CENTRE**POINT** Insight Watch

ActiGraph™

User Guide

CENTRE**POINT** Insight Watch

Model: CPW01 | E.200.6002 | Released: 03/22/2024 | Rev: 8

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Overview

CENTRE**POINT** Insight Watch

The CentrePoint Insight Watch (CPW01) 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 CPW01 to the CentrePoint software system. The intended user(s) of this CPW01 is the participant or end-user.
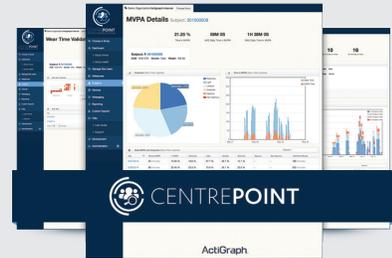
Dimensions	5.01 x 3.46 x 1.05 cm	Dynamic range	+/- 8G
Weight	14 grams	Communication	USB, Bluetooth® LE 5
Sample rate	32 Hertz (default) - 256 Hertz	Water resistance	1 meter, 30 minutes
Battery life	30 days*	Wear location	Wrist
Data storage	30 days/512 MB	Warranty	1 year

*At 32 Hz (default) sample rate.

Study **Package**

PC + ActiSync Software

CentrePoint Account

CP Insight Watch (CPIW01)

Charging Dock

USB Cable

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 CPW01(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 CPW01 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 a CPW01 and have not contacted your IT department yet, please do so.

CENTRE**POINT** 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
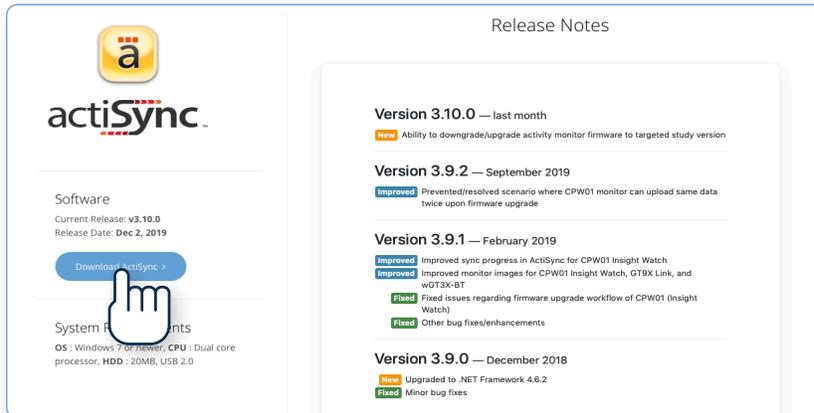
Operating Systems

- Windows 10 or newer*

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

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 CPW01

The CPW01 should be fully charged before assignment and deployment. It takes up to 2-3 hours to fully charge a CPW01. Charging temperature range is 0°C to 45°C.

1. Connect the charging dock to a wall outlet using the supplied wall plug.

2. Connect the CPW01 to the charging dock by pulling the plastic tab on the dock to the left and inserting the CPW01 with the screen facing up and the button on the opposite side of the charger cable.

3. The CPW01 is fully charged once a solid battery icon appears on the screen.

💡 **Please note:** An Internet connection is not required to charge the CPW01(s).

Assignment

CPW01(s) will be assigned to participants at Visit 1. Participants are instructed to bring the CPW01, charging dock, and all accessories back to the Final Visit, during which the CPW01 will be unassigned and returned to inventory.

Assigning a CPW01 to a new participant

Assigning a CPW01 to a new participant will take approximately 3-5 minutes. Make sure the CPW01 is fully charged prior to assignment.
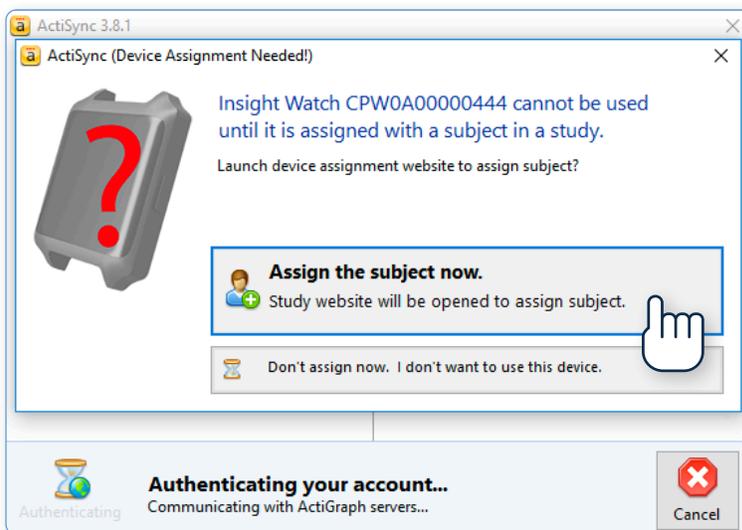
1. Verify that ActiSync is running on the PC by checking for small icon in the taskbar.

