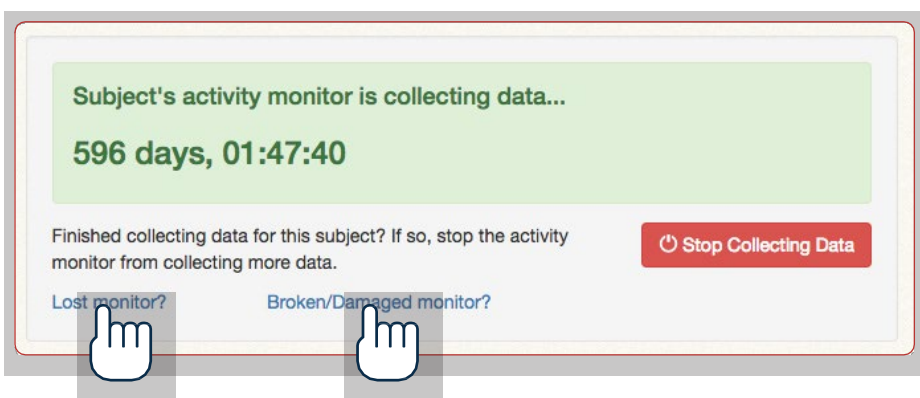
If a LEAP is lost or broken, it must be disassociated from the participant before assigning a replacement. Only one LEAP can be assigned to a participant at any given time.

Lost or broken

1. To disassociate an LEAP, select the **"Subjects"** tab from the left hand menu, and select the desired subject from the list.



2. From the **"Subject Details"** page, select either **"Lost monitor"** or **"Broken/Damaged"**



Lost or Broken LEAP(s) | Continued

3. Select **"Remove monitor assignment from this subject"** to disassociate the LEAP.

Broken/Damaged Activity Monitor?

Subject	0101800	Monitor	TAS1F49160234
Study	Demo Study	Assigned	2/8/2017 1:34:02 PM UTC
Site	Site 01	Last Activity Upload	8/30/2017 1:59:00 PM UTC
Milestone	Visit 2	Last Raw Upload	8/30/2017 1:56:10 PM UTC

Description of Problem

The activity monitor is broken or damaged and will not communicate with the CentrePoint software.

What Can I Do?

If the monitor assigned to this subject is known to be broken or damaged, use this page to remove the assignment of this monitor from this subject. Next, you may assign a replacement monitor to this subject by following the instructions in the [CentrePoint User Guide](#) for reassigning a monitor to an existing subject.

Is it possible to recover data from the damaged monitor?

In some cases it may be possible to recover data from a damaged monitor. Please contact [ActiGraph Support](#) or support@theactigraph.com for more information.

Cancel and go backRemove monitor assignment from this subject

4. To assign a replacement LEAP, follow the instructions on page 11 for assigning a monitor to an existing participant.

Frequently Asked Questions

Q Does the participant wear the LEAP for 24 hours?

The participant should be instructed to wear the LEAP 24 hours a day.

Q On which wrist should the LEAP be worn?

The LEAP should be worn on the non-dominant wrist. The non-dominant wrist is the one that is not used to write.

Q What is the battery life of the LEAP?

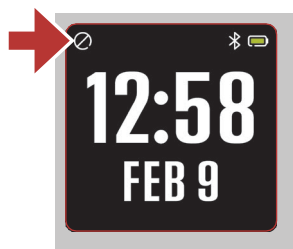
Q When and how often does the LEAP need to be charged?

The participant should be instructed to fully charge the LEAP once every 3 weeks.

Q How long does it take to charge the LEAP?

Q What if the LEAP battery dies in the field?

If the LEAP battery dies, the participant should be instructed to bring the LEAP, charging dock and USB cable back to the site for recharge and reinitialization of the LEAP using the CentrePoint system. Once the LEAP is recharged and reinitialized, verify it is on “**Active Mode**,” and return it to the participant for continued monitoring.



Halt Mode

Stop icon will be displayed if the LEAP is not collecting data.



Active Mode

A running person icon will be displayed if the LEAP is collecting data.

Q What if the LEAP is lost or broken?

If a LEAP is lost or broken, follow the instructions on page 20 to remove the device association and assign a new LEAP to the participant. Report lost or broken LEAP(s) to your Site Administrator and ActiGraph.

Q What should a participant do when traveling?

If a participant is traveling, the participant should be instructed to bring the charging dock and USB cable with them to charge the LEAP.

Frequently Asked Questions | Continued

Q What to do if a participant reports a skin reaction or issue?

If a participant reports a skin reaction from wearing the LEAP or becomes uncomfortable, the participant should be instructed to stop wearing the LEAP immediately and bring it back to the site. The site team should contact ActiGraph Support team for further assistance.

