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# User's Manual

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*Revision: A*

*Effective Date: 6/25/2014*



## Change Page

### About the change page table

The following table describes the changes that have been made to this document since its original conception. Documents affected by the changes made need to be listed and updated in order to keep procedures up to date. This table shall be maintained as long as this document is active.

Revision	Description of Change/Documents Affected	Effective Date
A	- Initial Release	6/25/14



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## Document Approval

Printed Name of Document Creator or Editor: \_\_\_\_\_

Printed Name of Reviewing Manager: \_\_\_\_\_

☐ Approved

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Printed Name of Reviewing Quality Department Representative: \_\_\_\_\_

Signature: \_\_\_\_\_

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


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## Important Information and Symbols

The ActiGraph Link abides by the following regulations listed below and gives explanation into the symbols that are found on each device.

	<p>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.</p>
	<p>The devices are compliant with IEC (International Electrotechnical Commission) standards for "Type BF Applied Part" - meaning they comply 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 Polycarbonate and/or Polyvinyl Chloride materials. If you have any allergic reactions to Polycarbonate and/or Polyvinyl Chloride materials, please consult your doctor before using an ActiGraph device.</p>
	<p>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<sup>1</sup></p> <p>CAUTION: Transporting or operating these devices outside of the temperature range of -10°C to +55°C could lead to dangerous conditions and/or incorrect data collection.</p> <p>CAUTION: Modification to ActiGraph devices is not permitted and will void all warranties if tampered and/or modified. Do not modify the device in any way.</p> <p>CAUTION: Do not swallow any part of this device. If a piece has been swallowed, contact your local poison control hotline or seek medical attention as soon as possible.</p> <p>NOTICE: Device does not have any contraindication(s)</p> <p>NOTICE: Only use a USB 2.0 cable to connect to the charger. Only use ActiGraph's approved USB hubs to charge the device. Do not connect the device to anything else but a computer and an ActiGraph approved USB hub.</p> <p>NOTICE: No precautions need to be taken in the event of changes in the performance of the device.</p>
	<p>Class II medical device</p>


<sup>1</sup> A patient vicinity is areas in which PATIENTS are normally cared for and the space with surfaces likely to be contacted by the PATIENT or an attendant who can touch the PATIENT. This encloses a space within the room 1,83 m (6 feet) beyond the perimeter of the bed (examination table, dental chair, treatment booth, and the like) in its intended location, and extending vertically 2,29 m (7-1/2 feet) above the floor.

	<p>These devices comply 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.</p> <ul style="list-style-type: none"> <li>• FCC Part 15.107 – AC Conducted Emissions</li> <li>• FCC Part 15.109 – Radiated Emissions</li> <li>• FCC Part 15.207 – Modular Transmitter AC Line Conducted Emissions</li> <li>• FCC Part 15.249 – Radiated Emission Limits of Intentional Radiators</li> </ul> <p>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:</p> <ul style="list-style-type: none"> <li>• Reorient or relocate the receiving antenna.</li> <li>• Increase the separation between the equipment and receiver.</li> <li>• Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.</li> <li>• Consult the dealer or an experienced radio/TV technician for help.</li> </ul>
	<p>The devices are classified as 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:</p> <ul style="list-style-type: none"> <li>• EN 60601-1 (3<sup>rd</sup> Edition) – Medical Electrical Equipment Part 1: General Requirements for Safety</li> <li>• EN 60601-1-2:2007, inc. C:2010 – Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and tests IEC 60601-1-2 (Modified)</li> <li>• EN 61000-4-2:2009 – Electromagnetic Compatibility – Part 4: Testing and measurement techniques – Section 2: Electrostatic discharge immunity test</li> <li>• 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</li> <li>• EN 61000-4-8:2010 – Electromagnetic Compatibility – Part 4: Testing and measurement techniques – Section 8: Power frequency magnetic field immunity test</li> </ul>