2. Connect the charging dock to the computer using the provided USB cable and insert the CPW01 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.

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

Assignment | Continued

9. Remove the CPW01 from the charging dock by pulling the plastic tab to the right and away from the CPW01. Wait for the CPW01 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 CPW01 is not collecting data.

Active Mode

A running person icon will be displayed if the CPW01 is collecting data.

10. **Pair the CP Data Hub with the CPW01**

(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.

USB Port   Power   Status Light

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

Assignment | Continued

- Insert the CPW01 into the charging dock. 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.

Upload in Progress

↓

Upload Complete

⚠ **Please note:** If you see a warning sign on the screen of the CPW01, remove it from the charging dock and insert 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 CentrePoint

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

- 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 CPW01 and the CP Data Hub are now paired.
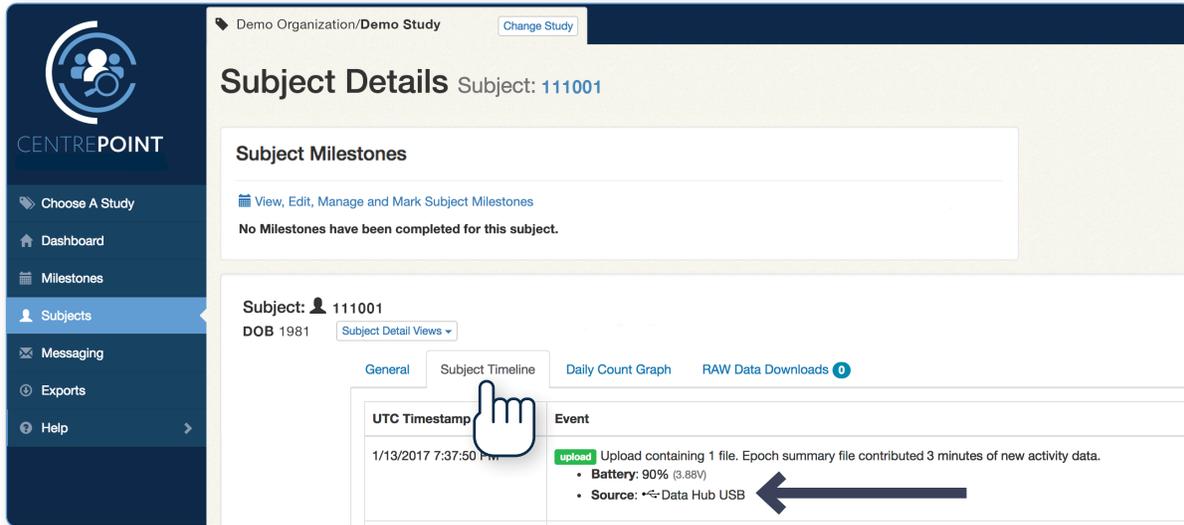
12. Remove the CPW01 from the charging dock by pulling the plastic tab to the left and away from the CPW01.

Assignment Completed

Give the CPW01, charging dock, and all accessories to the participant and provide the following instructions:

Wear the CPW01 securely on your non-dominant wrist for 24 hours a day for the duration of the study. There is no need to remove the CPW01 for bathing or other water activities. There is no need to remove the CPW01 at night or during sleep periods.

Use the charging dock to fully charge the CPW01 once every 3 weeks. Be sure to bring the CPW01, charging dock, and all accessories back to the Final Visit for a final upload and completion of the assessment.

