



Instructions for Use

ActiGraph LEAP[®]

Model: LEAP | E.200.6025 | Released: 12/4/2024 | Rev: 3

ActiGraph[™]

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Instructions for Use

ActiGraph LEAP®



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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	Microphone	100Hz to 10kHz
Weight	24 grams	PPG	Green (530nm), Red (655nm) and IR(940nm) LEDs
Sample Rate	32 - 256 Hertz	Skin Temperature	-20C to 50C
Battery Life	32 Days*	Event Marker	Yes
Data Storage	79 Days / 1 GB*	Communication	USB, Bluetooth® LE 5.3
Dynamic Range	+/- 8g	Water Resistance	IPX7 (1 meter, 30 minutes)
Barometer	300 to 1100 hPa (~ -500m to 9000m)	Wear Location	Multiple
IMU Gyroscope	+/-2000 dps	Warranty	1 year
IMU Accelerometer	+/- 2g or +/- 16g		

*Accelerometer at default 32 Hz sample rate and display on 48 times/day

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. The ActiGraph LEAP is FDA 510(k) cleared (K231532) for the above Intended Use / Indications for Use

Overview | Continued

Device Orientation



GRAVITY
↓

ACCEL
 $X = -1, Y = 0, Z = 0$

GYRO
X = Positive if rotate clockwise, negative if rotate counterclockwise, assume rotation occurs while looking along x direction toward center of Earth

$Y = 0, Z = 0$



GRAVITY
↓

ACCEL
 $X = +1, Y = 0, Z = 0$

GYRO
X = Negative if rotate clockwise, positive if rotate counterclockwise, assume rotation occurs while looking along x direction toward center of Earth

$Y = 0, Z = 0$



GRAVITY
↓

ACCEL
 $X = 0, Y = -1, Z = 0$

GYRO
Y = Positive if rotate clockwise, negative if rotate counterclockwise, assume rotation occurs while looking along y direction toward center of Earth

$X = 0, Z = 0$



GRAVITY
↓

ACCEL
 $X = 0, Y = +1, Z = 0$

GYRO
Y = Negative if rotate clockwise, positive if rotate counterclockwise, assume rotation occurs while looking along y direction toward center of Earth

$X = 0, Z = 0$



GRAVITY
↓

ACCEL
 $X = 0, Y = 0, Z = -1$

GYRO
Z = Positive if rotate clockwise, negative if rotate counterclockwise, assume rotation occurs while looking along z direction toward center of Earth

$X = 0, Y = 0$



GRAVITY
↓

ACCEL
 $X = 0, Y = 0, Z = +1$

GYRO
Z = Negative if rotate clockwise, positive if rotate counterclockwise, assume rotation occurs while looking along z direction toward center of Earth

$X = 0, Y = 0$

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 24,000 published scientific papers to date, ActiGraph is the most experienced and trusted wearable technology partner in the industry.

ActiGraph LEAP **Accessories**



ActiGraph LEAP Silicone Wristband



ActiGraph LEAP Charger



Wall Plug and Country Specific Adapters

For use with the ActiGraph LEAP (Serial numbers beginning with STM).

For all accessory details and technical specifications, please visit <https://theactigraph.com/accessories>

Charging the LEAP

The LEAP should be fully charged before assignment and deployment. It takes up to 2-3 hours to fully charge a 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. 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



4. The LEAP is fully charged once a solid battery icon appears on the screen. Remove the LEAP from the charger by pulling the LEAP away from the charger.



Please note:

- An internet connection is not required to charge the LEAP(s) if connected to computer.
- On older LEAP monitors, if the button is accidentally held down for 20 seconds or more, the device will go into Halt mode and the time will reset to Dec 30th at 8:00. To re-initialize the monitor and get back to Active mode, the monitor will need to be synced with CentrePoint Connect, CentrePoint Data Hub or ActiSync.

Storing the LEAP

When the LEAP monitor is going to be stored for long periods of time, the battery should be fully charged every three months.



Wearing the **Activity Monitor**



Wear the activity monitor on your non-dominant wrist like a wristwatch. The non-dominant wrist is the one that is not used to write. The activity monitor should only be worn by the study participant.

Silicone and Leather Wrist Strap Instructions

Pull the strap through the buckle so that it is comfortably snug and there is no slack or gaps between the strap and your skin. Insert the tongue of the buckle into the nearest hole. For the best data quality, tighten the strap one hole further during exercise.