	<ul style="list-style-type: none"> <li>• EN 55011:2009, inc. A1:2010 – Limits and methods of measurement of radio disturbance, characteristics of industrial, scientific and medical radio frequency equipment</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 301 489-3 V1.4.1 – Electromagnetic compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment; Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9kHz and 40GHz</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> </ul>
  <b>Australia/New Zealand</b>	<p>The devices comply 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.</p> <p>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.</p> <p>The devices comply with the Australian and New Zealand standards:</p> <ul style="list-style-type: none"> <li>• AS/NZS 4268 (2008) – Radio equipment and systems – Short range devices</li> <li>• AS/NZS CISPR 11:2011 - Information technology equipment – Radio disturbance characteristics – Limits and methods of measurement</li> <li>• AS/NZ CISPR 22 (2009) – Information technology equipment – Radio disturbance characteristics – Limits and methods of measurement</li> </ul>
<b>Physiological Effects</b>	This device does not produce any known physiological effects.
	This device is manufactured Lead-Free and complies with RoHS standards (Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment)





<b>IP27</b>	The devices are water resistant in accordance with IEC 60529 and have the International Protection Rating: <b>IP27</b> or immersion in one (1) meter of water for up to 30 minutes.
	Contact ActiGraph Customer Service regarding the disposal of these products.
<b>Environmental Conditions</b>	Do not expose the devices to temperatures outside the limitations of -10°C to +55°C. If a device is going to be exposed to temperatures higher than +60°C, keep the device isolated from the user. If a device is going to be exposed to temperatures lower than -10°C, keep the device as close to the user as possible to try and insulate the device.



## Introduction

The ActiGraph Link activity monitors provide objective measurements of human activity and are used in many research and clinical applications. They include a microelectromechanical system (MEMS) based accelerometer, gyroscope, magnetometer, and a capacitive touch based wear sensor as data collection end points. No formal training is required to use the ActiGraph Link and patients may be the intended operator. This document will serve as the only necessary training guide needed to get full functionality from the device.

## Specifications and Functionality of the ActiGraph Link

### Data

The Link includes two accelerometers, gyroscope, and magnetometer sensors. Data will not be negatively affected by lint, dust, or direct sunlight.

### Acceleration

Acceleration is measured by two accelerometers; a primary that is utilized for all historical and standard data collection efforts and a secondary which is used in very specific use cases where a higher dynamic range is necessary.

Parameter	Primary	Secondary	Units
Axis	3	3	
Sensitivity	0.5	4	mg/LSB
Dynamic Range	+/-16	+/- 8	g

Table 1 – Accelerometer Key Specifications

Acceleration data from the primary sensor is sampled at rates ranging from 30 Hz to 100 Hz (user selectable) and the secondary accelerometer data is sampled at a fixed 100 Hz. Output from both devices are stored in a raw, non-filtered/accumulated format in the units of gravity (g's). This data is stored directly into a non-volatile flash memory. The accelerometer is very sensitive and is accurate within +/- 0.5% of the data collected.

### Gyroscope

A three axis gyroscope collects angular velocity in units of degrees/sec. Data is sampled at 100 Hz.

Parameter	Value	Units
Axis	3	
Sensitivity	0.06	Deg/LSB



Dynamic Range	+/- 2000	Deg/sec
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Table 2 – Gyroscope Key Specifications

### Magnetometer

A three axis gyroscope collects angular velocity in units of degrees/sec. Data is sampled at 100 Hz.

Parameter	Value	Units
Axis	3	
Sensitivity	0.6	μT/LSB
Dynamic Range	+/- 4800	μT/LSB

Table 3 – Magnetometer Key Specifications

### Steps

Step counts are accumulated on a per-epoch basis and are based on accelerometer data collected on the vertical axis. An algorithm present in the device firmware filters out the accelerometer's baseline noise level to help accurately accumulate the steps-per-epoch.

### Inclinometer

The inclinometer feature can help users identify the orientation of the device and, more importantly, when the device itself was taken off. Each epoch is flagged with a number (1 through 4) to indicate the orientation of the device during that epoch. For ActiGraph Link devices, this is done within the ActiLife software when converting the \*.gt3x file to \*.agd format. **As noted, the inclinometer feature is only valid when the device is worn vertically on the point of the hip.** More details are available in the [Inclinometer Whitepaper](#).