Assignment | Continued

Assigning an CPW01 to an existing participant

To assign a CPW01 to an existing participant (such as in the case of a lost or broken device) or if the visit schedule requires collection and reassignmen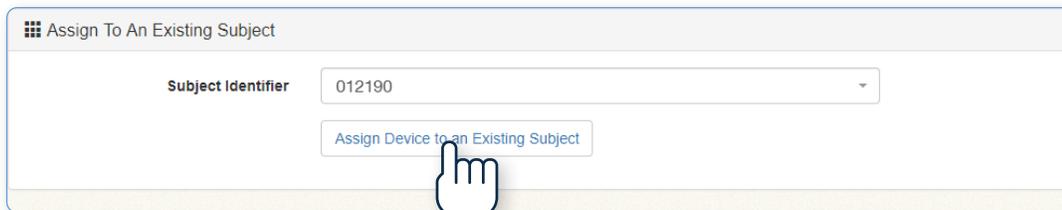t. Follow these steps to assign a CPW01 to an existing participant (such as, in the case of a lost or broken device) or if the visit schedule requires collection and reassignment:

• Complete steps 1– 6 above on page 8.

• Scroll to the bottom of the page and select the corresponding subject identifier from the list.
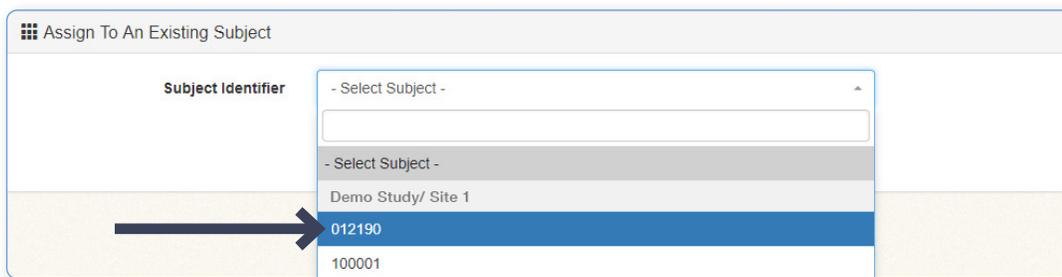
• Select **"Assign Device to an Existing Subject."** Wait for the progress bar to indicate that assignment is complete.

💡 **Please note:** We encourage the reuse of the previously assigned CPW01 that the participant used during the first monitoring period. Otherwise, a new CPW01 and watch band should be used.

Information for **Participants**

Wearing the CPW01

How do I wear the CPW01?

Fasten the CPW01 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 <u>not</u> used to write. The CPW01 should only be worn by the study participant.

When do I wear the CPW01?

- The CPW01 should be worn 24 hours a day according to the schedule below. There's no need to remove the CPW01 at night or during sleep periods.

- Be sure to bring the CPW01 with you to every site visit. Bring the CP Data Hub, charging dock, and all other accessories to your final site visit.

Please note:

- You may wear the CPW01 while bathing or showering. However, remove the CPW01 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.

Charging the CPW01

You will be required to fully charge the CPW01 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 CPW01 is connected to the CP Data Hub.

1. Insert the CPW01 into the charging dock connected to the CP Data Hub by pulling the plastic tab to the left and inserting the CPW01 until the button on the right side fits in the side opening of the plastic tab. 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

Information for **Participants** | Continued

2. While the CPW01 is connected to the charging dock, an animated battery icon will appear on the screen to indicate charging. The CPW01 is fully charged once a solid battery icon appears on the screen.

Charging   Fully Charged

3. Remove the CPW01 from the charging dock by pulling the plastic tab to the left and away from the CPW01. Continue wearing the CPW01 according to instructions.

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 charging dock.

Uploading

Upload CPW01(s)

Participants are instructed to bring the CPW01 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 charging dock to the computer using the provided USB cable and insert the CPW01 into the charging dock. 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 CPW01 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 CPW01 from the charging dock, and return it to the participant for continued monitoring.

Viewing Participant **Data**

Go to the CentrePoint Main Portal at **https://centrepoint.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."**

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.

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, CPW01 battery level, and upload source are provided.

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 CPW01 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 for this study.**

Unassignment

At the Final Visit, the CPW01 will be uploaded and unassigned from the participant. Sites will then collect the CPW01(s), charging docks, and all accessories and return them to inventory.

