Activinsights

GENEActiv

Instructions for Use (1.2)

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Overview

a) 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 digital ambient light sensor to record luminous intensity (lux) of white light.

Digital Temperature Sensor measures near-body temperature which is influenced by both the wearer and environment. The device has a range of 0 – 60 degrees Celsius, taking measurements a minimum of every 30 seconds.

b) 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	1.0 Gb non-volatile
Logging Frequencies	Selectable 10-100Hz
Maximum Logging Periods	60 days @20hz, 14 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	Digital Ambient Light Sensor
Wavelength	Peak wavelength 560 nm
Range	0 – 20,000 Lux typical
Resolution	3 - 48 Lux dynamic
Accuracy	+/- 10% @ 1000 Lux calibration
Event Logger	
Sensor Type	Mechanical membrane switch
Temperature Measurements	
Sensor Type	Digital Temperature Sensor
Range	0 to 60 deg C
Resolution	0.25 deg C
Accuracy	+/- 1 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:

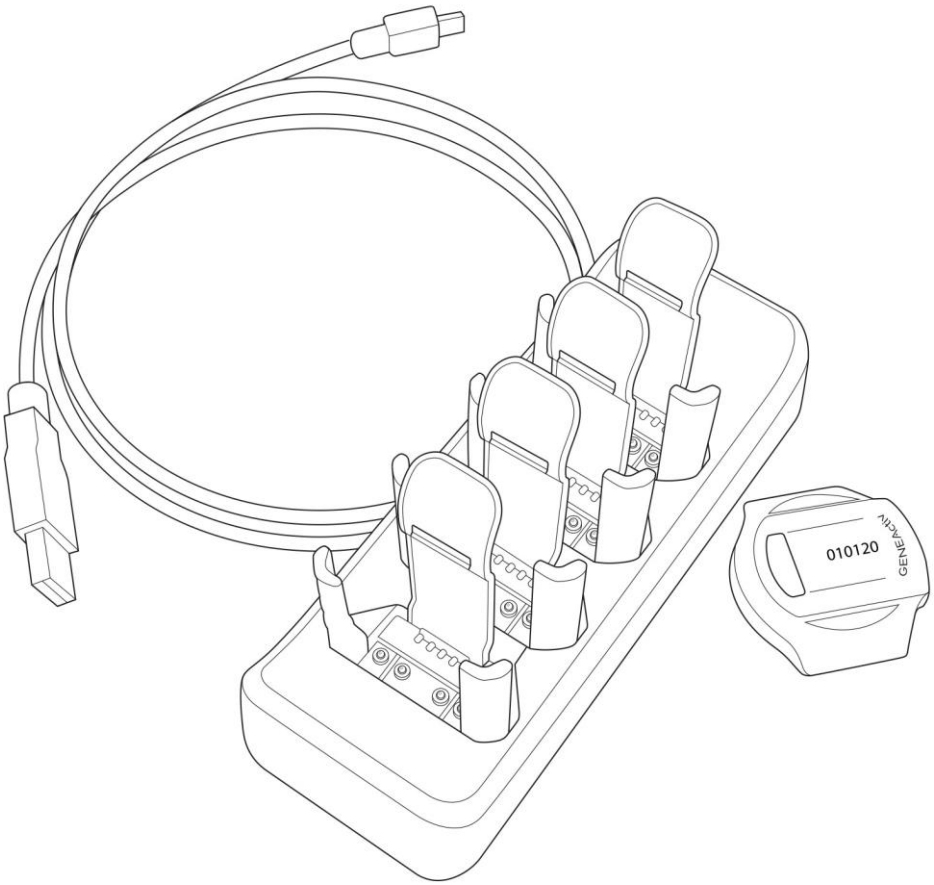
- PC with Intel Core i3 Processor, 2GB Memory
- Windows 10/11 Intel x64 MAC MacOS 11.0
- .NET Framework 4.7.2

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 the USB cable.

Additional body straps and accessories are available upon request.



