

Activinsights

GENEActiv Instructions for Use





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Overview

About GENEActiv

GENEActiv is a body-worn accelerometer and data logger. It is a wristwatch-like battery-operated activity recording device. It is a compact and lightweight device which can also be worn at different body locations.

The device is intended to be used for the acquisition of data related to limb or body movements during daily living and sleep.

The motion sensor (accelerometer) inside GENEActiv records the occurrence and degree of motion. The device's relative movement data is stored internally.

The captured data can be further downloaded through the charging cradle and the software. GENEActiv also incorporates a light sensor to record luminous intensity (lux) of white light.





Technical Specification

Physical Parameters	
Size	43mm x 40mm x 13mm
Weight	16g (without strap)
Main Housing Material	PC/ABS (medical device grade)
Light Guide Material	PC (medical device grade)
Data Contact Material	Gold-plated
Strap	PU resin
Battery Type	Rechargeable lithium ion polymer
Environmental Protection	
Moisture Ingress	Water-resistant to 10m (IP67 – 1m 24hrs)
Material Ingress	Dust tight (IP67)
Operating Temperature	5 to 40 deg C
Mechanical Impact	0.5m drop resistant
Measurement Capabilities	
Memory	0.5Gb non-volatile
Logging Frequencies	Selectable 10-100Hz
Maximum Logging Periods	30 days @20hz, 7 days @100hz
Internal Clock	
Type	Quartz Real Time Clock
Frequency	32.768kHz
Accuracy	+/- 20ppm (+/- 1.7s per day)
Acceleration Measurements	
Sensor Type	MEMS
Range	+/- 8g
Resolution	12 bit (3.9mg)
Light Measurements	
Sensor Type	Silicon photodiode
Wavelength	400 to 1100 nm
Range	0 - 3000 Lux typical
Resolution	5 Lux typical
Accuracy	+/- 10% @ 1000 Lux calibration
Event Logger	
Sensor Type	Mechanical membrane switch
Temperature Measurements	
Sensor Type	Linear active thermister
Range	0 to 60 deg C
Resolution	0.25 deg C
Accuracy	+/- 2 deg C
Measurement Frequency	Every 30s minimum
USB Connection	
Device USB	USB 2.0 Full Speed
Charging Cradle	Format 4 unit cradle USB 2.0 High Speed
Charge Time	90% @ 2 hours, 100% @ 3 hours
Data Download Time	Maximum 20 minutes for 4 concurrent units

Getting Started

a) System Requirements

In order to run the GENEActiv PC software you must have the following Windows PC specification:

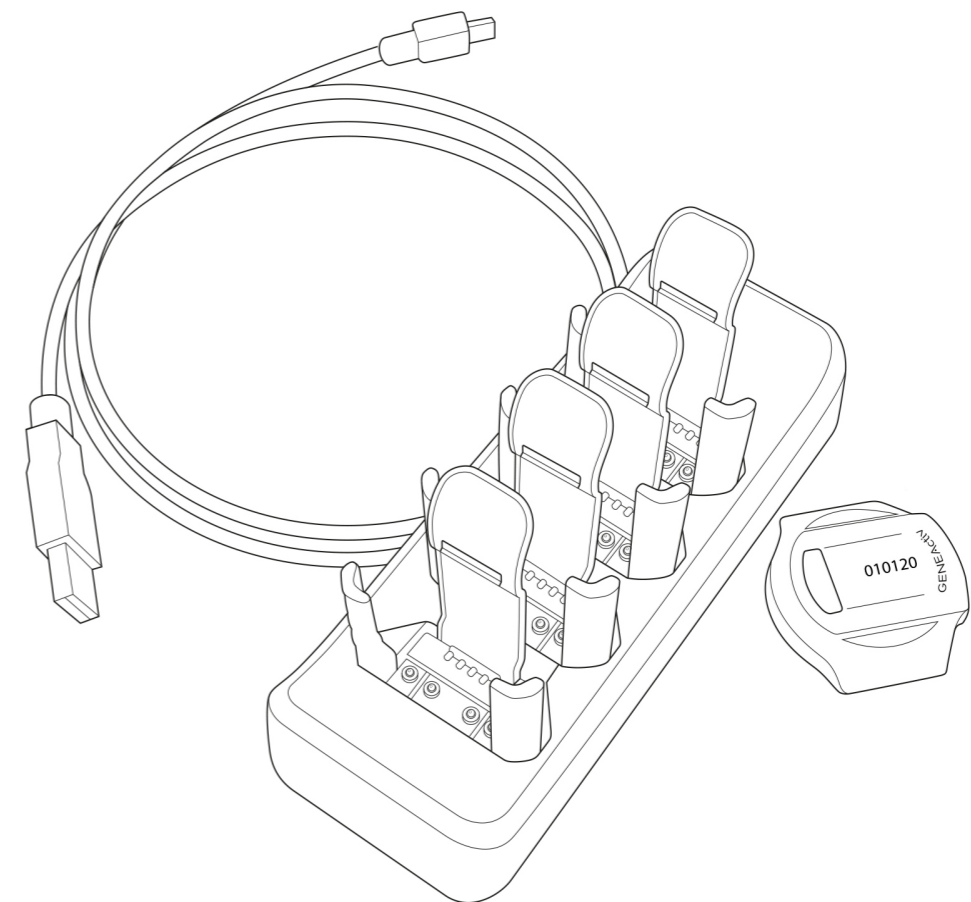
- PC with Intel Core i3 Processor, 2GB Memory
- Windows 10
- .NET Framework 4.7.2

b) What's Included

- GENEActiv single device with black resin wrist strap
- Spring bar tool with pins
- 4-up charger/download cradle with USB cable

To successfully use the GENEActiv, you must have access to the 4-up charger/download cradle to connect to the PC via USB cable.