***Important** The inclinometer feature is only valid if the device is worn on the hip with Axis 1 upward facing.*

Inclinometer Code (Stored with each Epoch)	Interpretation
0	Device Off (Not Being Worn)
1	Subject Standing
2	Subject Lying Horizontal
3	Subject Sitting

Table 4 - Inclinometer Definitions



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### **Off Indication on ActiGraph Link versus other devices**

The Inclinometer feature offers researchers the ability to detect periods of time during which the device was not worn. For devices other than the wGT3X+, wActiSleep+, GT3X+, and ActiSleep+, the inclinometer algorithm makes this prediction by examining the angle at which the device is placed. In the wGT3X+, wActiSleep+, GT3X+, and ActiSleep+ devices, off detection is performed by analyzing both the angle at which the unit is placed as well as the length of time the device remains still. Absolute stillness for three (3) minutes indicates that the unit is likely in an “off” condition regardless of orientation. As such, epochs that follow three motionless minutes of activity are flagged as “off,” i.e., the inclinometer code is equal to zero. These values are not retroactive. That is, the first three minutes of zero activity are not flagged as “off.” In addition, 30 minutes in the “off” orientation will cause the inclinometer value to indicate off after that time period has elapsed regardless of motion.

At this time, the inclinometer feature is being validated by the research community.

### **Low Frequency Extension**

The Low Frequency Extension (LFE) option, though not a mode or channel, is another data collection option during post-processing for the ActiGraph Link. The **Normal** proprietary filter algorithm used in ActiGraph products is used to eliminate any acceleration noise outside of the normal human activity frequency bandwidth. This filter is customized to work with ActiGraph’s [Energy Expenditure Algorithms](#). The LFE option, when enabled, extends the lower end (baseband) of the filter cutoff, effectively expanding the bandwidth of the accumulated data. This option is useful when measuring actigraphy data for subjects who move slowly or take very light steps (for example, the elderly). For more details, contact ActiGraph at [support@theactigraph.com](mailto:support@theactigraph.com).

### **Data Collection**

During initialization, the user chooses the raw data sample frequency (30Hz up to 100Hz in 10Hz increments). The ActiGraph Link collects data from all on-board sensors in raw data format. Data recorded includes:

- Vertical Axis Activity Acceleration Data (**Axis 1**)
- Horizontal Axis Activity Acceleration Data (**Axis 2**)
- Perpendicular Axis Activity Acceleration Data (**Axis 3**)
- Ambient Light (**Lux**)

*Although Steps and Inclinometer are not directly measured during data collection, these values can be derived from the 3-axis data during \*.gt3x file decompression.*

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Unlike previous ActiGraph products, the ActiGraph Link does not filter or accumulate data into epochs. Raw data is collected at the selected sample rate and is post-processed in the ActiLife. Because these devices collect data from all sensors at all times, users can generate native ActiLife \*.agd files containing any desired combination of parametric data at a later time. This helps facilitate backward compatibility

and enhances the flexibility of the data by allowing users to compare data to studies which use different filter techniques or accumulation sizes (e.g., 1 second epochs versus 60 second epochs).

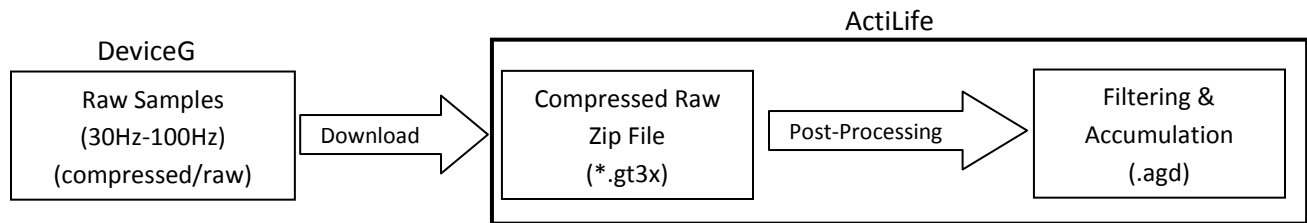


Figure 1 – Raw Data Collection and Processing

### Water Resistance

ActiGraph Link devices are water resistant in accordance with IEC 60529 IP27, or immersion in one (1) meter of water for up to 30 minutes

### Wireless

In addition to the standard features and functionality of their predecessor devices (wGT3X+ and wActiSleep+), ActiGraph Link provides a wireless interface by way of Bluetooth 4.0™ wireless communication protocol. This 2.4 GHz based interface allows for interoperability with millions of already fielded nodes as well as provides a means of rapidly gathering device and/or subject information. The wireless functionality can be disabled when not needed in order to increase battery life.