Final data upload and CPW01 unassignment

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 CPW01 into the charging dock. 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."**
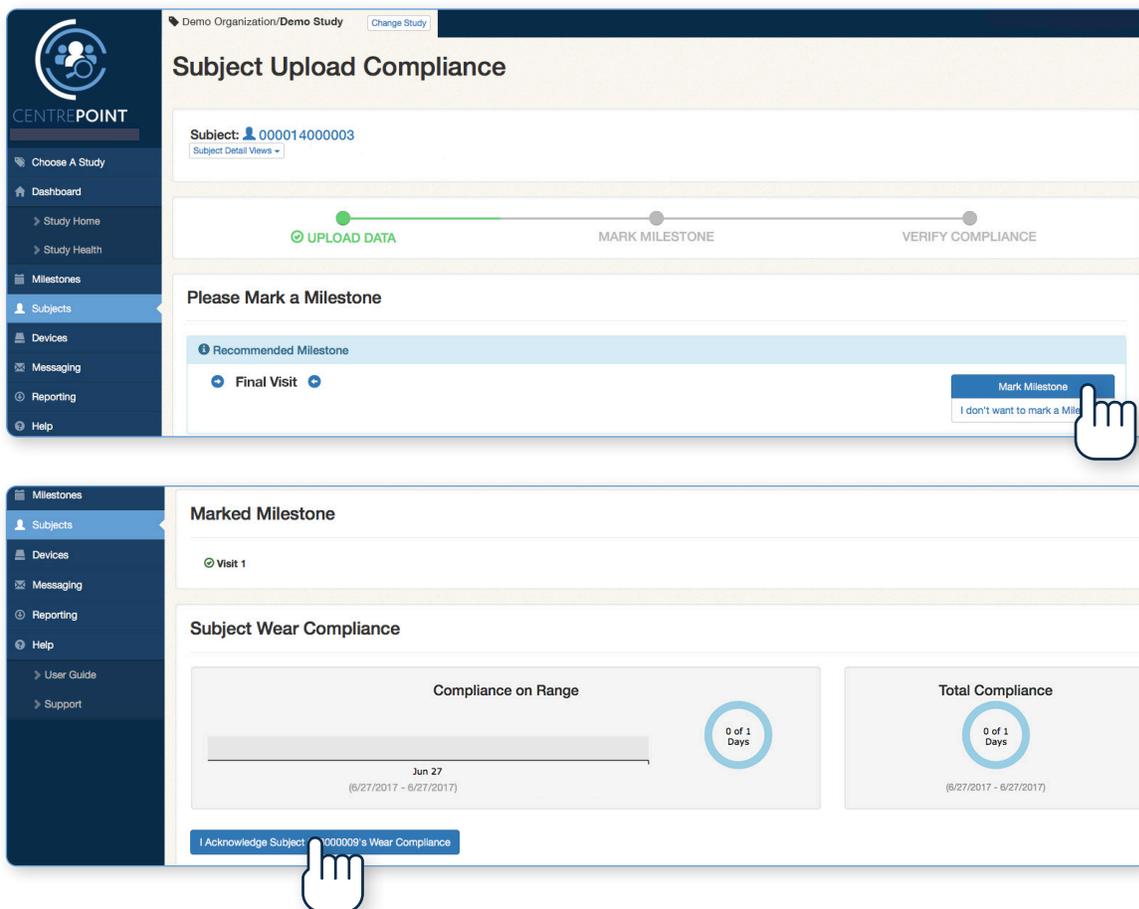
Unassignment | Continued

