

## **Change History**

Rev	CRF # or	Description of Change
	Effective Date	
0	2018-08-09	Initial Release

CentrePoint Insight Watch Technical Manual

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## 1.0 Introduction

The ActiGraph CentrePoint Insight Watch (CPW01) activity monitor provides objective measurement of human activity and is used in many research and clinical applications. ActiGraph understands that patients may be the intended operators of the ActiGraph CPW01 which is why it was designed to be easy to use with no formal training required for use. This Technical Manual will describe all the regulatory symbols, technical specifications, unique functionality, and safety statements are required for regulatory purposes.

# 2.0 Specifications and Functionality of the CentrePoint Insight Watch (CPW01)

## 2.1 Sensors

The CentrePoint Insight Watch includes one primary 3 axis accelerometer. It should be noted that data will not be negatively affected by lint, dust, or direct sunlight.

#### 2.1.1 Acceleration

Acceleration is measured using a digital MEMs accelerometer that is utilized for all historical and standard data collection efforts.

Acceleration data from the primary sensor is sampled at 32 Hz, 64 Hz, 128 Hz, or 256 Hz (user selectable). Outputs are stored in a raw, non-filtered format in the units of LSB's. This data is stored directly into a non-volatile flash memory. Table 1 lists some key specifications for the accelerometers utilized in the CPW01 device.

Parameter	Primary	Units
Axis	3	
Sensitivity	4	mg/LSB
Dynamic Range	+/-8	g

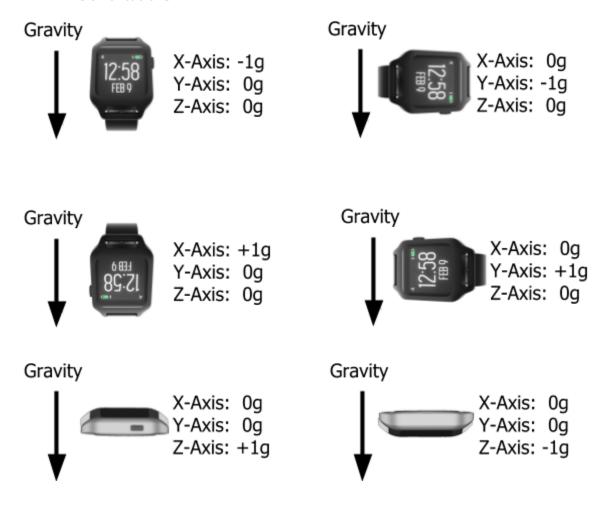
Table 1: Accelerometer Key Specifications

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#### 2.1.1.2 Axis orientations



### 2.1.2 Operating the device

ActiGraph supplies a companion software application, CentrePoint Software, to communicate with the device for the purposes of initiating data collection, sending configuration instructions, and downloading the collecting data.

## 2.1.2.1 Starting and Stopping the Device

Initiation and stopping of data collection will be handled through CentrePoint Software. Users will be trained on the CentrePoint Software to be able to use the CPW01 device.

## 2.2 Battery

The ActiGraph CPW01 device uses a lithium polymer rechargeable battery that has a maximum voltage of approximately 4.20 volts and a total life expectancy of two to five (2-5) years. Batteries are to be serviced by ActiGraph authorized personnel only. In order to slow the aging of the lithium polymer battery, it is recommended that devices be stored in a partially charged state (40 - 60% battery capacity)

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in low ambient temperatures. Also, every three (3) months devices need to be plugged in to monitor their voltages and charged in order to extend the life expectancy of the battery. Using the backlight on the device screen will impact the battery capacity.

Table 2 demonstrates the impact the storage has on the long term capacity of the battery.

Temperature	Recoverable Capacity when stored at 40% charge	Recoverable Capacity when stored at 100% charge
0°C	98%	94%
25°C	96%	80%
40°C	85%	65%
60°C	75%	60% - After 3 Months

Table 2: Estimated recoverable capacity when storing a battery for one year. Elevated temperature hastens permanent capacity loss. Lithium-ion is sensitive to charge levels (*Data is from batteryuniversity.com*)

IMPORTANT: ActiGraph's devices do not come fully charged from the manufacturer and are recommended to be charged fully before their initial use. If the battery performance is not performing as expected, call ActiGraph's Customer Service immediately.

## 2.3 Device Storage and Life Expectancy

The CPW01 is recommended to be stored at 20°C to achieve the maximum life expectancy and battery life performance. The minimum/maximum storage temperature range is between -20°C and 55°C. For optimal battery life performance, routinely charge the device as described above.