Charging & Storing

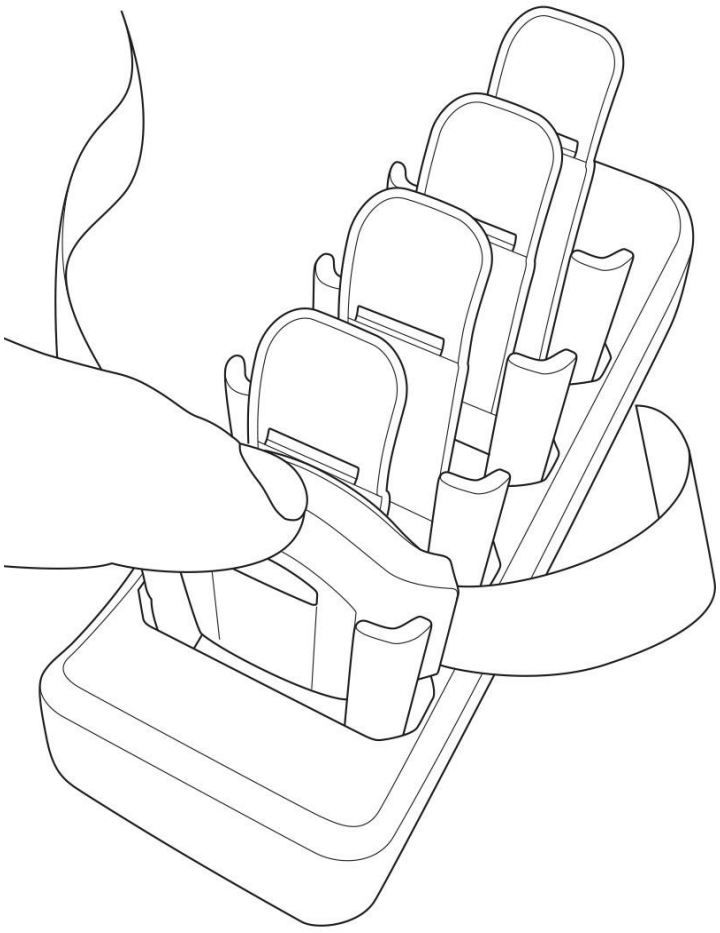
a) Charging

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 hour charge, the GENEActiv should have over 90% battery, prior to deployment. When devices are not in use, they should be fully charged every 6 months. This will ensure good battery health.

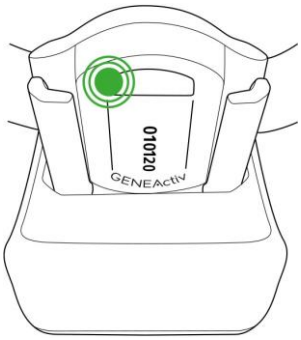


b) LED Signals

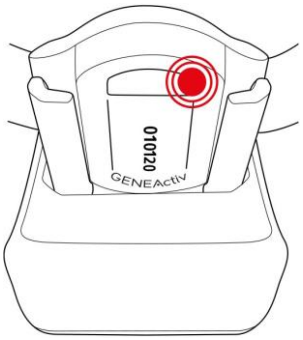
When not recording, the battery charge level can be checked by pressing the button on the device. See diagram below for LED indicators.

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

i. Installing Software for Windows

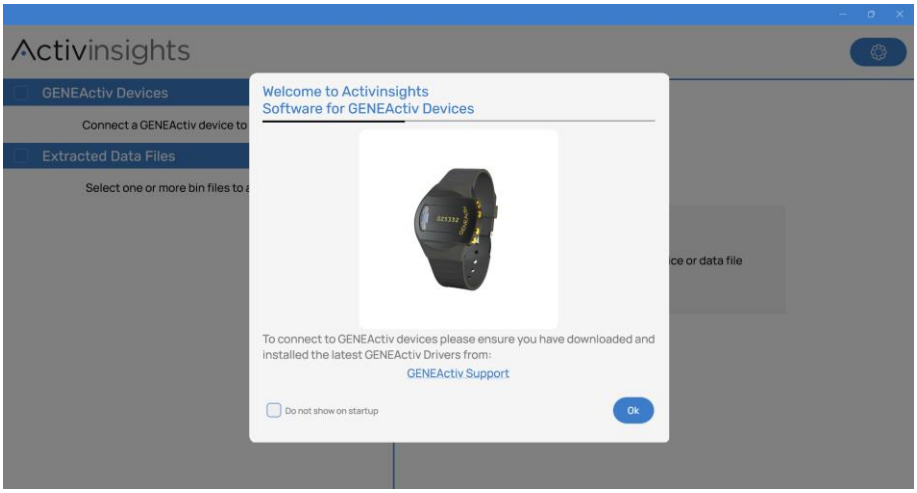
The software may be download from the Microsoft Store using the following link:
https://apps.microsoft.com/store/detail/geneactiv-software/9NTLZLBXNHR6

The Microsoft Store is the recommended source as the software will be kept up to date automatically with the new releases. If the store is not available on your PC, however, please email info@activinsights.com

It is important that once the GENEActiv software has been downloaded, users also need to download the 'GENEActiv Drivers' (.zip) from the Activinsights website, unzip the file into a local folder, double-click the unzipped install.bat file and follow the popup wizard steps.

