User's Manual for the wGT3X+ and wActiSleep+

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Change Page

About the change page table

The following table describes the changes that have been made to this document since its original baseline. This table shall be maintained as long as this document is active.

Revision	Brief Description of Change	Date of Approval
A	Initial version	5/30/2012

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Important Information and Symbols

The wGT3X+ and wActiSleep+ devices abide by the following regulations listed below and give explanation into the symbols that are found on each device. These symbols and statements apply to both the wGT3X+ device and the wActiSleep+.

	The devices are compliant with IEC (International Electrotechnical Commission) standards for "Type BF Applied Part" - meaning they comply with requirements for protection against electrical shock.
	CAUTION: Do not simultaneously charge and wear the device. The end user should not be in the patient vicinity when being charged[1]
	CAUTION: Transporting or operating these devices outside of the temperature range of -20°C to +60°C could lead to dangerous conditions and/or incorrect data collection.
	Class II medical device
	• 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 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.

[1] 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.

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CE	These 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: • EN 60601-1: 1988 + A1: 1991 + A2: 1995 – Medical Electrical Equipment Part 1: General Requirements for Safety • 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) • 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 • EN 55011:2009, inc. A1:2010 – Limits and methods of measurement of radio disturbance, characteristics of industrial, scientific and medical radio frequency equipment • EN 300 440-2 V1.4.1 – Electromagnetic compatibility and Radio spectrum Matters (ERM); Short range devices; Radio equipment to be used in the 1 GHz to 40 GHz frequency range; Part 2: Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive (wGT3X+ device only) • 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
Industry Canada Industrie Canada Canada	These 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. 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.

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Australia/New Zealand	These devices comply 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 • AS/NZ CISPR 22 (2009) – Information technology equipment – Radio disturbance characteristics – Limits and methods of measurement
Physiological Effects	The wGT3X+ and wActiSleep+ do not produce any known physiological effects.
	The wGT3X+ and wActiSleep+ are manufactured Lead-Free and comply with RoHS standards (Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment)
	The wGT3X+ and wActiSleep+ are water resistant in accordance with IEC 60529 and have the International Protection Rating: ***IPX7***, or immersion in one (1) meter of water for up to 30 minutes.
	Contact ActiGraph Customer Service regarding the disposal of these products.

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Introduction

The wGT3X+ and wActiSleep+ 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 and an ambient light as data sensors.

Specifications and Functionality of the wGT3X+ and wActiSleep+

Data

The devices include both an acceleration sensor as well as an ambient light sensor.

Acceleration

The devices include an acceleration sensor that consists of a microelectromechanical systems (MEMS) accelerometer yielding the following product specifications:

Parameter	Value	Units
Axis	3	
Sensitivity	220	mV/g
Dynamic Range	+/- 6	G

Table 1 – Accelerometer Key Specifications

The acceleration data is sampled by a 12 bit analog to digital converter at rates ranging from 30 Hz to 100 Hz (user selectable) and stored in a raw, non-filtered/accumulated format in the units of gravity (G's). This data is stored directly into a 256 or 512 MB non-volatile flash memory.

Ambient Light

Ambient light data is sampled and stored to memory at a 1 Hz rate. When a downloaded data file is converted into an accumulated *.agd format with epoch lengths greater than one second, the lux values for that epoch are averaged. An estimate of lux values is shown in Table 1.

Lux Level	Interpretation Comparison
1	Twilight
50	Family living room
100	Very dark overcast day
320-500	Office lighting

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400	Sunrise/sunset
1,000	Overcast day
10,000-25,000	Full daylight
32,000-130,000	Direct sunlight

Table 1 – Lux Level Interpretation Estimates

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 wGT3X+ and wActiSleep+ 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 3 - Inclinometer Definitions

Off Indication on wGT3X+ and wActiSleep+ 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

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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 device initialization, and during post-processing for the wGT3X+ and wActiSleep+. 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.

Data Collection

During initialization, the user chooses the raw data sample frequency (30Hz up to 100Hz in 10Hz increments). The wGT3X+ and wActiSleep+ collect 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.***

Unlike previous ActiGraph products, the wGT3X+ and wActiSleep+ do 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).

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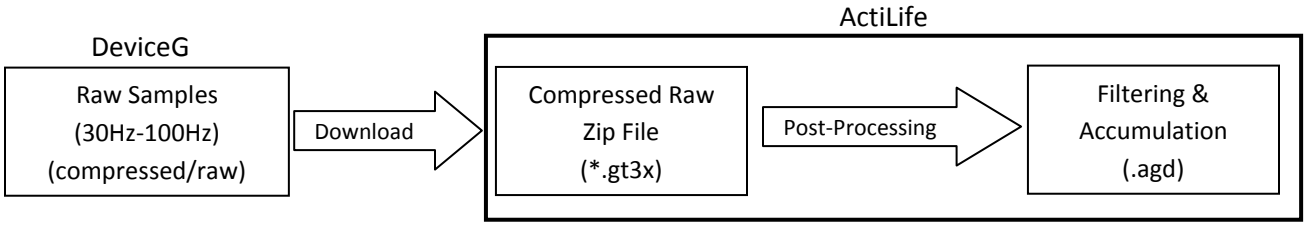

Figure 1 – Raw Data Collection and Processing

Water Resistance

The wGT3X+ and wActiSleep+ are water resistant in accordance with IEC 60529 IPX7, 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 (GT3X+ and ActiSleep+), the wGT3X+ and ActiSleep+ provide a wireless interface by way of the ANT 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.