4. Remove the CPW01 from the charging dock by pulling the plastic tab to the left and away from the CPW01.

5. From the **"Subject Details"** page, select **"Stop Collecting Data"** to remove the participant assignment from the CPW01.
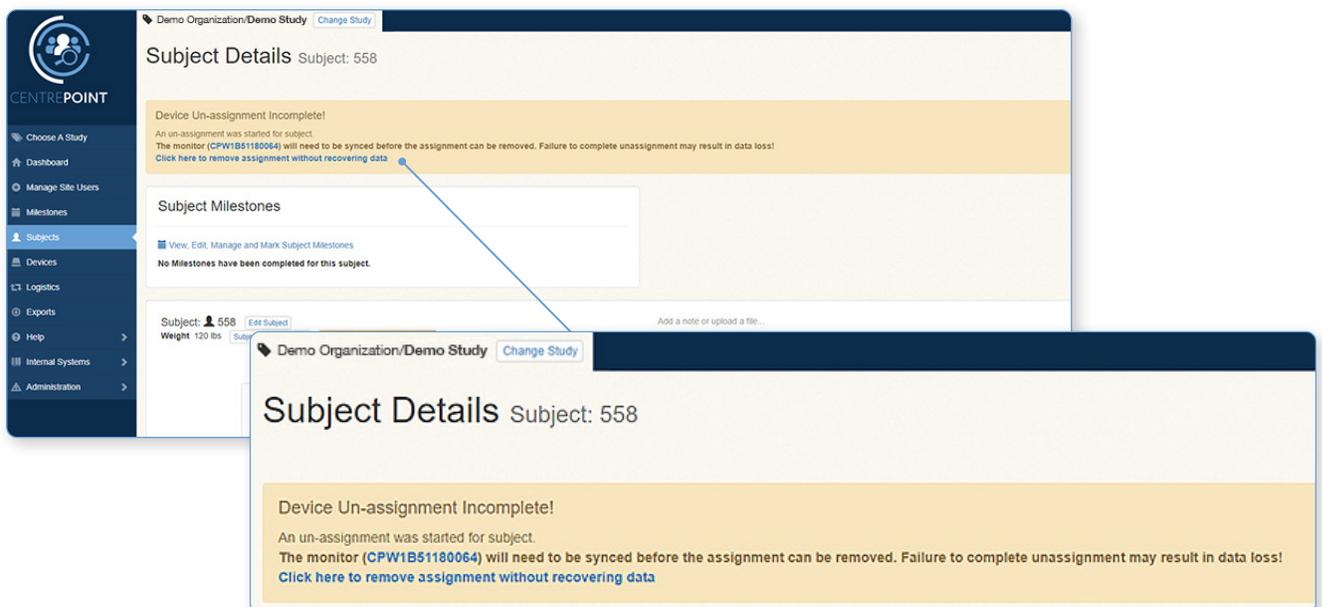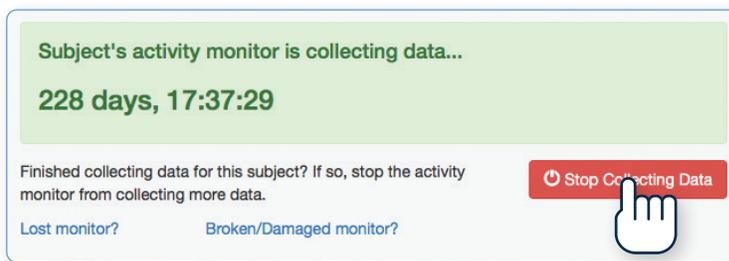
6. Insert the CPW01 back into the charging dock to perform the final upload and complete the unassignment.

7. A **"Data Collection Complete"** tag will appear in the general tab under the **"Subject Details"** page.
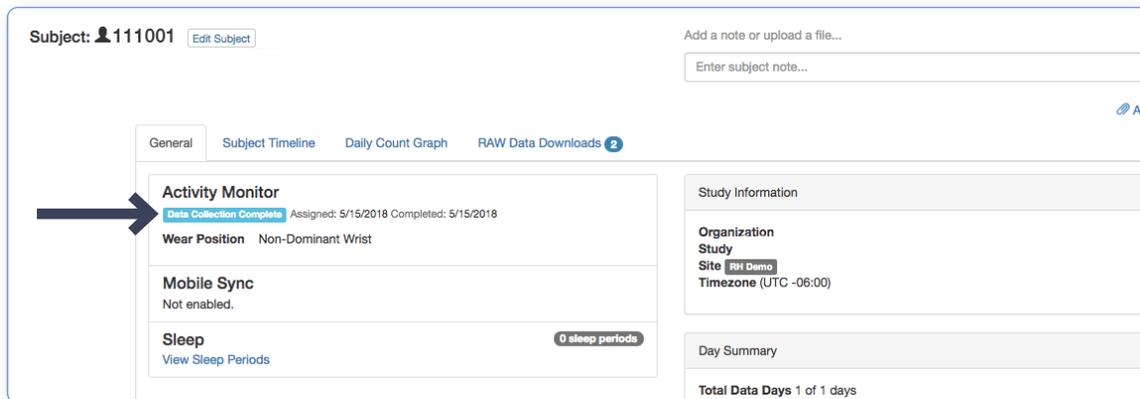
8. Collect the CPW01, charging dock, and all accessories. Clean the CPW01 with an alcohol-based solution (wipes or swabs) and store all equipment until the end of the study.

