

GT3X+ and wGT3X+ Device Manual

ActiGraph products are for prescription use only and not intended or approved for consumer use.



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
А	Initial version	5/30/2012
В	First Public Release	9/20/2012
С	Updated LFE section.	12/13/2012
D	Update ANT/ANT+ Specific Information	5/13/2013





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Important Information and Symbols

The GT3X+ wGT3X+ 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 GT3X+ and the wGT3X+.

*	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.
<u> </u>	CAUTION: Do not simultaneously charge and wear the device. The end user should not be in the patient vicinity when being charged ¹
<u> </u>	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
F©	 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.

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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.





These devices 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



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.

Australia/New

These devices comply with the Australian and New Zealand standards:

AS/NZS 4268 (2008) – Radio equipment and systems – Short range devices

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Zealand	 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.	
Pb	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)	
9.9	The wGT3X+ and wActiSleep+ are water resistant in accordance with IEC 60529 and have the International Protection Rating: <i>IPX7</i> , or immersion in one (1) meter of water for up to 30 minutes.	
7	Contact ActiGraph Customer Service regarding the disposal of these products.	



Introduction

The GT3X+ based activity monitors provide objective measurements of human activity and are used in many research and clinical applications. They include both a micro-electro-mechanical system (MEMS) based accelerometer and an ambient light sensor. The GT3X+ can also be ordered with a wireless option, wGT3X+, further extending the capabilities of the device.



Model	Functionality
GT3X+	Activity, lux, programmable sample rate, water resistant housing, high speed USB
wGT3X+	Activity, lux, programmable sample rate, water resistant housing, high speed USB, heart rate, wireless interface (ANT+ TM)

Specifications and Functionality of the GT3X+

Sensors

The GT3X+ and wGT3X+ include both an acceleration sensor and an ambient light sensor.

Acceleration

The acceleration sensor yields the following product specifications:

Parameter	Value	Units
Axis	3	
Sensitivity	3	mg/LSB
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 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 2.

Lux Level	Interpretation Comparison
1	Twilight
50	Family living room
100	Very dark overcast day
320-500	Office lighting
400	Sunrise/sunset
1,000	Overcast day
10,000-25,000	Full daylight
32,000-130,000	Direct sunlight

Table 2 – Lux Level Interpretation Estimates

Post Processed Data

The collected activity data can be utilized in a post-processed environment (ActiLife 6) to determine steps per epoch as well as inclinometer information.

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 post-processed inclinometer feature helps 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. More details are available in the <u>Inclinometer</u> Whitepaper.

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

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

Table 3 - Inclinometer Definitions



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 GT3X+ and wGT3X+. The standard 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, increases sensitivity to very low amplitude activities allowing for the study of population groups who move slowly or take very light steps (for example, the elderly). For more details, contact ActiGraph at support@theactigraph.com. .

Data Collection

Initialize time options/selections have been reduced significantly due to the new data collection method used by the GT3X+ and beyond devices. During initialization, the user is now only required to select the desired raw data sample frequency (30Hz up to 100Hz in 10Hz increments). Data is automatically collected from all on-board sensors in raw data format. The 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).

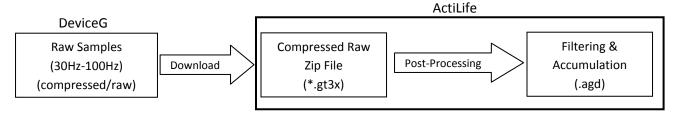


Figure 1 - Raw Data Collection and Processing



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 the GT3X+, the wGT3X+ provides a wireless interface by way of the ANT wireless communication protocol. Coupled with ANT+ standards, 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.

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

The wGT3X+ 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, soon to be 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.

Data Summary

A new feature being introduced with the wGT3X+ and wActiSleep+ is data summary. This feature provides a wireless means 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).

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. 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.



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 Normal operating condition or battery dead

(LED Off)

2 Flashes Low Battery (use ActiLife 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 Actively collecting data ("Flash Mode" disabled) or battery dead

(LED Off)

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 4 – LED Reference Table



Battery Conditioning and Storage

While Lithium Ion batteries provide the highest energy density on the market, their shelf life can be negatively impacted if not properly stored during periods of no use. 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 is ideal) in low ambient temperatures. 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	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 5 - 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.



Expected Battery Life

The inclusion of wireless and heart rate monitoring on the wGT3X+ make battery life projections very difficult due to the varying ways a researcher could incorporate these features. The tables below provide guidelines on battery life expectancy of the GT3X+ as well as the wGT3X+ when the wireless feature is disabled.

While ActiGraph is working towards providing some base guidelines on wireless impact to battery life, as a general rule the end user can expect approximately a 60% reduction in battery life. Testing is ongoing and once firm numbers are available this document will be updated to reflect.

wGT3X+			
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 6 – Battery life based on 16 Hrs Active, 8 Hrs sleep.

wGT3X+			
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 7 – Battery life based on no sleep (24 hrs active).



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 tool². 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.

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49 E. Chase St.

² Formulas for this tool were developed by Dr. Avi Sadeh. Department of Psychology, Tel Aviv University.