### Heart Rate

By way of Blue Tooth Smart chest straps, the ActiGraph Link is capable of measuring and storing both standard heart rate in Beats Per Minute (BPM) format as well as providing R-to-R measurements thus enabling the researcher to better understand heart the subject's activity profile.

### Wireless Reporting and Control

In addition to enhancing and increasing the sources for data collection, the wireless functionality of the ActiGraph Link enables the user to perform many functions that previously required USB connection or weren't possible before. Many functions can now be performed in the field rather than requiring the researcher to be tethered to a computer in the lab.

### Initialization

The ActiGraph Link can be fully initialized wirelessly. This can be performed with ActiGraph's new ActiLife Mobile available on the iPhone and Android platforms.

### Device Status

Device specific status information can be obtained. Some of the items retrieved include; firmware version, battery voltage, current mode, subject name, and device serial number.



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### *Stopping the device*

In order to stop the device from collecting data, the device needs to be plugged into a computer with the ActiLife Software running. One easy way to stop the device from collecting data is to set a stop time during initialization. Once a device is told to stop, it will go into HALT mode and go into a low power stopped state. Another way to get a device to stop collecting data is to plug it into a computer with the ActiLife Software running and update the firmware on the device. This also will put it into HALT mode and have the device go into a lower power stopped state.

### *Unexpected operations and events*

If a device performs in an unexpected manner and does not collect data, does not perform 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, 8A.M. to 5P.M Central Standard Time. Customer Service may also be contacted through email at [support@theactigraph.com](mailto:support@theactigraph.com).

### *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 and 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 possibly completely 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 and described by ActiGraph.

### **Battery**

All ActiGraph devices use a lithium polymer rechargeable battery that has a maximum voltage of approximately 4.20 volts and have a total life expectancy of five (5) years. Even though these batteries are replaceable, only ActiGraph personnel are to replace the batteries. At 3.1 volts the devices enter a low voltage mode state (HALT mode).

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) in low ambient temperatures. Every three (3) months plug the devices in to monitor their voltages and to extend the life expectancy of the battery. Table 5 demonstrates the impact of storage temperature and charge state on battery long term capacity.



Temperature	Remaining capacity at 40% charge (recommended storage charge level)	Remaining capacity at 100% charge (typical user charge level)
0°C	98% after 1 year	94% after 1 year
25°C	96% after 1 year	90% after 1 year
40°C	85% after 1 year	65% after 1 year
60°C	75% after 1 year	60% after 3 months

Table 5 - Lithium Polymer Storage

*Note: If a computer is not available or if multiple devices need to be recharged, a self-powered USB hub can be used.*

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

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ActiGraph Link		
Sample Rate (Hz)	Battery Life (Days)	Memory Limit (Days)
30	16	120

Table 6 – Battery life based on 16 Hrs Active, 8 Hrs sleep.

ActiGraph Link		
Sample Rate (Hz)	Battery Life (Days)	Memory Limit (Days)
30	10	120

Table 7 – Battery life based on no sleep (24 hrs active).

### Low Voltage Mode (HALT)

ActiGraph devices enter a “Low Voltage Mode” (or HALT) state when the battery discharges beyond a point of being able to power the device. In this mode, all important variables and data are stored in flash memory to secure the device download. Because the device’s internal clock stops in HALT mode, the device cannot be recharged and redeployed; the device must be downloaded and reinitialized to continue use.

### Recharging

Recharging is automatic and is accomplished by connecting the device to ActiGraph’s charging station. Charging time will depend on the battery life, but typically will not exceed three hours for a fully depleted battery to become fully charged. If the battery voltage drops below 3.1 volts while in use, the device will not have sufficient power to collect data and will display a warning to the user. The battery level, reported in volts, can be viewed at any time by starting the ActiLife software and plugging in the device.

***Important: ActiLife will not allow initialization if the voltage is below 3.85 volts.***





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## **Wearing the Device**

All ActiGraph activity monitors are designed to monitor activity and record energy expenditure (calories spent during normal activity, METs, everyday activity, and exercise). Additionally, these devices can also function as a very accurate sleep assessment tool<sup>2</sup>. While collecting day-to-day energy expenditure data, the device should be affixed securely to the body's center-of-mass to ensure the most accurate caloric measurements. Wrist worn (non-validated) EE for kids is now available for 3-axis ActiGraph devices. When being used for sleep assessment, ActiGraph devices may be worn anywhere on the body: wrist, waist (hip), arm, or ankle.