To install the GENEActiv Drivers:

- Connect cradle via USB cable
- Insert device into cradle
- Unzip the downloaded file into a local folder
- Navigate to this local folder which now contains the unzipped files
- Double left click the 'install.bat' file
- Follow the automatic pop-up Wizard steps

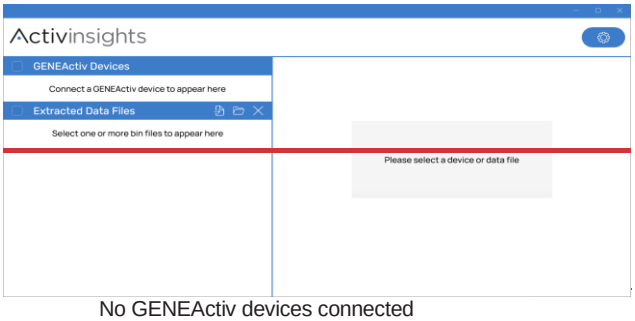


ii. Installing Software for Mac

GENEActiv software supports Apple Mac OS 11 (Big Sur) or later, on Intel and Apple Silicon-based Mac computers. It may be installed from the App Store by clicking on the following link:
https://apps.apple.com/us/app/geneactiv-software/id1658154045

b) Software Overview

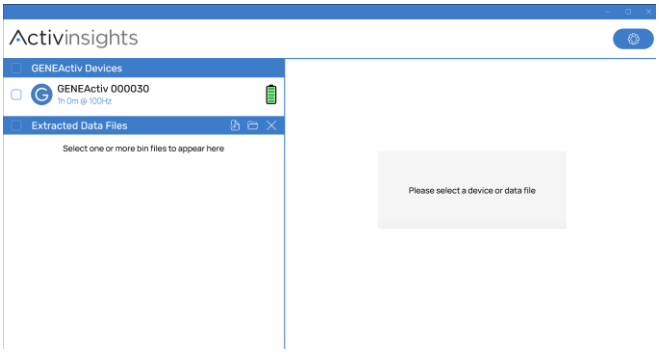
Once you have completed the installations, open the software and you will then see the main dashboard and the menu on the left-hand side. Connect one or more devices via the cradle.



No GENEActiv devices connected

i. GENEActiv devices

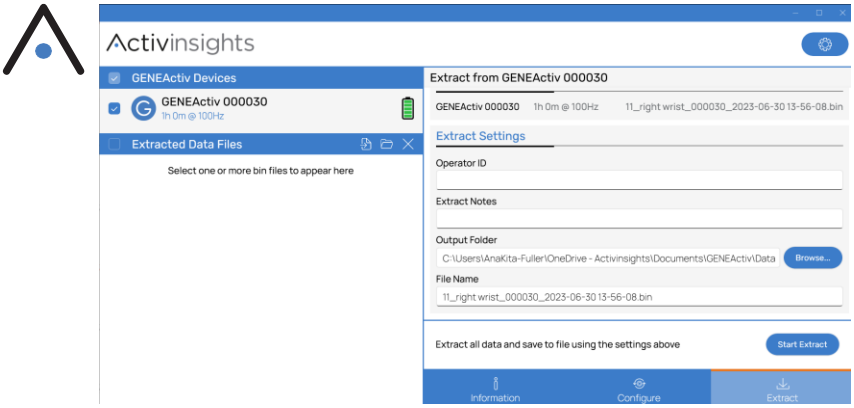
Once the device is connected, you will see the device number(s) displayed in the panel underneath GENEActiv devices section.



Under the device(s) serial numbers you will see the the length of data recorded and frequency, together with the battery charge level. Hover over the battery icon, it will give you the percentage of battery charge.

Once you select/click a device, at the bottom of the page, on the right-hand side you will notice three tabs.