Additional body straps and accessories are available upon request.





Charging & Storing

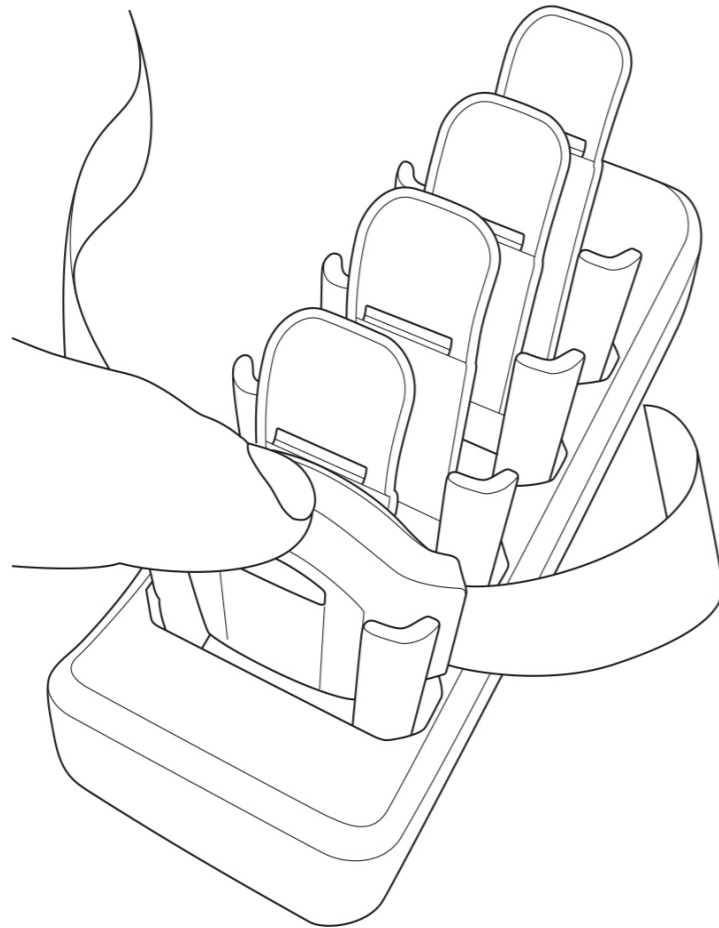
a) Charging

Once you have received your GENEActiv device(s) allow them to fully charge in the cradle for **3 hours** before configuring with the software.

This can be done via the USB port on your computer or using a USB wall plug. We recommend using a wall plug when charging your devices so that it does not interfere with the GENEActiv software. It is essential that the power supply provides 500mA on every port to ensure the devices fully charge.

A red light on the device will indicate that the device is charging. After 3 hours, once a green light flashes, this indicates that the device can be checked by the software to ensure the battery is full and the device is ready for configuration. The LED lights are just visual indicators - it is essential to check the battery level in the GENEActiv PC software for a reliable reading. When fully charged, unplug and remove devices from the cradle if you are not configuring straight away.

IMPORTANT: DO NOT leave GENEActiv devices on charge for longer than **3 hours** at a time. Following a full 3 hours charge, the GENEActiv should have over 90% battery, prior to deployment.

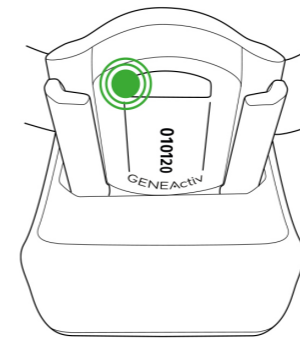


b) LED Signals

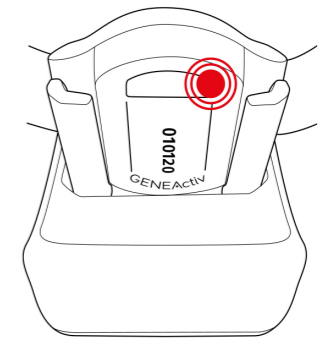
When not recording, the battery charge level can be checked by pressing the button on the device. See diagram below for LED indicators.

A green flash indicates that the device is OK to go into storage if it is no longer in use. A red flash or no flash at all means that the device should be charged (this function is not available if a device has been configured to record).

To ensure that a device is fully charged, it must be left in the cradle for a full 3 hours before deployment. To check the battery level, connect the device to the software. It should show at least a 90% battery level before deploying.



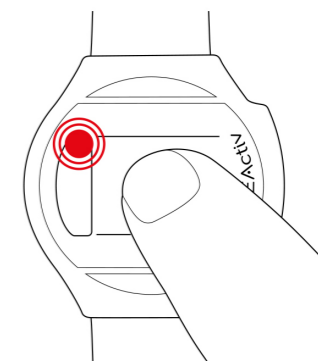
Green Flashing = check battery level in software (after 3 hours charge)



Constant Red = communicating
Flashing Red = charging



Long Flash (in button start mode) = recording started
Short Flash (when unconfigured) = battery good for storage



Long Flash (in button start mode) = recording stopped
Short Flash (when unconfigured) = battery needs charging



Device Setup & Configuration

a) Installing Software

Download the GENEActiv PC software from the Activinsights website: www.activinsights.com/geneactiv-support

It is important that once the GENEActiv software has been downloaded, users also need to download the 'GENEActiv Drivers' (.zip) from the Activinsights website.

To install the GENEActiv Drivers:

- Connect cradle via USB cable
- Insert device into cradle
- Navigate to the local drivers folder
- Double left click the 'install.bat' file
- Follow the automatic pop-up Wizard steps
- Once complete, the GENEActiv serial number will appear listed at the top of the GENEActiv PC software.