It is recommended that children under 12 years of age wear ActiGraph devices on the elastic belt (versus the adhesive belt clip) as it is the most secure way to wear the device. Belt loop pouches, wrist and ankle straps are also available.

If irritation of the skin occurs due to wearing the device, discontinue wearing the device and consult a doctor for treatment. Although the Polycarbonate and Polyvinyl Chloride 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. Also, notify the individual that issued the device to you that you have taken the device off since data collection will be effected.

## **Miscellaneous Device Information**

### **Degradable Components**

ActiGraph's devices are made with high quality components that are not subject to deterioration over time. The battery within each device is the only component that has a determined life expectancy (5 years). If a device seems to be under-performing, call ActiGraph's Customer Service department immediately so the problem may be resolved. Batteries are only to be changed by ActiGraph trained personnel.

### **Other Possible Negative Effects**

Pets have the potential to destroy a device. Keep devices away from pets and other animals that may chew on, bite, urinate on, swallow, and destroy a device in any other method imaginable.

### **Wear Locations**

ActiGraph's devices can be worn in 6 different locations; the ankle, thigh, in a pants pocket, on the waist, wrist, or on a lanyard around the neck. When initializing the ActiGraph Link within ActiLife, choose the appropriate wear location to ensure accurate data collection.

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<sup>2</sup> Sleep analysis can also be performed by purchasing ActiGraph's ActiSleep analysis program, which is part of the Virtual Trainer, web-based, analysis software. Formulas for this tool were developed by Dr. Avi Sadeh, Department of Psychology, Tel Aviv University.



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## Device Serial Number Label

Each ActiGraph device is equipped with a label stuck to it with pertinent device information inside the serial number. For example the serial number MRA3A29120016 means:

- MRA3 = device model
- A = device model version
- 29 = week of the year it was manufactured (29<sup>th</sup> week)
- 12 = year it was manufactured (2012)
- 0016 = number of device manufactured that week

## Cleaning the Device

ActiGraph devices are approved to be cleaned with a non-abrasive cloth and isopropyl alcohol. For optimal results, apply isopropyl alcohol to the cloth, clean the device for 15-20 seconds, and let air dry. ActiGraph devices are not to be sterilized because damage may occur. Though ActiGraph 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.

## Device Storage and Life Expectancy

There is no specific requirement for storing ActiGraph devices but a dry location with temperature limitations between 0°C and 50°C is suggested. For optimal battery life expectancy, routinely charge the device according to Table 5.

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 performance of the components inside the device does not degrade over time so the life expectancy of a device is immeasurable.

## Device Maintenance

ActiGraph's 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 [www.actigraphcorp.com](http://www.actigraphcorp.com) 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, will be made available to the trained ActiGraph service technicians.

## Accessories

Accessories sold at ActiGraph are constantly changing due to the ever changing features available with the ActiGraph Link. For a full list of current accessories available for the ActiGraph Link, please visit ActiGraph's website [www.actigraphcorp.com/product-category/accessories](http://www.actigraphcorp.com/product-category/accessories) . Use the accessories

provided by ActiGraph only 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 USB caps have a life expectancy of 1-3 years. The Waist straps have a life expectancy of 5+ years. 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.

### Connection and disconnect of detachable accessories

#### *Wrist Watch*



1)



2)

Step 1) Wrist watch by itself

Step 2) Insert device into one side of the watch device holder



3)

Step 3) Push the top of the device into the watch device holder until it is flush with the edges of the watch

### Belt Clip



Step 1) Belt clip by itself

Step 2) Insert the device into one side of the belt clip



Step 3) Push the top of the device into the belt clip until you hear an audible “click” securing the device into the belt clip



## Appendix

### Risk Management Documentation

Below is a required list of internal ActiGraph documents created or used to comprise the Risk Management File for the ActiGraph Link.

Document Number	Description	Revision	Effective Date
TAS14DOC02	Design Requirements	A	4/25/14
TAS14DOC01	Risk Management Plan	A	4/25/14
TAS14DOC04	Development Life-Cycle	A	4/25/14
TAS14DOC03	Risk Management Summary	A	4/25/14
TAS14TRD01	Taso Verification Plan	A	4/25/14