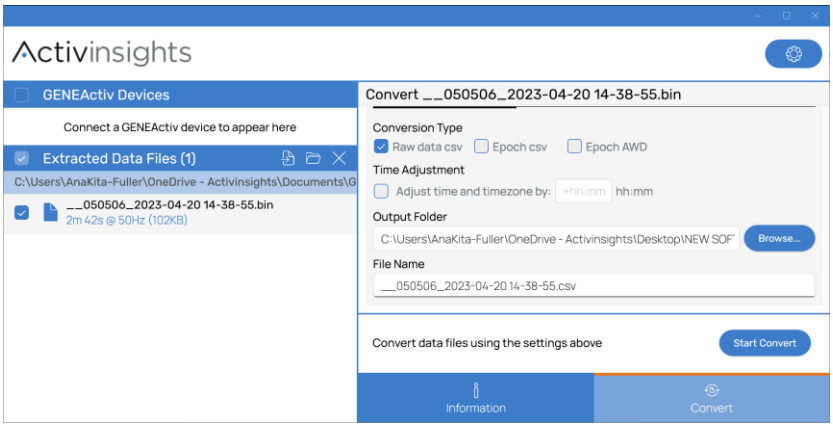
- **INFORMATION:** this is where the device's capabilities will be displayed. This tab displays information about the device(s) connected and existing stored data.
- **CONFIGURE:** this tab allows the GENEActiv device(s) to be configured and details of the trial and test subject to be entered on the device.
- **EXTRACT:** This is where you will go to extract the data once recording has finished



ii. Extracted Data Files

This tab allows you to convert one or more .bin files into Raw data csv files and Epoch csv files that can be read by the GENEActiv viewer and Excel. You can use this tab to convert .bin files into AWD files which can be analysed using Actiware software.

Click Extracted Data Files, on the same line select if you wish to view one .bin file or a folder with multiple files. At the bottom of the page, right-hand side you will notice two tabs.



- **INFORMATION:** this is where the file details will be displayed. This tab displays information about the existing stored data: file details, device information and settings, trial, and subject settings.

- **CONVERT:** this tab allows the .bin file to be converted to Raw data csv, Epoch csv or Epoch AWD.

c) DEVICE SETUP

Once the device is connected, the device number(s) will be displayed in the right-hand side panel and the battery level. 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.

This process will overwrite any data onboard the device. It is important that any previous data collected has been successfully extracted. 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 the device 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).

i. Measurement Frequency

Select the device, click the “Configure” tab at the bottom of the page, and choose your Measurement Frequency (Hz). The Maximum Measurement Period will be automatically calculated. The Maximum Measurement Period is dependent on the frequency selected as shown in the table below.

Measurement Frequency	Max. Measurement Period (Days)
10	60
20	60
25	56
30	42
40	36
50	30
60	24
66.7	22
75	20
85.7	18
100	14

ii. Start Mode

There are four 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.

'Allow Stop & Restart' 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 one month 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.

iii. Time Settings

Choose which time setting the device should use. This should be the Local PC Time. The Time Setup dictates the timestamps for the measurement period. Please be aware of the daylight saving hours changing during the data collection period.

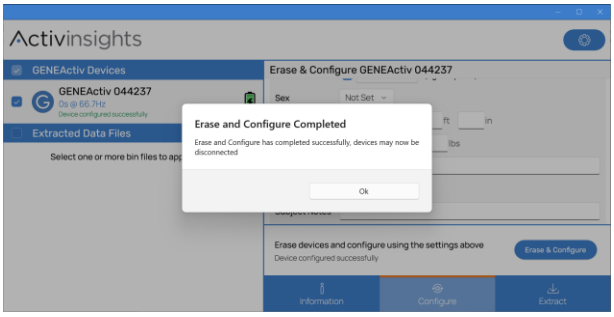
iv. Trial Settings

Enter any relevant information related to the trial/study.

v. Study Settings

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.