The only limiting factor of an ActiGraph device when calculating life expectancy is the battery. The battery has a life expectancy of five (5) years but can be replaced by ActiGraph personnel thus extending the life of the device. The performances of the components inside the device do not degrade over time so the life expectancy of a device is immeasurable.

#### 2.3.1 Low Voltage Mode (HALT)

CPW01 will enter a "Low Voltage Mode" (or HALT) state when the battery discharges beyond 3.1 volts. In this mode, all important variables and data are stored in flash memory to secure the device download. The device can be downloaded via the CentrePoint system. Once the device's battery has been charged to an acceptable level the CentrePoint system can restart/resume the devices data collection.

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## 3. Miscellaneous Device Information

## 3.1 Device Irritation

If irritation of the skin occurs due to wearing the device, discontinue wearing the device and consult a doctor for treatment. Although the copolymer materials are not known to be irritating to the skin, some irritation to individuals with sensitive skin may occur. If this happens, consult your doctor for treatment and stop wearing the device.

## 3.2 Degradable Components

ActiGraph's devices are made with high quality components that are not subject to deterioration over time. However, if a device seems to be underperforming, call ActiGraph's Customer Service immediately at (877) 497-6996 so they problem may be resolved.

## 3.3 Other Possible Negative Effects

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.

#### 3.3.1 Household Interference

Within a household environment many different factors can negatively affect the device. Putting a device close to hot sources such as a fireplace or baseboard heater will melt the housing of a device and destroy it. Putting a device in the freezer for extended periods of time will reduce the capacity of the battery's lifespan and negatively affect its performance. Putting a device in a microwave will destroy various parts of the device and potentially destroy it. Wireless internet connections, wireless television service, and other wireless services will not negatively affect the performance of the device. As a rule of thumb, do not put the device in extreme cold or hot temperatures and do not apply any electrical sources to the device unless explicitly approved by ActiGraph.

## 3.4 Wear Locations

The ActiGraph CPW01 is designed to be worn on the wrist. Other wear locations would have to be selected in the CentrePoint system and ActiGraph should be contacted if other wear locations are desired.

## 3.5 Button Operation

The button can be used to enable a backlight on the display for viewing in low light areas. Simply press the button to activate the light.

#### 3.6 Device Serial Number Label

Each device is equipped with a label stuck to it with pertinent device information inside the serial number. For example the serial number (01)00853048008039 (21)CPW1E24180001 means:

(01) = GS1 Application Identifier for GTIN

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- 0 = Indicator Digit
- 0853048008 = GS1 Company Prefix for ActiGraph
- 03 = Item Reference for CPW01
- 9 = GS1 Check Digit
- (21) = GS1 Application Identifier for Serial Number
- CPW = Device Model (CPW01)
- 1 = Manufacturing location
- E = PCB revision
- 24 = Week of the year the device was manufactured (24<sup>th</sup> week)
- 18 = Year the device was manufactured (2018)
- 0001 = Number of device manufactured that week

## 3.7 Cleaning the Device

ActiGraph CPW01 devices 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 ActiGraph CPW01 devices are not required to be cleaned on any predetermined schedule, it is advised that the devices be cleaned after each use by a user.

#### 3.8 Device Maintenance

The ActiGraph CPW01 devices do not require routine maintenance or calibration. Calibration is performed during manufacturing of the device and will last for the life of the device. If maintenance is required on a device, or a piece of a device has gone missing, call ActiGraph Customer Support or visit the support section on the ActiGraph website <a href="https://www.actigraphcorp.com">www.actigraphcorp.com</a> and initiate an RMA for your device.

Any critical components that require maintenance are to be performed by trained ActiGraph personnel only. All necessary training manuals, schematics, parts listings, and other necessary documentation, are only made available to trained ActiGraph service technicians.

## 3.9 Unexpected operations and events

If a device performs in an unexpected manner and does not collect data, or it is not performing as long as expected, will not download data, or acts in any other manner that is unexpected, notify ActiGraph immediately. ActiGraph's Customer Service can be contacted at the phone number (877) 497-6996 and is available every week, Monday through Friday, 8 A.M. to 5 P.M. Central Standard Time. Customer Service may also be contacted through email at <a href="mailto:support@theactigraph.com">support@theactigraph.com</a>.

#### 3.10 Accessories

For a full list of current accessories available for the ActiGraph CPW01, please visit ActiGraph's website at <a href="https://www.actigraphcorp.com/product-category/accessories">www.actigraphcorp.com/product-category/accessories</a>. Only use the accessories provided by

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ActiGraph and only use them as described since the misuse of accessories and other detachable parts may be harmful to the user.

The life expectancy of each accessory is different since each accessory is subject to different elements. The Wrist straps have a life expectancy of 5+ years. These are not exact life expectancies but are suggested values that can be less or more depending on the use of the accessory.