Nylon Wrist Strap Instructions

Open the strap to its maximum size. Then pull the end of the Nylon strap through the loop so that it is comfortably snug and there is no slack or gaps between the strap and your skin. Attach the Velcro to the strap, taking care not to over loosen or over tighten the strap. For the best data quality, slightly tighten the strap some more during exercise.

Upper Arm Instructions

Open the strap to its maximum size and place the monitor about 1.5 inches (38mm) above the middle of the bicep with the button facing up, if on the right arm or down, if on the left arm. Slide both sides of the strap through the loop until the device is snug enough to not fall down the arm but not too snug such that it causes discomfort. The final position of the monitor should be pointing out to the right or to the left when the arm is relaxed at the waist.

Confirming the Fit of a Wrist Strap

- The strap should feel secure but comfortable on the wrist. Participants can rotate their wrist back and forth quickly and check if the device stays in position on their wrist.
- The device should not be affixed too far up the arm, such that it might slide down toward the hand and loosen.
- The device should not be affixed too far toward the hand; if the wrist is bent upwards, the back of the hand should not touch the body of the device.

Wearing the **Activity Monitor** | Continued

Ankle Strap Instructions

Open the strap to its maximum size and place the monitor over the foot and about 1 inches (25mm) above the ankle bone with the button facing up, if on the right leg or down, if on the left leg. Slide both sides of the strap through the loop until there is no slack or gaps between the strap and your skin.

Preventing a skin reaction while wearing the LEAP device

Avoid using perfume, lotion, suntan/sunscreen or insect repellent on the area where the activity monitor is worn. If the activity monitor comes in contact with these or any other chemicals, clean the device and silicone strap with 70% IPA and the skin with soapy water, making sure to completely rinse and dry the skin, device, and strap before putting back on. As a preventative measure, the activity monitor and strap can be cleaned on a regular basis. To clean the Nylon and Lycra accessories use soapy water, making sure to rinse thoroughly, then dry with a towel or paper towel prior to wearing again.



Please note:

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

LEAP Display Icons



Active Mode

This icon will appear when the LEAP is collecting data.



Reset Mode

This icon will appear when the LEAP is not collecting data.



Halt Mode

This icon will appear when the LEAP is not collecting data.



Delay Mode

This icon will appear when the LEAP is set to start collecting data in Active Mode sometime in the future and is currently not collecting data.



Charging Battery

This icon will appear when the battery on the LEAP monitor is currently being charged.



Battery Level Indicator

This icon shows the level of the battery. In this instance, the battery is fully charged.



Low Battery

This icon will appear when the battery level is low and the monitor needs to be charged.



Sync In Progress

This icon will appear when the data transfer from monitor to CentrePoint, using the CentrePoint Data Hub, is in progress.



Sync Successful

This icon will appear when the data transfer from monitor to CentrePoint, using the CentrePoint Data Hub, was successful.



Sync Warning

This icon will appear when the data transfer from monitor to CentrePoint, using the CentrePoint Data Hub, was unsuccessful for any reason.

LEAP Display Icons | Continued



Monitor Error

This icon will appear when the monitor has detected a possible hardware issue. Pressing the button for 20 seconds might resolve the issue. However, if it goes into Halt Mode a re-initialization will need to be performed.



Event Marked

This icon will appear when an event has been marked by pressing the button for 2.5 seconds.



Event Mode

The icon will be displayed when the desired sensors are set to event mode and the participant marks an event using the side button which turns the sensors on. The icon will disappear and the sensors will turn off when the participant marks a second event or the specified time is reached.



Bluetooth®

This icon will appear when the monitor is advertising (looking for a device to connect with).



Bluetooth®

This icon will appear when a Bluetooth connection has been accepted.

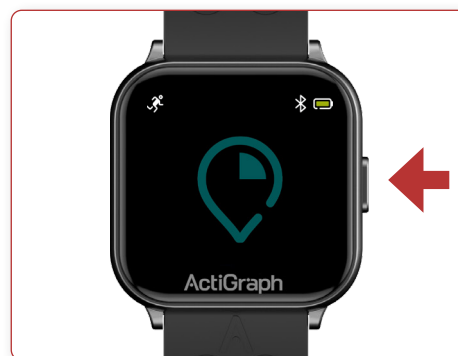
Turning On the **Activity Monitor Screen**

To activate the activity monitor screen, simply press and release the button located on the right side within 2 seconds. The screen will stay illuminated for five seconds before automatically shutting off.



Marking an Event on the **Activity Monitor**

1. Press and hold the button located on the right side of the activity monitor for at least 2.5 seconds. After one second, you will see the icon displayed below.