If device does not appear in software, drivers have not installed correctly. In this instance:

- Open device manager
- Find GENEActiv device, should be listed as Geneactiv_01
- Right click device and select update drivers
- Point the installation dialog to the drivers folder on the desktop
- Drivers should install
- Device manager should now list GENEActiv V1.1
- GENEActiv device serial number should appear in software

b) Software Overview

Once you have completed the installations, open the software and click the 'Advanced Mode' checkbox in the bottom right hand corner. You will then see the main dashboard and the menu along the left-hand side. Connect one or more devices via the cradle.

1. Device Capabilities

This tab displays information about the device(s) connected and existing stored data.

2. Config. Setup

This tab allows the GENEActiv device(s) to be configured and details of the trial and test subject to be entered on the device.

3. Data Extractor

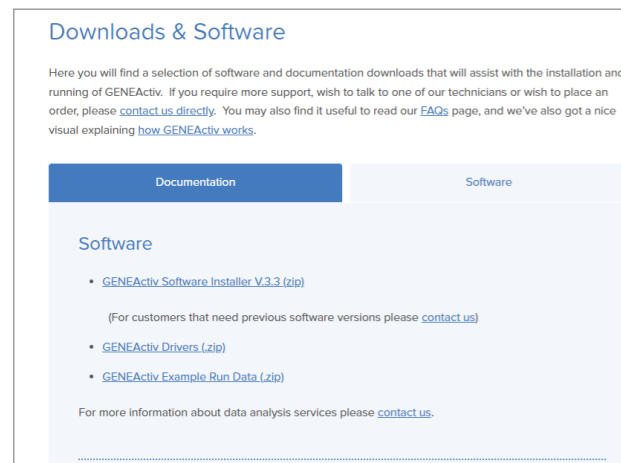
This is where you will go to extract the data once recording has finished.

4. Data Converter

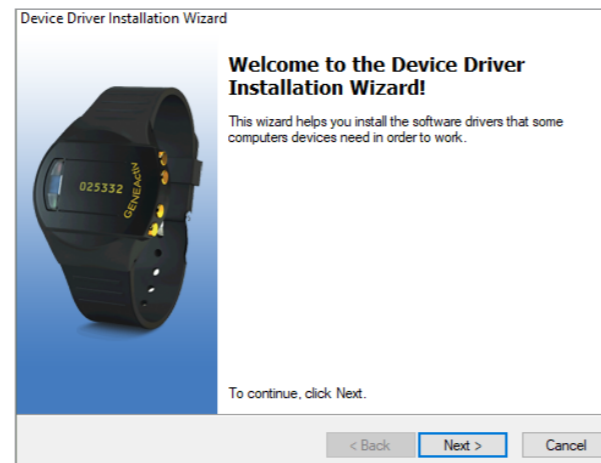
The Data Converter allows you to convert one or more .bin files into .csv files that can be read by the GENEActiv viewer and Excel. The convertor can combine the data for up to 5 devices to have a single time stamp. The combine .bin files function is not recommended for trials of more than a couple of hours due the data processing time and file size. Data conversions can take up to 15 minutes to complete.

5. Data Analysis

The Data Analysis tab allows you to view .bin and .csv files and zoom in on a particular section. This subsection can then be saved as a raw data .csv file.



Download the Software and Drivers from the Activinsights Website.



Follow the installation wizard on your PC.



Ensure the **Advanced Mode** box is checked.



c) Device Setup

Once the device is connected, you will see the device number(s) displayed in the panel at the top of the screen.

i). Measurement Frequency

Choose your Measurement Frequency (hz). The Maximum Measurement Period will be automatically calculated. The Maximum Measurement Period will depend on the frequency selected below.

Measurement Frequency	Max. Measurement Period (Days)
20	30
25	28
30	21
40	18
50	15
60	12
66.7	11
75	10
85.7	9
100	7

ii). Time Settings

Choose which time setting the device should use. This should be the Local PC Time (unless the PC time is known to be wrong, in which case the Manual Time setting can be used instead). The Time Setup dictates the timestamps for the measurement period.

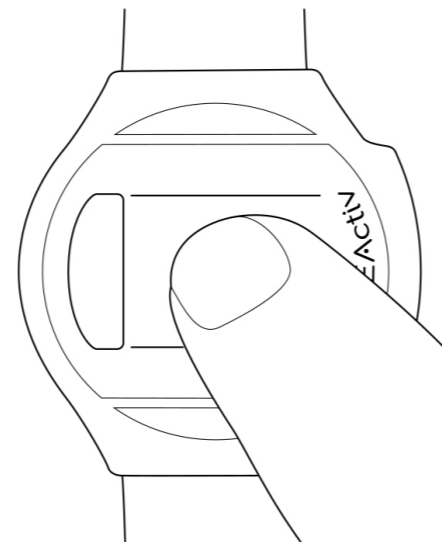
iii). Recording Start Mode

There are three different start modes:

'On Button Press' means that recording will start after the device is removed from the charger cradle and the button (hidden under the serial number) on the device is pressed. In this mode the green light will give a longer flash when the button is pressed to indicate recording has started.

When this mode is selected, the option to 'Allow Stop & Restart' will also appear. Leaving this unselected means that once recording starts, the button becomes inactive so recording cannot be accidentally interrupted.

The button will not interrupt recording, but instead will be used as an event marker only, when required.



Selecting the 'Allow Stop & Restart' option allows the button to remain active and control recording stopping and starting. This is only recommended for laboratory testing.

'Immediately on Disconnect' starts recording as soon as the device is removed from the cradle. The LEDs are inactive in this mode and the button will not interrupt recording, but instead will be used as an event marker only, when required.