Q What do the lights on the back of the CP Data Hub

- **Blinking blue light:** The CP Data Hub is attempting to connect to the cellular network. If the blinking blue light lasts more than several minutes or happens intermittently throughout the day, remove it from power and wait for the blue light to stop flashing. Once the blue light is off, connect the CP Data Hub back to power and try again. If the problem persists, the CP Data Hub should be moved to a different area with good cellular connection. If the CP Data Hub is still unable to establish a connection, contact your study team to report the problem.
- **Solid blue light:** The CP Data Hub is connected to the cellular network and working properly.
- **Red light:** The CP Data Hub is not working. Contact your study team to report the problem.

Q What is the typical service life of the LEAP and accessories battery?

The only limiting factor of an ActiGraph device, including accessory devices, when calculating life expectancy is the battery. The battery has a life expectancy of five (5) years. The performances of the components inside the device do not degrade over time so the life expectancy of a device is immeasurable.

Q What is the shelf life of the LEAP and accessories battery?

Q What is the time to warm the LEAP to ambient temperature 20°C?

Q What is the time to cool the LEAP to ambient temperature 20°C?

Q What are the packaging materials included in the Participant Package?

The boxes we ship in are 200 lb test-rated cardboard boxes (double ream). The bubble wrap that we use is 1.8 mil - low density polyethylene, ½" thick and also we use a 3/16" thick wrap.

Q What to do at the end of the study?

At the end of the study and after collecting all LEAP(s), chargers, charging docks, and cables, contact our ActiGraph Support team at support@theactigraph.com and provide your Study Protocol, Site Number, and Serial Number of the LEAP(s) being returned. The ActiGraph Support team will provide you with the return shipping label and further instructions.

Regulatory Information

Regulatory Statements

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received including interference that may cause undesired operation. Changes or modifications not expressly approved by ActiGraph, LLC will void the user's authority to operate the equipment under FCC regulations.

- FCC Part 15.107 – AC Conducted Emissions
- FCC Part 15.109 – Radiated Emissions



Please note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help

Regulatory Information | Continued

Regulatory Symbols



WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Use of accessories, transducers, and cables other than those specified or provided by ActiGraph could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ActiGraph LEAP™, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING: Both the ActiGraph Leap device and charger contain magnets. Under certain conditions, magnets and electromagnetic fields might interfere with medical devices. For example, implanted pacemakers and defibrillators might contain sensors that respond to magnets when in close contact. To avoid any potential interactions with these types of medical devices, keep this device and charger a safe distance away from your medical device (more than 6 inches / 15 cm apart). Consult with your physician and your medical-device manufacturer for specific guidelines.

If you suspect that your ActiGraph Leap device or charger is interfering with your medical device, stop using your ActiGraph Leap device and consult your physician and your medical-device manufacturer.

CAUTION: Do not simultaneously wear and charge, service, or provide any maintenance on the product.

CAUTION: Transport and storage of this product outside of the temperature range of -20° C to 55° C, 15 - 90%, non-condensing 700 hPa to 1060 hPa could lead to dangerous conditions.

CAUTION: Operating this product outside of the temperature range of 0° C to 40° C could lead to dangerous conditions.

CAUTION: Modification to ActiGraph products are not permitted and will void all warranties if tampered and/or modified. Do not modify the product in any way as this can be unsafe to the end user.

CAUTION: Do not swallow any part of this product. If a piece has been swallowed, contact your local poison control hotline or seek medical attention as soon as possible.

NOTICE: No precautions need to be taken in the event of changes in the performance of the product.

NOTICE: Product does not have any contraindication(s)

NOTICE: Only use ActiGraph's approved charging dock to charge the device. Do not connect the device to anything else but a computer and an ActiGraph approved product or accessory.

NOTICE: Only use ActiGraph's approved USB cables with the charging dock.

NOTICE: The ActiGraph LEAP™ may be used in any instance where quantifiable analysis of physical motion is desirable.

NOTICE: ME Equipment charged via certified external power supply with input rated 90-264 Vac and output of up to 5Vdc.

Regulatory Information | Continued

Regulatory Symbols



CAUTION:

- Replacement of battery with an incorrect type that can defeat a safeguard (for example, in the case of some lithium battery types);
- Disposal of a battery into fire or a hot oven, or mechanically crushing or cutting of a battery, that can result in an explosion;
- Leaving a battery in an extremely high temperature surrounding environment that can result in an explosion or the leakage of flammable liquid or gas;
- A battery subjected to extremely low air pressure that may result in an explosion or the leakage of flammable liquid or gas.

FCC RADIATION EXPOSURE

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

ISED RADIATION EXPOSURE

This equipment complies with IC RSS-102 radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Cet équipement est conforme aux limites d'exposition aux radiations IC CNR-102 établies pour un environnement non contrôlé. Cet émetteur ne doit pas être colocalisé ou fonctionner en conjonction avec une autre antenne ou un autre émetteur.

Regulatory Information | Continued



Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

AUSTRALIAN SPONSOR
Emergo Australia
Level 20, Tower II
Darling Park
201 Sussex Street
Sydney NSW 2000
Australia

Emergo Consulting (UK) Limited
c/o Cr360 – UL
International
Compass House, Vision
Park Histon
Cambridge CB24 9BZ
United Kingdom

Authorized Representative in European Community

ActiGraph's Australia Sponsor

Indicates ActiGraph's authorized Australian Sponsor.