# 3.11 Regulatory and Safety Information

[]i	CAUTION: The battery is to only be changed by trained ActiGraph personnel. The battery is only allowed to be connected in a certain manner and any incorrect replacement can result in a hazard.
☀	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.
	CAUTION: Do not simultaneously wear and charge, service, or provide any maintenance on the device. The end user should not be in the patient vicinity when being charged  CAUTION: Transporting and/or operating the CPW01 outside of the temperature range of -20°C to +55°C could lead to dangerous conditions and/or incorrect data collection.  CAUTION: Do not modify the device in any way. Modification to an ActiGraph device is not permitted and will void all warranties if tampered and/or modified.  CAUTION: Humans and animals are not to swallow any part of this device. If a piece of the housing has been swallowed, or battery fluid has been ingested, contact your local poison control hotline or seek medical attention as soon as possible.  NOTICE: Device 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 approved USB cables with the charging dock.  NOTICE: No precautions need to be taken in the event of changes in the performance of the device.

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Class II double insulated electrical appliance. Earth ground is not required. Insulation breakdown will not result in an electrical shock risk.

The CPW01 and Charger 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



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 of 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.

The CPW01 is classified as a Class I medical devices within the European Union and have been approved to be sold as medical devices according to the European Union's regulatory requirements listed below:



- EN 60601-1 (3<sup>rd</sup> Edition) Medical Electrical Equipment Part 1: General Requirements for Safety
- EN 60601-1-2:2015 Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance Collateral Standard: Electromagnetic Disturbances Requirements and tests
- EN 61000-4-2:2009 Electromagnetic Compatibility Part 4: Testing and measurement techniques Section 2: Electrostatic discharge immunity test
- EN 61000-4-3:2006, inc. A2:2010 Electromagnetic Compatibility Part 4:
   Testing and measurement techniques Section 3: Radiated, radio-frequency, electromagnetic field immunity test

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Industry Industrie Canada  Canada	<ul> <li>EN 61000-4-8:2010 – Electromagnetic Compatibility – Part 4: Testing and measurement techniques – Section 8: Power frequency magnetic field immunity test</li> <li>EN 55011:2016 + A1:2017 – Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement</li> <li>EN 301 489-1 – Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements</li> <li>EN 301 489-17 – Electromagnetic Compatibility (EMC) standard for radio equipment; Part 17: Specific conditions for Broadband Data Transmission Systems</li> <li>EN 300 328 – Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2.4 GHz ISM band and using wide band modulation techniques</li> <li>The CPW01 complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.</li> <li>Le présent appareil est conforme aux CNR d'Industrie 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, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.</li> </ul>	
ICES-3 (B)/NMB-3(B)	The CPW01 and Charger complies with the Canadian electronic emission standard CAN ICES-3 (B)/NMB-3(B)	
CAN ICES-1 (B)/NMB-1(B)	The CPW01 and Charger complies with the Canadian interference-causing equipment standard CAN ICES-001 (B)/NMB-1(B).	
	The CPW01 and Charger complies with the Australia Communications and Media Authority (ACMA) and carry the Regulatory Compliance Mark (RCM) since they acceptably passed all electrical emission tests.	
Australia/New Zealand	The CPW01 complies with the Australian and New Zealand standards:  • AS/NZS 4268 (2008) – Radio equipment and systems – Short range devices  • AS/NZS CISPR 11:2011 - Information technology equipment – Radio disturbance characteristics – Limits and methods of measurement	

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	AC/NIZ CICRE 22 /2000) Information took polary any immort. Radio disturbance
	<ul> <li>AS/NZ CISPR 22 (2009) – Information technology equipment – Radio disturbance characteristics – Limits and methods of measurement</li> </ul>
Physiological Effects	This device does not produce any known physiological effects.
Pb	This device is manufactured Lead-Free and complies with RoHS standards (Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment)
IP57	The devices are water resistant in accordance with IEC 60529 and have the International Protection Rating: <i>IP57</i> or immersion in one (1) meter of water for up to 30 minutes.
	Contact ActiGraph Customer Service regarding the disposal of these products.
Environmental Conditions	Do not expose the devices to temperatures outside the limitations of -20°C to +55°C. If a device is going to be exposed to temperatures higher than +55°C, keep the device isolated from the user. If a device is going to be exposed to temperatures lower than -20°C, keep the device as close to the user as possible to try and insulate the device.
5 VDC 200 mA	Rated voltage and maximum current for the CentrePoint Insight Watch Charging Station.
-10C -45C	Minimum and maximum operating temperature are -10C to 45C.

Table 3: Regulatory Symbols