'At Future Time' allows the operator to choose a start time up to 2 weeks in the future. Recording will start automatically at this point. The LEDs are inactive in this mode and the button will not interrupt recording, but instead will be used as an event marker only, if required.

iv). Subject info

Once the date of birth is selected, the age will be calculated automatically. Enter the height in cm and weight in kg. The height in feet/inches, weight in stones/pounds and BMI will then be calculated automatically.

We do not recommend entering personal data, such as date of birth, as this can be entered post data collection if required. It does not directly affect any data collected and means there is no Personally Identifying Information stored on the device.

v). Configuration

Select which device(s) are to be configured. A tick box will appear next to the relevant device serial number. At least one device must be selected. It can be useful to configure multiple devices together when a trial subject will wear several GENEActiv devices on different body locations.

When **'Erase & Configure'** is clicked, a pop-up message will automatically appear to warn that continuing will erase all previously stored data and to confirm the recording start mode. There will also be warning pop-ups if any mandatory information is missing, or if the battery charge is below 80%. If the warning message appears due to the battery being less than 80% do not deploy the device.

Device configuration will take about 10 seconds and a pop-up message will automatically appear to confirm that it has been set up successfully and is ready for deployment. The device will record for the given data collection period. There is no need for any additional charging (this should be avoided due to the important note below).

IMPORTANT: Once the configuration of the device is complete, it is important that the device is not returned to the charger cradle at any point, until after data collection. If the device is re-entered into the cradle for any reason, it will stop data recording and must be reconfigured to start the data collection process.

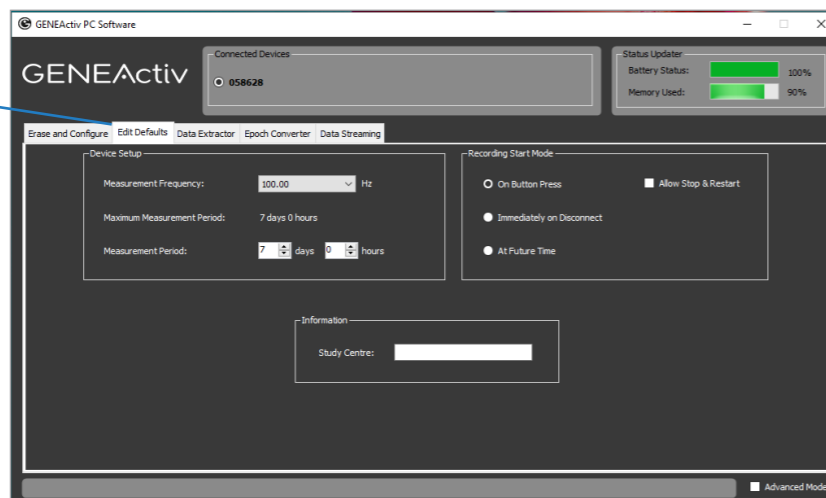


vi). Quick Setup

Quick setup mode is most useful if the frequency data being collected is going to be the same for all devices and there is no additional trial or subject information to enter.

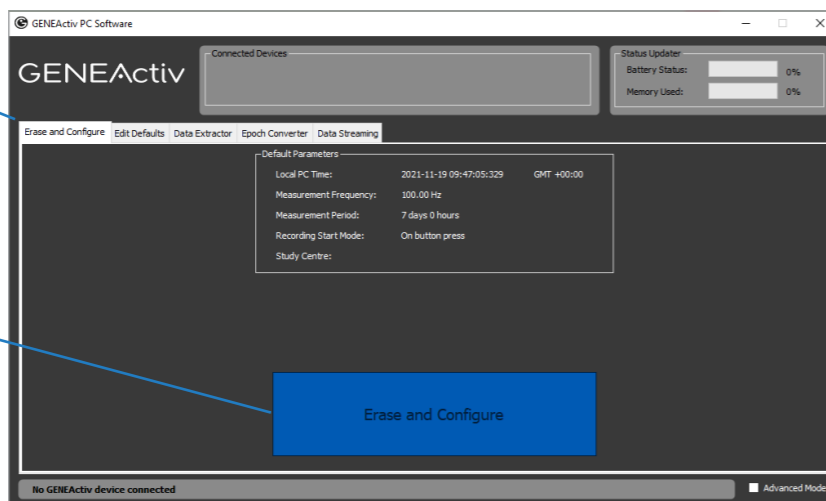
To get started, click the 'Edit Defaults' tab and complete the required fields. Then, return back to the 'Erase and Configure' tab and click 'Erase and Configure' to apply settings to all devices.