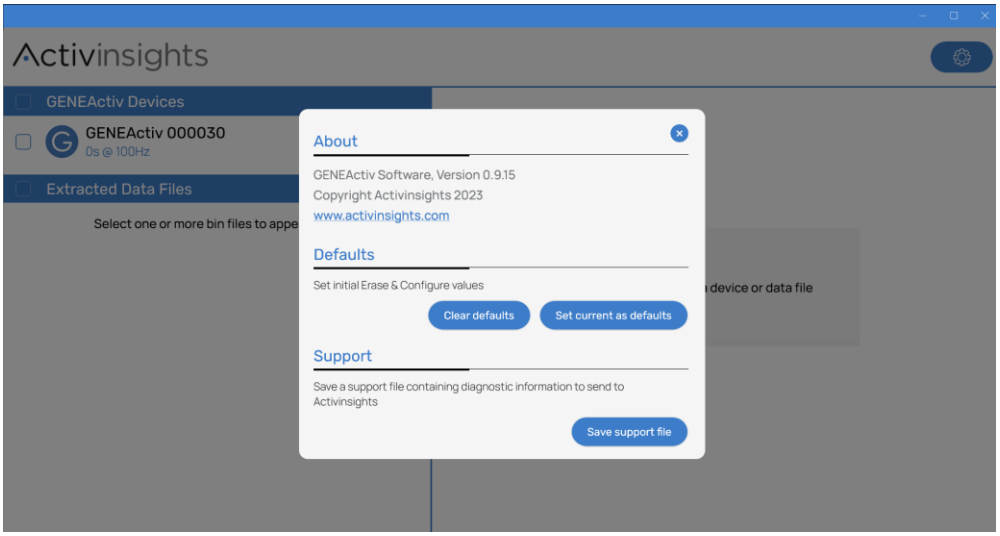
We do not recommend entering personal data, such as date of birth, as this can be entered post data collection if required. It does not directly affect any data collected and means there is no Personally Identifying Information stored on the device.



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.

d) SETTINGS

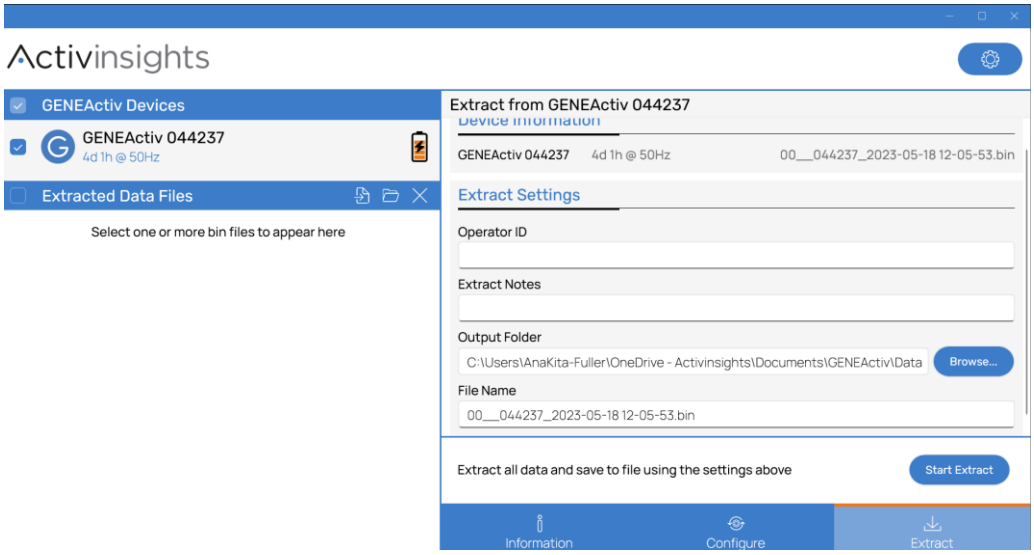
If you are configuring multiple devices with the same settings, you can set default Erase and Configure values. Click the Settings icon at the top right corner of the page and click Set current as defaults. You can change this at any point by clicking Clear defaults.



Data Collection & Extraction

a) Extracting data

- Open the GENEActiv software and connect the charging cradle to a USB port. Insert a GENEActiv device into the cradle and select the device you wish to extract data from.
- Click '**Extract**' from the bottom right menu.
- Choose the file location in the Output Folder field. 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. These files can also be converted to AWD to analyse with Actiware Software.
- Click the '**Start Extract**' button.