CPW01 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 CPW01 devices are not to be sterilized because damage may occur. Although the CPW01 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 CPW01 multiple times during its expected service life will not cause a loss of basic safety or essential performance.

> **Please note:** The CentrePoint Insight Watch (CPW01) 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 **CPW01(s)**

If a CPW01 is lost or broken, it must be disassociated from the participant before assigning a replacement. Only one CPW01 can be assigned to a participant at any given time.

Lost or broken CPW01(s)

1. To disassociate an CPW01, select the **"Subjects"** tab from the left hand menu, and select the desired subject from the list.
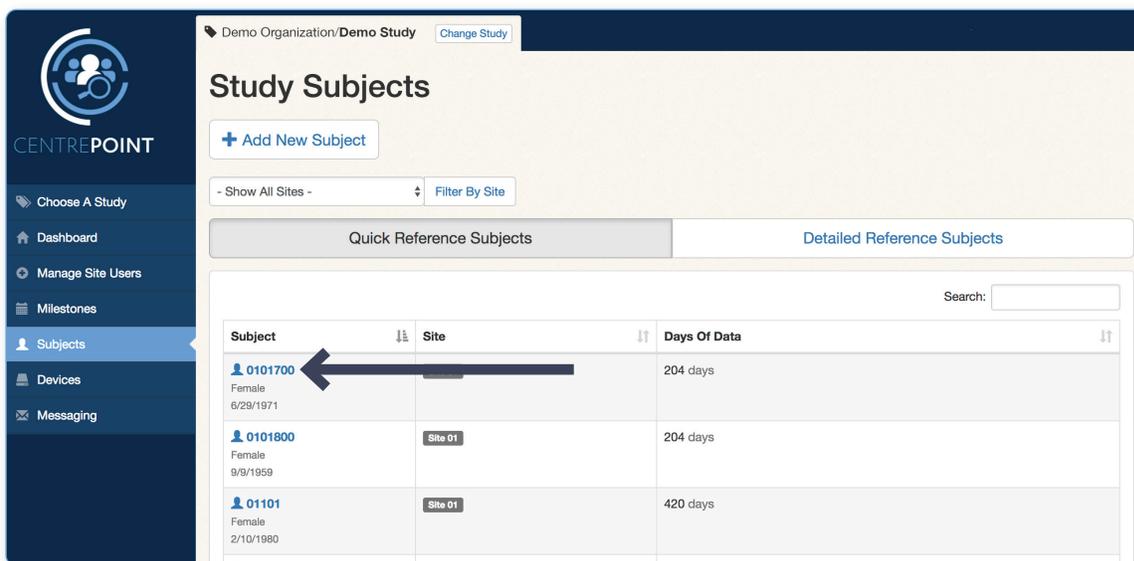
2. From the **"Subject Details"** page, select either **"Lost monitor"** or **"Broken/Damaged monitor."**
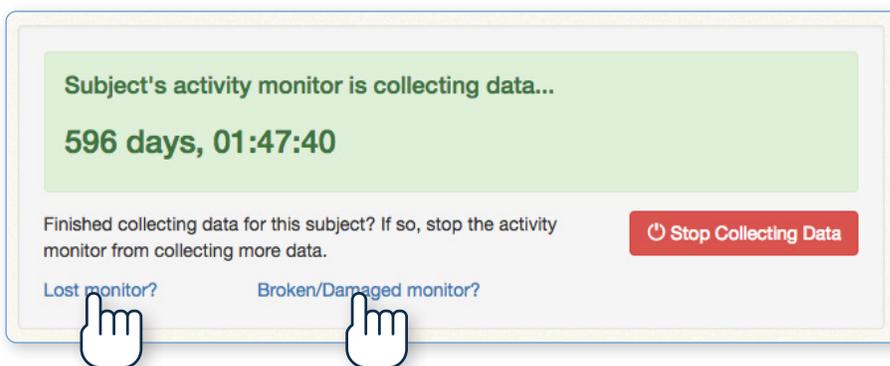
3. Select **"Remove monitor assignment from this subject"** to disassociate the CPW01.