Click Edit Defaults



Return to Erase and Configure tab

Click Erase and Configure



Data Collection & Extraction

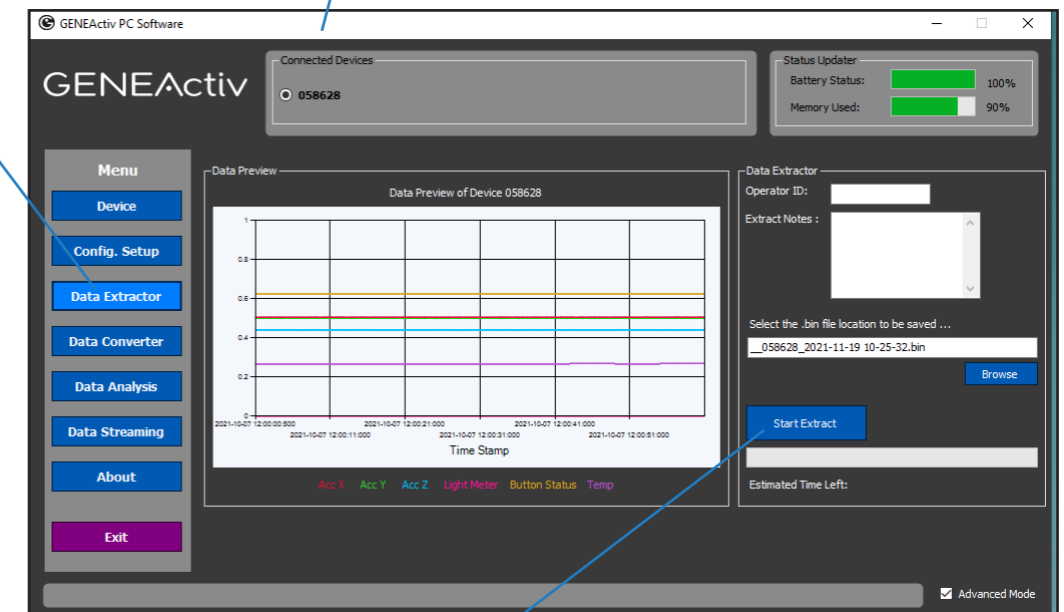
a) Extracting Data

1. Open the GENEActiv software and connect the charging cradle to a USB port. Insert a GENEActiv device into the cradle. Ensure 'Advanced Mode' is checked in the bottom right-hand corner.
2. Click 'Data Extractor' from the left-hand menu. This page previews the first few minutes of recorded data and allows for the download of the data to a chosen file location.
3. Chose a file location and select whether to also create a .csv format file. The default data format is a compressed .bin file. To interpret this file, you will need statistical analysis software (such as R) as .bin files are not readable in Excel.
4. Click the 'Start Extract' button.

Please note: The data extraction can take up to 20 minutes per device. A pop-up window will confirm successful completion.

Click Data Extractor in the left hand panel

Connected devices will show in the top panel



Click Start Extract button



b) Reading Data

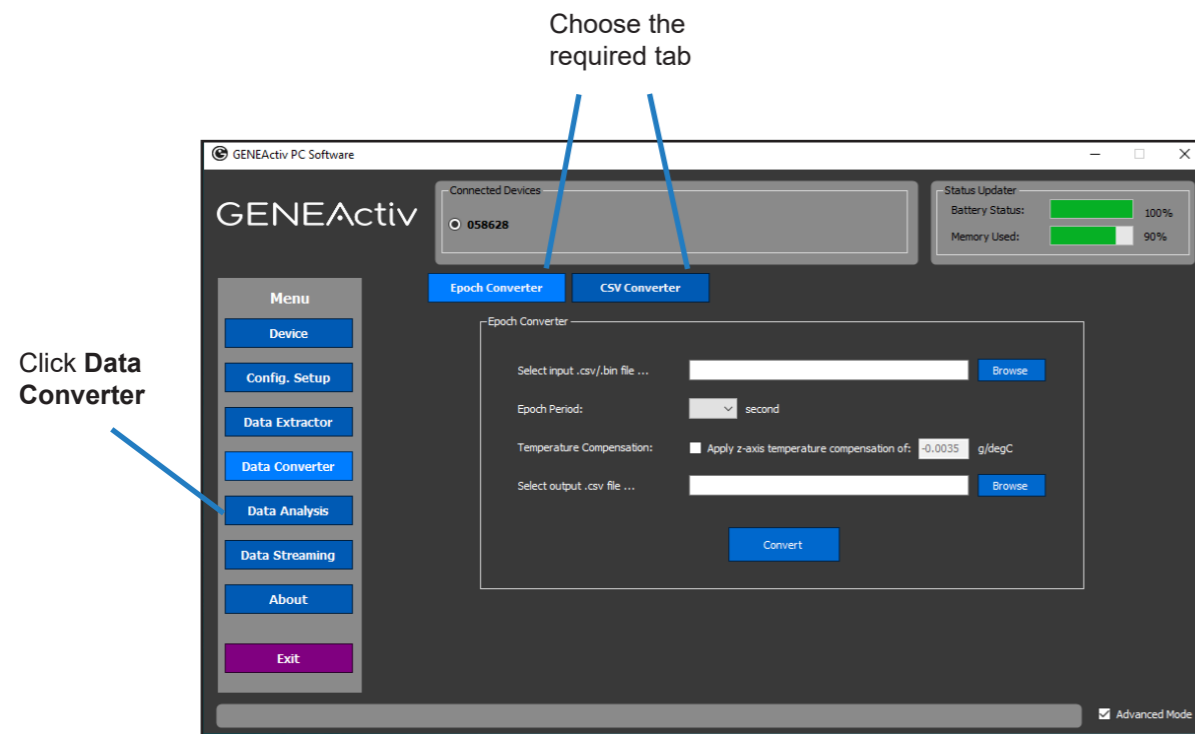
i). Data Converter and Data Analysis

To convert the .bin file to .csv format/compressed .csv format, select the 'Data Converter' and 'Data Analysis' tabs from the left-hand menu. This will allow files to be opened in Excel and the original format can be saved and converted to other formats when needed.

The 'Data Converter' creates .csv files, which can be used by Excel, from .bin files. Please note that older versions of Excel cannot manage very large .csv files. To convert a .bin file to .csv, select the input .bin file and copy the name of the file. After this select the output .csv file path and paste the file name and type .csv at the end then you will be able to Start Convert.

The 'Epoch Converter' can be used to turn .bin and large .csv files into a smaller compressed version. It does this by creating epochs of 1, 5, 10, 15, 30, or 60 seconds – the means for each parameter and the Sum Vector Magnitude are calculated for each epoch.