2. As you continue to press and hold the button, the circle will gradually fill up until the final event marker icon is displayed below.



Frequently Asked Questions

Q On which wrist should the LEAP be worn?

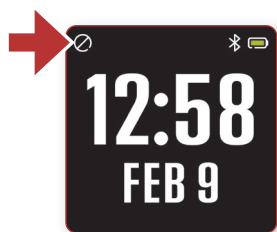
The LEAP should be worn on the non-dominant wrist. The non-dominant wrist is the one that is not used to write.

Q What is the battery life of the LEAP?

Approximately 32 days at default 32 Hz sample rate, accelerometer sensor only, and display on 48 times/day.

Q What if the LEAP battery dies in the field?

If the participant is using the CentrePoint Data Hub or CentrePoint Connect during the study, charge the LEAP using either the CentrePoint Data Hub or the Wall Plug. If they are not using either the CentrePoint Data Hub or CentrePoint Connect, the participant will need to bring the LEAP back to the site to recharge and reinitialize since depleting the battery will cause the LEAP to lose its time.



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, report lost or broken LEAP(s) to 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.

Q What if a participant reports a skin reaction?

Although the LEAP device and LEAP silicone strap are tested to the ISO 10993 standard for biological safety, we do receive occasional reports of skin irritation as it's not something that can be 100% guarded against. This can be due to allergies, environmental factors, or extended exposure to irritants like soap, sweat or other chemicals. For components which contact the skin, ActiGraph does not use materials which are known to be irritants such as Nickel and Latex. If the reaction is mild, the recommendation is to remove the activity monitor and clean the device and silicone strap with 70% IPA and the skin with soapy water, making sure to completely rinse and dry the skin, device, and strap before putting back on. If there are any open wounds or severely irritated skin, discontinue wearing the activity monitor to prevent further irritation and have it returned to the site. Then contact ActiGraph Support team for further assistance. We do offer alternative wristband options that might be more suitable for the participant.

Frequently Asked Questions | Continued

Q What is the typical service life of the LEAP?

The LEAP monitor is not serviceable. Therefore the service life of LEAP depends upon the service life of the battery. The battery has a service life of at least three years during normal use or if the monitor is stored for long periods, the battery must be fully charged every three months during that storage period.

Q What is the shelf life of the LEAP?

The part that has the shortest shelf life is the battery. The battery has a shelf life of two years during storage. It can be extended if proper battery maintenance is done (fully charging every three months).

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.

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.

WARNING: This product can expose you to chemicals including Bisphenol A which is known to the State of California to cause birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov

CAUTION: Do not simultaneously wear and charge. Do not 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.

CAUTION: Do not allow small children or pets to play with, bite, or chew on the product or supplied cords to avoid injury or choking. Keep the cord out of reach of children to avoid strangulation.

Regulatory Information | Continued

Regulatory Symbols



CAUTION:

- Do not replace the battery. 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.

NOTICE: Product does not have any contraindication(s)

NOTICE: Only use ActiGraph's approved charging dock to charge the device. Charging Dock input: 5Vdc, 1000mA. Only use ActiGraph's approved USB cables with the charging dock. Do not replace the battery; it cannot be replaced (3.85Vdc 250mAh Li-ion Polymer Battery).

NOTICE: ME Equipment charged via certified external power supply (e.g., IEC 62368 safety standards for information technology equipment or IEC 60601-1 safety standards for medical electrical equipment) with input rated 100-240 VAC, output rated 5V DC, 1 A. The power supply adaptor should be Class II.

NOTICE: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

FCC 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

Indicates the authorized representative in the 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.



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.



STM2XXXXXXXXXX

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.



Medical Device

Indicates the item is a medical device

Regulatory Information | Continued



Manufacturer

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



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.



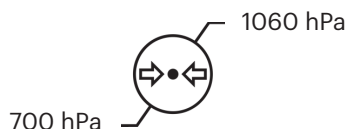
Lithium Ion (EU)

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

IP67

IP67 Rating

The devices are water resistant in accordance with IEC 60529 and have the Ingress 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.



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.



R 020-230407

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 their 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 license-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's license-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: 2023DJ19409

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).



BC

The mark applies to the California Energy Commission (CEC) Battery Charger System (BCS) certification. The electrical appliance efficiency regulations promulgated by the CEC impose energy-saving efficiency requirements on almost all BCS (battery charging system) products sold in the California market.

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, USA
+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.