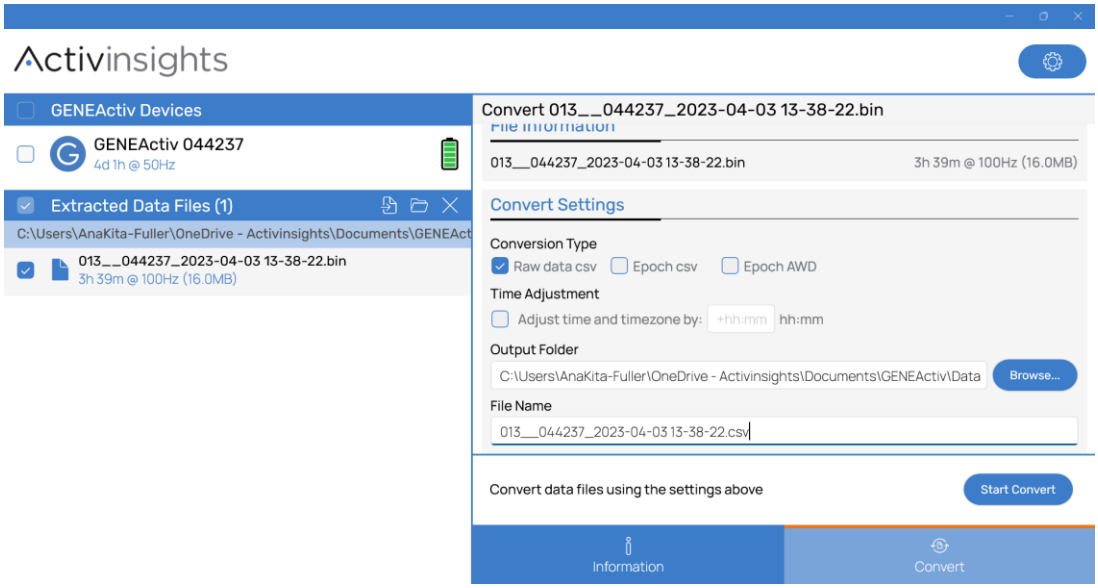
Please note: The data extraction can take up to **20 minutes.** A pop-up window will confirm successful completion.

b) Reading Data

i. Converting Data

On the Extracted Data Files section, you have the option to select one file or a folder containing one or more .bin files to load. Once you have selected the file, on the right-hand side of the screen, at the bottom of the page, you will see two tabs.

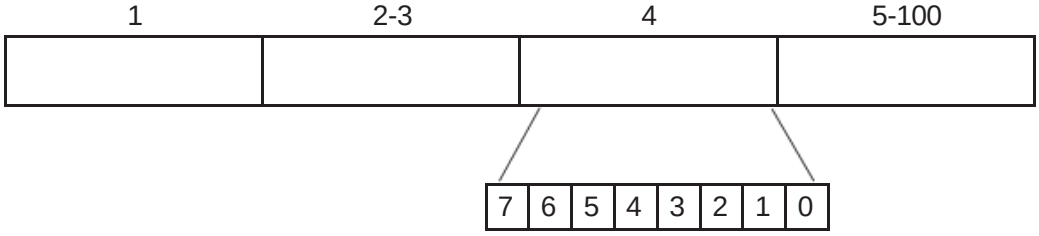
- **INFORMATION** with all the file details.
- **CONVERT** here you have three conversion types.
  - Raw csv file creates .csv files, which can be used by Excel, from .bin files. Please note that older versions of Excel cannot manage very large .csv files. To convert a .bin file to .csv, select the output .csv file path and paste the file name and type .csv at the end then you will be able to Start Convert.
  - Epoch csv file 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.
  - Epoch AWD, these files can then be analysed using Actiware software.



ii. **Understanding .bin files**

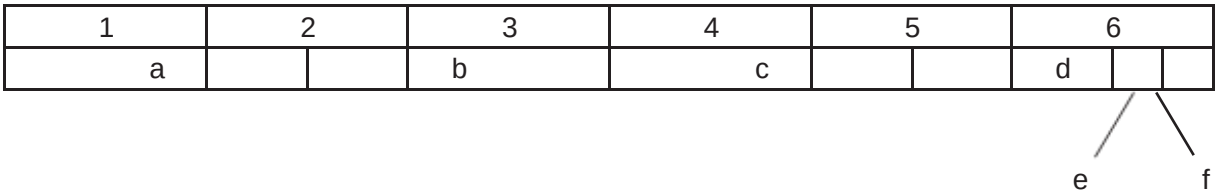
The .bin file output when opened will display as the following:

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 organized 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:

$$SVM^{g}s = \sum | (x^2+y^2+z^2)^{½} - 1g |$$

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.