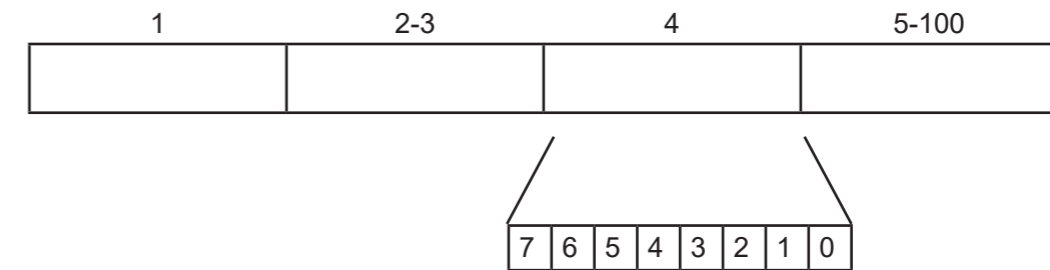
The 'Data Analysis' tab has a viewer which allows data from .bin and .csv files to be previewed. There is an option to look more closely at sections of the data.



ii). Understanding .bin files

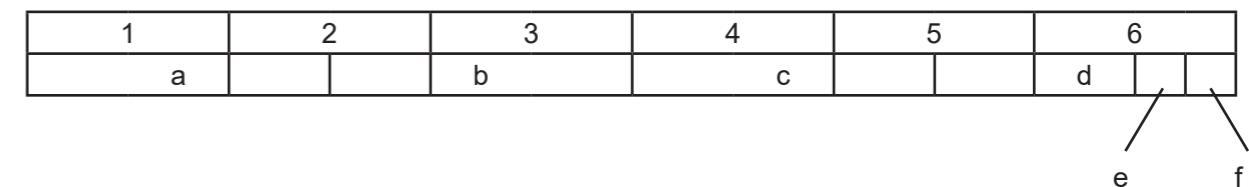
The .bin file output when opened will display as the following:

- Main header (lines 1 to 59)
- Pages of 300 measurements (lines 60 to 72, 73 to 85 etc)
- Each page will have a sub header (e.g. lines 61 to 68)
- Data block (e.g. lines 69 to 72)



The time span of a page is dependent on the measurement frequency. Each measurement consists of 3 axis of acceleration, a light measurement, and the button status. In the page header, the battery voltage and the temperature are recorded as well as some of the basic set-up information.

The time stamp of the page corresponds to the first measurement of the page. The first 300 measurements block of the hexadecimal data starts on line 69 of the file. This is a sequential stream of 6-byte data blocks, starting at the timestamp in the page header.



- a 12 bits accelerometer x axis (+/- 2048)*
- b 12 bits accelerometer y axis (+/- 2048)*
- c 12 bits accelerometer z axis (+/- 2048)*
- d 10 bits light meter (0-1024)*
- e 1 bit button status (1 on / 0 off)
- f 1 bit reserved (set to zero)

The GENEActiv device stores raw data to allow all processing to be completed off-line. Calibration data is created in production and recorded to be applied in post-processing.

Accelerometer x, y & z axis: calibrated measurement = (output*100 - offset) / gain (g)

Light meter: calibrated measurement = output * lux / volts (lux)



iii). Understanding .csv files

The first 100 rows of the .csv file contains all the information about the device, its firmware and the trial information included upon device configuration. In both the raw data and the epoch compressed files, the data starts from line 101 and is organised in the following columns.

Column	Raw Data	Epoch Compressed
A	Time stamp	Time stamp of epoch end
B	X axis (g)	Mean x axis
C	Y axis (g)	Mean y axis
D	Z axis (g)	Mean z axis
E	Light level (lux)	Mean lux
F	Button (1/0)	Sum of button press time
G	Temperature (°C)	Mean temperature
H	-	Sum of vector
I	-	X axis standard deviation
J	-	Y axis standard deviation
K	-	Z axis standard deviation
L	-	Peak lux

In the epoch compressed .csv, the gravity-subtracted sum of vector magnitudes is calculated as follows:

$$SVM^s = \sum | (x^2+y^2+z^2)^{1/2} - 1g |$$

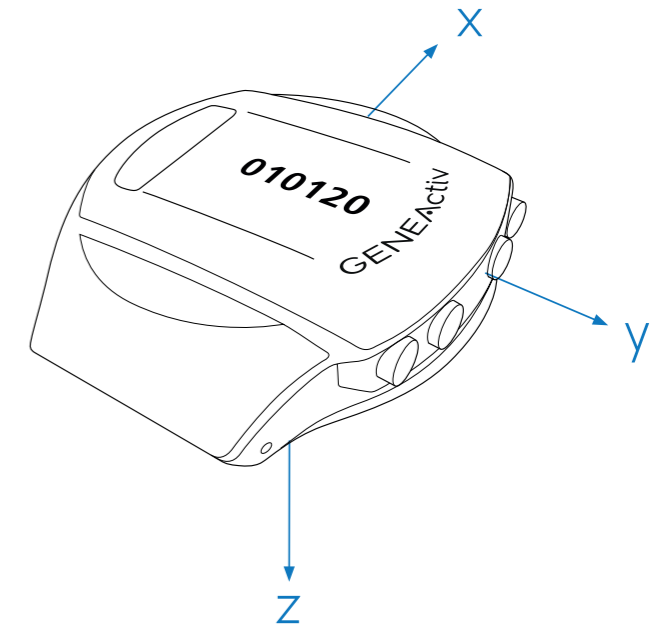
For each measurement in the epoch the vector magnitude is created and 1g is subtracted. When the accelerometer is static and the earth's gravitation pull is the only acceleration, the result of this will be close to zero.

The total number of measurements in the sum is defined by multiplying the recording frequency by the epoch length. Measurements from different recording frequencies and epoch lengths can be compared with suitable scaling.