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 back   Remove monitor assignment from this subject

4. To assign a replacement CPW01, follow the instructions on page 11 for assigning a monitor to an existing participant.

Frequently Asked **Questions**

Q **Does the participant wear the CPW01 for 24 hours?**

The participant should be instructed to wear the CPW01 24 hours a day.

Q **On which wrist should the CPW01 be worn?**

The CPW01 should be worn on the non-dominant wrist. The non-dominant wrist is the one that is <u>not</u> used to write.

Q **What is the battery life of the CPW01?**

Approximately 30 days.

Q **When and how often does the CPW01 need to be charged?**

The participant should be instructed to fully charge the CPW01 once every 3 weeks.

Q **How long does it take to charge the CPW01?**

It takes up to 2-3 hours to fully charge a CPW01.

Q **What if the CPW01 battery dies in the field?**

If the CPW01 battery dies, the participant should be instructed to bring the CPW01, charging dock and USB cable back to the site for recharge and reinitialization of the CPW01 using the CentrePoint system. Once the CPW01 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 CPW01 is not collecting data.

Active Mode

A running person icon will be displayed if the CPW01 is collecting data.

Q **What if the CPW01 is lost or broken?**

If a CPW01 is lost or broken, follow the instructions on page 20 to remove the device association and assign a new CPW01 to the participant. Report lost or broken CPW01(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 CPW01.

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

If a participant reports a skin reaction from wearing the CPW01 or becomes uncomfortable, the participant should be instructed to stop wearing the CPW01 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 mean?

- **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 CPW01 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 CPW01 and accessories battery?

The battery has a life expectancy of two (2) years.

Q What is the time to warm the CPW01 to ambient temperature 20° C?

19 minutes.

Q What is the time to cool the CPW01 to ambient temperature 20° C?

21 minutes.

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 CPW01(s), 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 CPW01(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
- FCC Part 15.207 – Modular Transmitter AC Line Conducted Emissions
- FCC Part 15.249 – Radiated Emission Limits of Intentional Radiators

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 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 CentrePoint Insight Watch, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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 -10° 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 charging dock.

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

NOTICE: The CentrePoint Insight Watch 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 100-240 Vac.

Regulatory **Information** | Continued

EC | REP

Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

Authorized Representative in European Community

Indicates the authorized representative in the European Community.

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

ActiGraph's Australia Sponsor

Indicates ActiGraph's authorized Australian Sponsor.

REF

Catalog Number

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

CE

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.

ANATEL
06584-19-09607
"Este equipamento não tem direito à
proteção contra interferência prejudicial e
não pode causar interferência em sistemas
devidamente autorizados."

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.

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i
10 ISO 3864-1

Consult Instructions for Use

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

SN

Serial Number

Indicates the manufacturer's serial number so that a specific medical device can be identified.

Regulatory **Information**

Manufacturer

ActiGraph is the medical device manufacturer and is located at 49 E. Chase Street, Pensacola, Florida 32502.

Operating Temperature Range

40° C

0° C

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

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.
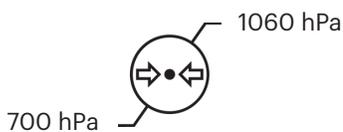
Lithium Ion (EU)

Li-ion

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

90%

15%

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

Atmospheric Pressure

1060 hPa

700 hPa

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

Type BF Applied Part

The CPW01 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

IP67

IP67 Rating

The devices are water resistant in accordance with IEC 60529 and have the International Protection Rating: IP67 or immersion in one (1) meter of water for up to 30 minutes.

IP21

IP21 Rating

The charging docks are protected against solid foreign objects of 12.5 mm and greater and vertically falling water drops in accordance with IEC 60529 and have the International Protection Rating: IP21.

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.

Giteki

GITEKI CERTIFICATION **(TECHNICAL STANDARDs CONFORMITY CERTIFICATION AND CONSTRUCTION DESIGN CERTIFICATION)**

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

U.S. federal law restricts this device for sale by or on the order of a physician.

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.

ActiGraph™