Sensor Connectivity

One of the primary benefits of the ANT protocol being implemented on the wGT3X+ and wActiSleep+ activity monitors is the ability to seamlessly merge data from other relevant sensors. Some of the device types currently supported by the ANT protocol are; Heart Rate Straps, Weight Scales, and Blood Pressure Cuffs. The ability to integrate data from different sensors significantly increases the usability of the devices.

Wireless Reporting and Control

In addition to enhancing and increasing the sources for data collection, the wireless functionality of the wGT3X+ and the wActiSleep+ 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

Both the wGT3X+ and the wActiSleep+ can now be fully initialized wirelessly. This can be performed with a PC utilizing a USB ANT dongle or with ActiGraph's new ActiLife Mobile available on the iPhone platform.

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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Data Summary

A new feature being introduced with the wGT3X+ and wActiSleep+ is data summary. This feature provides a wireless mean to rapidly tell information about the subject data. Daily and cumulative totals are provided for counts, steps, and cut points. Additionally, a non-sedentary value is presented in order to allow the researcher to rapidly gain insight into subject wear time/compliance.

Battery

All ActiGraph devices use a lithium ion rechargeable battery that has a maximum voltage of approximately 4.20 volts. At 3.1 volts the devices enter a low voltage mode state (HALT mode).

In order to slow the aging of the Lithium Ion battery, it is recommended that devices be stored in a partially charged state (40 – 60% battery capacity) in low ambient temperatures. Table 4 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	80% after 1 year
40°C	85% after 1 year	65% after 1 year
60°C	75% after 1 year	60% after 3 months

Table 4 - Lithium Ion 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.

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wGT3X+ and wActiSleep+		
Sample Rate (Hz)	**Battery Life (Days)**	**Memory Limit (Days)**
30	31.00	42.50
40	27.50	32.00
50	24.50	25.00
60	22.50	21.00
70	20.50	18.00
80	19.00	16.00
90	17.50	14.00
100	16.50	12.50

Table 5 – Battery life based on 16 Hrs Active, 8 Hrs sleep.

wGT3X+ and wActiSleep+		
Sample Rate (Hz)	**Battery Life (Days)**	**Memory Limit (Days)**
30	22.50	42.50
40	20.50	32.00
50	17.50	25.00
60	16.00	21.00
70	15.00	18.00
80	13.25	16.00
90	12.25	14.00
100	11.50	12.50

Table 6 – Battery life based on no sleep (24 hrs active).

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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 and LED Decoding

Recharging is automatic and is accomplished by connecting the device to a standard USB port. Charging time will depend on the battery life, but typically will not exceed four hours for a fully depleted battery to become fully charged. Once the battery is completely charged, the green LED will remain illuminated. If the battery voltage drops below 3.1 volts while in use, the device will not have sufficient power to collect data and will warn the user through a series of coded flashes (see **Error! Reference source not found.**). 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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Device Connected to PC

Red LED (Fault Indicator)

2 Flashes	Li-Ion Battery is Faulty
3 Flashes	A hardware failure occurred while recording data. Contact customer support at support@theactigraph.com

Green LED

1 Flash	Battery Charging
Multiple Flashes	Communicating with PC via USB
Steady On	Battery Fully Charged

Device Not Connected to PC

Red LED (Fault Indicator)

No Flashing (LED Off)	Normal operating condition or battery dead
2 Flashes	Low Battery (use ActiLife Lifestyle software to check for remaining battery life). The unit needs to be recharged.
3 Flashes	- Unexpected Battery Failure (Temporary battery power loss) or - Battery Level has fallen below 3.1V and the unit has entered Halt Mode

Green LED

No Flashing (LED Off)	Actively collecting data ("Flash Mode" disabled) or battery dead
1 Flash	- Delay before start mode (the LED always flashes prior to starting data collection) - Actively taking data ("Flash Mode" enabled – not recommended)
2 Flashes	N/A
3 Flashes	- End of memory reached (Device no longer collecting data) - Battery died while unit was in delay before start mode (no data collected on device)

- **Wireless Feature Enabled**	
- **Yellow LED (Wireless Indicator)**	
1 Flash Every 5 Seconds	- Actively paired with and receiving Heart Rate data
1 Flash Every Second	- Actively paired and communicating with ActiLife or ActiLife Mobile

Note: The Red LED will ALWAYS flash to indicate LOW BATTERY regardless of whether "Flash Mode" is enabled or disabled. If a "stop time" (optional) has been reached, the Green LED will stop flashing all together regardless of its previous state.

Table 7 – wGT3X+ and wActiSleep+ LED Reference Table

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Wearing the Device

All ActiGraph activity monitors are designed to monitor human 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[2]. 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.

Note: It is not safe to wear devices while they are charging.

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.

[2] 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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