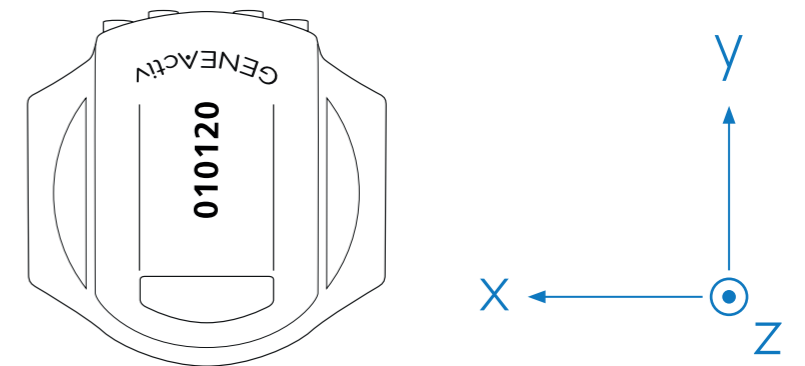


Sensor Axes & Body Positions

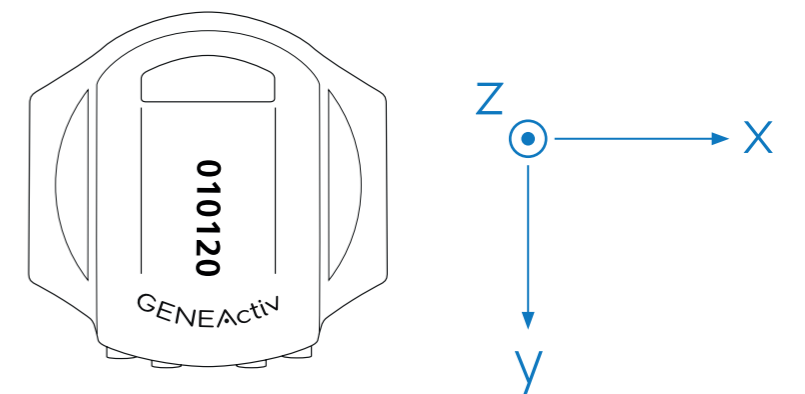
The device should be fitted to the wrist in the most intuitive manner – with the serial number in the correct orientation to be read by the wearer and with the 'crown' to the right – like a watch.



On the right hand, with the arm relaxed to the side, the device will appear to the observer:

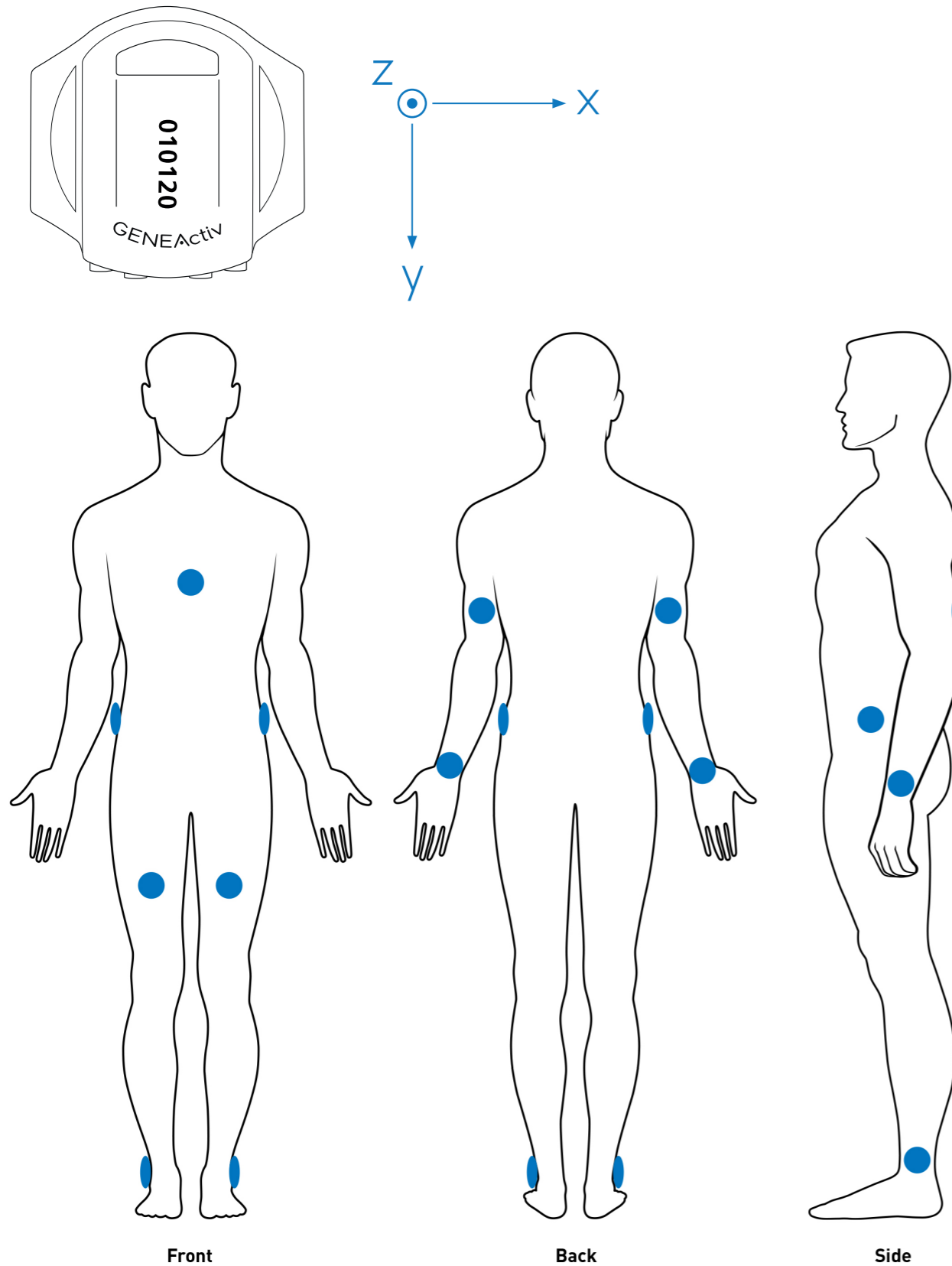


On the left hand, with the arm relaxed to the side, the device will appear to the observer:





In all other body positions, the device should be fitted with gold contact pins towards the ground.



