Overview

CENTREPOINT 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.

<table>
<thead>
<tr>
<th>Specifications</th>
<th>Details</th>
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</thead>
<tbody>
<tr>
<td>Dimensions</td>
<td>5.01 x 3.46 x 1.05 cm</td>
</tr>
<tr>
<td>Weight</td>
<td>14 grams</td>
</tr>
<tr>
<td>Sample rate</td>
<td>32 Hertz (default) - 256 Hertz</td>
</tr>
<tr>
<td>Battery life</td>
<td>30 days*</td>
</tr>
<tr>
<td>Data storage</td>
<td>30 days/512 MB</td>
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<tr>
<td>Dynamic range</td>
<td>+/- 8G</td>
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<tr>
<td>Communication</td>
<td>USB, Bluetooth® LE 5</td>
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<tr>
<td>Water resistance</td>
<td>1 meter, 30 minutes</td>
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<td>Wear location</td>
<td>Wrist</td>
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<td>Warranty</td>
<td>1 year</td>
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</tbody>
</table>
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.

<table>
<thead>
<tr>
<th><strong>ActiSync Service</strong></th>
<th><strong>Main Web Portal</strong></th>
</tr>
</thead>
</table>

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

** 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

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**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.

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**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 10.1or higher
- Mozilla NSS 3.15.1or 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](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.
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.

- 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](image)

![Upload Complete](image)

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.
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 reassignment. 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 not 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.
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.

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](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.
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.”
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.
Unassignment  |  Continued

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.”
Lost or Broken CPW01(s) | Continued

3. Select “Remove monitor assignment from this subject” to disassociate the CPW01.

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

- **Does the participant wear the CPW01 for 24 hours?**
  The participant should be instructed to wear the CPW01 24 hours a day.

- **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 not used to write.

- **What is the battery life of the CPW01?**
  Approximately 30 days.

- **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.

- **How long does it take to charge the CPW01?**
  It takes up to 2-3 hours to fully charge a CPW01.

- **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.

- **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.

- **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.
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.

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.

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.

What is the shelf life of the CPW01 and accessories battery?
The battery has a life expectancy of two (2) years.

What is the time to warm the CPW01 to ambient temperature 20° C?
19 minutes.

What is the time to cool the CPW01 to ambient temperature 20° C?
21 minutes.

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 18 mil low density polyethylene, ½” thick and also we use a 3/16” thick wrap.

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 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 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.
Authorized Representative in European Community
Indicates the authorized representative in the European Community.

ActiGraph’s Australia Sponsor
Indicates ActiGraph’s authorized Australian 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.

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.

Serial Number
Indicates the manufacturer’s serial number so that a specific medical device can be identified.
Manufacturer
ActiGraph is the medical device manufacturer and is located at 49 E. Chase Street, Pensacola, Florida 32502.

Operating Temperature Range
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)
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 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.

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.