ActiGraph's United Kingdom Sponsor

Indicates ActiGraph's authorized United Kingdom Sponsor.



Catalog Number

Indicates the manufacturer's catalogue number so that the medical device can be identified for reordering.



CE Symbol

By affixing the CE marking to a product, a manufacturer declares that the product meets all the legal requirements for CE marking and can be sold throughout the EEA. ActiGraph's products abide with the Medical Device Directive 93/42/EEC and Radio Equipment Directive 2014/53/EU.



"Este equipamento não tem direito à proteção contra interferência prejudicial e não pode causar interferência em sistemas devidamente autorizados. Para maiores informações, consulte o site da ANATEL – www.anatel.gov.br

Brazil National Telecommunications Agency (ANATEL) Homologação Number

This equipment operates on a secondary basis, that is, not entitled to protection from harmful interference, even for stations of the same type, and may not cause interference to systems operating on a primary basis.



Consult Instructions for Use

Indicates the need for the user to consult the instructions for use.



STM2XXXXXXXXX

Serial Number

Indicates the manufacturer's serial number so that a specific medical device can be identified. The manufacturing date is included in the serial number.

Regulatory Information | Continued



Manufacturer

ActiGraph is the medical device manufacturer and is located at 70 North Baylen Street, Suite 400. Pensacola, Florida 32502.



Operating Temperature Range

Indicates the operating temperature range to which the medical device can be safely exposed.



Storage Temperature Range

Indicates the operating temperature range to which the medical device can be safely stored.



Recycle: Electronic Equipment

Indicates the medical device should not be disposed of in the trash. Contact ActiGraph Customer Service regarding the disposal of these products.



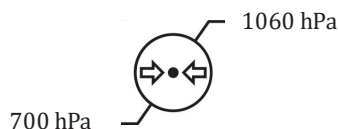
Lithium Ion (EU)

Indicates the lithium ion battery within the device should not be disposed of in the trash. Contact ActiGraph Customer Service regarding the disposal of these batteries.



Humidity Range

Indicates the operating humidity range to which the medical device can be safely exposed.



Atmospheric Pressure

Indicates the operating atmospheric pressure to which the medical device can be safely exposed.



Type BF Applied Part

The LEAP is compliant with IEC (International Electrotechnical Commission) standards for “Type BF Applied Part” - meaning it complies with requirements for user protection against electrical shock. The housing of the device is the only part that is to come into contact with the end user and is made out of copolymer. If you have any allergic reactions to copolymer materials, please consult your doctor before using an ActiGraph device.

Regulatory Information | Continued



FCC ID: DFW-05

Part 15 FCC Rules

FCC Part 15 is a federal regulation that sets limitations on the amount of electromagnetic interference allowed from digital and electronic devices such as wristwatches, musical instruments, computers, telephones, and low power transmitters.



YYY-XXXXXX

Giteki

GITEKI CERTIFICATION (TECHNICAL STANDARDS CONFORMITY CERTIFICATION AND CONSTRUCTION DESIGN CERTIFICATION)



UKCA

By affixing the UKCA marking to a product, a manufacturer declares that the product meets all the legal requirements for UKCA marking and can be sold throughout the UK.



CSEM

Centre Suisse d'Electronique et de Microtechnique (swiss center of electronic and microtechnology) CSEM is the PPG experts and ActiGraph's partners in developing the PPG portion of ActiGraph LEAP™ device.

Rx Only

Rx Only

Caution: U.S. Federal law restricts this device to sale by or on the order of physician or other a practitioner for use in the course of his professional practice.

Regulatory Information | Continued



RCM

An RCM compliance label indicates a device has been certified by the supplier as meeting any applicable, and the standards that apply to that device.

IC

IC: 10333A-05

ISED COMPLIANCE

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

1. This device may not cause interference.
2. This device must accept any interference, including interference that may cause undesired operation of the device.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

1. L'appareil ne doit pas produire de brouillage;
 2. L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.
-

CMIIT-ID

CMIIT-ID

This product has received the SRRC Type Approval certification in compliance with Chinese standards for radio transmission equipment. The SRRC Certificate is issued by MIIT (Ministry of Industry and Information Technology).

Support Information

How do I contact support in case help is needed?

Go to theactigraph.com/support for user manuals, frequently asked questions, and a common knowledge database with step-by-step solutions. Contact the ActiGraph Support team via email at support@theactigraph.com, or call the U.S. toll free number +1 (877) 497-6996 from Monday to Friday 8am-5pm CST. **Please provide Study Protocol and Site Number.**

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70 North Baylen Street, Suite 400. Pensacola, FL 32502
+1 (850) 332-7900 | +1 (877) 497-6996 (U.S. toll free)
support@theactigraph.com



Please note: If an ActiGraph device is broken, malfunctioning, or does not appear to be working as intended, the participant should stop wearing it immediately and return it to the site. The site team should then return the device to ActiGraph.