Cleaning & Storing

a) Cleaning the Device

To clean the GENEActiv, wipe with a cloth or scrub with a soft bristle brush using warm soapy water or a mild detergent solution and allow to air dry. Alcohol wipes and mild sterilising solutions are also appropriate.

To disinfect the GENEActiv, use the Clinell Universal Wipe or equivalent product. Thoroughly cover and wipe the device so all surfaces are wetted. Ensure the device is allowed time to air dry completely before next use. Change the wipe if it becomes dry or soiled and dispose of it appropriately.

The charging cradle can be cleaned with a dry cloth.

If the GENEActiv is excessively soiled, we recommend removing the wrist strap to clean the parts separately. Should wrist straps become increasingly worn, additional straps can be purchased and easily replaced.

IMPORTANT: Do not use hot water, scouring pads, abrasive cleaning agents or aggressive liquids (such as petroleum-based solvents, acetone, and strong alkaline cleaners) on the GENEActiv or its charging cradle.

b) Storing

GENEActiv units should be stored at temperatures between 5-35 degrees Celsius to ensure optimal battery life.

IMPORTANT: It is important that GENEActiv devices are charged every 2 months for 3 hours to maintain good battery health, even when not in use.



Regulatory Compliance

European Compliance

GENEActiv is a Class I Medical Device based on Rules 1 & 12 from Annex IX, conforming to the Essential Safety & Health requirements and provisions of EC Council Directives 93/42/EEC, Annex VII. The application of the classification rules is governed by the intended purpose of the device.

US Compliance

GENEActiv is an FDA Regulatory Class II, 21 CFR 882.1400 Neurological Diagnostic Devices and Class II, 21 CFR 882.5050 Biofeedback Devices.

FDA Compliance

The GENEActiv is currently FDA 510(k) exempt. Products are made in the UK in cGMP accredited facilities, ISO 13485, ISO 9001.

Applicable Standards

Standards which have been applied in full to document compliance with the Essential Requirements for Conformance.

Applicable Standards	Description
BS EN ISO 13485:2016	Medical devices. Quality management systems. Requirements for regulatory purposes.
BS EN ISO 14971:2019	Medical devices. Application of risk management to medical devices.
BS EN 62366-1:2015+A1:2020	Medical devices. Application of usability engineering to medical devices.
BS EN 62304:2006+A1:2015	Medical device software – Software lifecycle processes
BS EN 60601-1:2006+A12:2014	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
BS EN 60601-1-2:2015	Medical electrical equipment. General requirements for basic safety and essential performance. Collateral Standard. Electromagnetic disturbances. Requirements and tests.
BS EN 60601-1-6:2010+A1:2015	Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Usability.
ISO 10993-1:2018	Biological evaluation of medical devices. Evaluation and testing within a risk management process.
BS EN 1041:2008 + A1:2013	Information supplied by the manufacturer of medical devices.
BS EN ISO 15223-1:2016	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements.
BS EN 60529:1992+A2:2013	Degrees of protection provided by enclosures (IP Code)
Directive 2011/65/EU (RoHS)	The restriction of the use of certain hazardous substances in electrical and electronic equipment.



Regulatory Standards



GENEActiv 1.1. 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.



This product is compliant with the Directive 2004/108/EC; the relevant Declaration of Conformity is available from ActivInsights Ltd. This product has been tested to BS EN 61000-6-1 :2007 and BS EN 61000-6-3 :2007 (Electromagnetic compatibility (EMC), Generic standards, Immunity for residential, commercial and light-industrial environments). Directive 2011/65/EU (RoHS) The restriction of the use of certain hazardous substances in electrical and electronic equipment.



In accordance with European Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE), this item must not be disposed of in the normal unsorted municipal waste stream.

Instead, it is the user's responsibility to dispose of this product by returning it to a collection point designated for the recycling of electrical and electronic equipment waste or directly to Activinsights Ltd. Separate collection of this waste helps to optimize the recovery and recycling of any reclaimable materials and also reduces the impact on human health and the environment. For more information concerning the correct disposal of this product, please contact your local authority or our issuing authority.

This product meets the minimum standards of the RoHS Directive 2002/95/EC.

The lithium polymer cell has met the acceptance criterion for the UN Recommendations on the Transport of Dangerous Goods relating to lithium batteries, reference Para 38.3 of Manual tests and Criteria document No. ST/SG/AC.10.11/Rev.4:2003.



Safe Handling Guidelines

- Do not use with children without supervision or further safety assessments.
- Do not disassemble the device or charger. The battery in the device is not replaceable. If the device or charger is damaged, dispose of it responsibly or return to Activinsights.
- If the device becomes warm to the touch whilst in use, remove and return to Activinsights.
- Do not wear while charging or connected to USB.
- Clean the device with a soft moistened cloth. Do not use abrasive cleaners or solvents.
- Do not subject the device to excessive force, shock or extreme temperature changes.
- Do not put the device in a microwave, oven, dishwasher, or washing machine.
- Do not use an external heat source such as a hair dryer or heater to dry the device.
- At the end of the product life, please return it to your issuing authority.



Getting More Help

For more information about Frequently Asked Questions (FAQs), please visit our website:

www.activinsights.com

For further information or assistance, please contact:

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