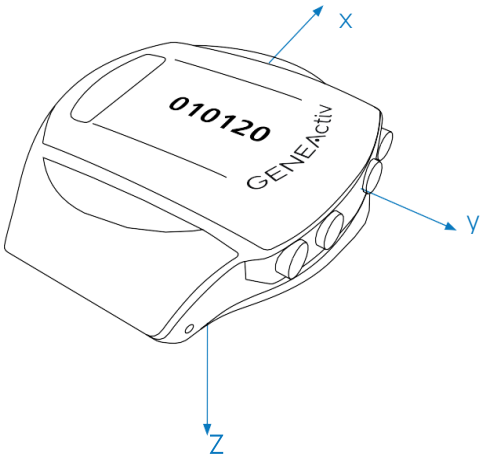
iv. AWD files

The upgraded GENEActiv software also now supports AWD file outputs from raw data for seamless integration into existing sleep analysis packages (Actiware software from Philips / Respironics).

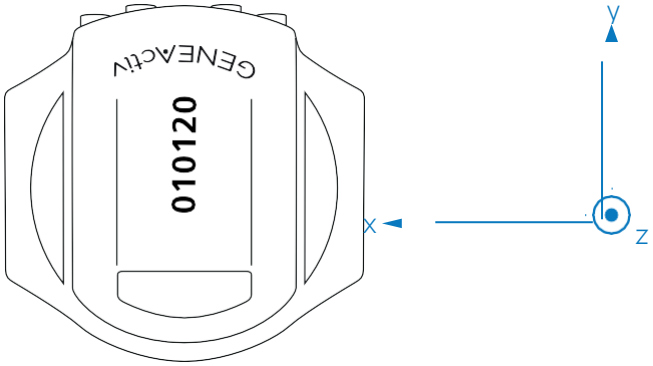
The conversion algorithms and their implementation have been verified and validated by Activinsights to ensure the approximation is fit for purpose. The algorithm and validation report are available on request. This new functionality will allow sleep clinicians ongoing access to epoch-based sleep analysis functionality while we continue to work with the community on novel raw data approaches.

Sensor Axes & Body Positions

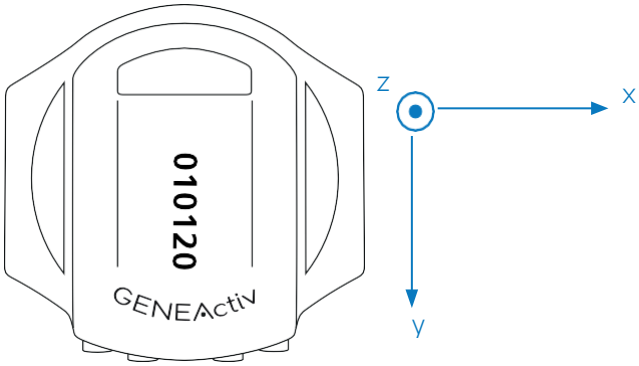
The device should be fitted to the wrist in the most intuitive manner – with the serial number in the correct orientation to be read by the wearer and with the ‘crown’ to the right – like a watch.



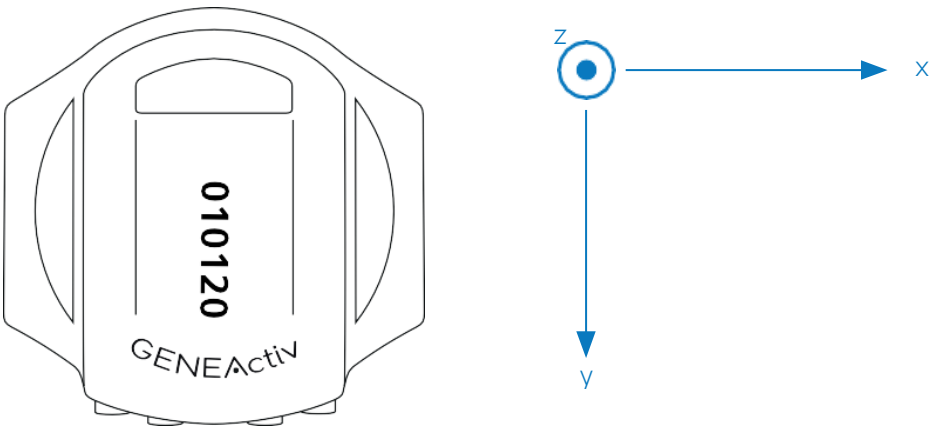
On the right hand, with the arm relaxed to the side, the device will appear to the observer:

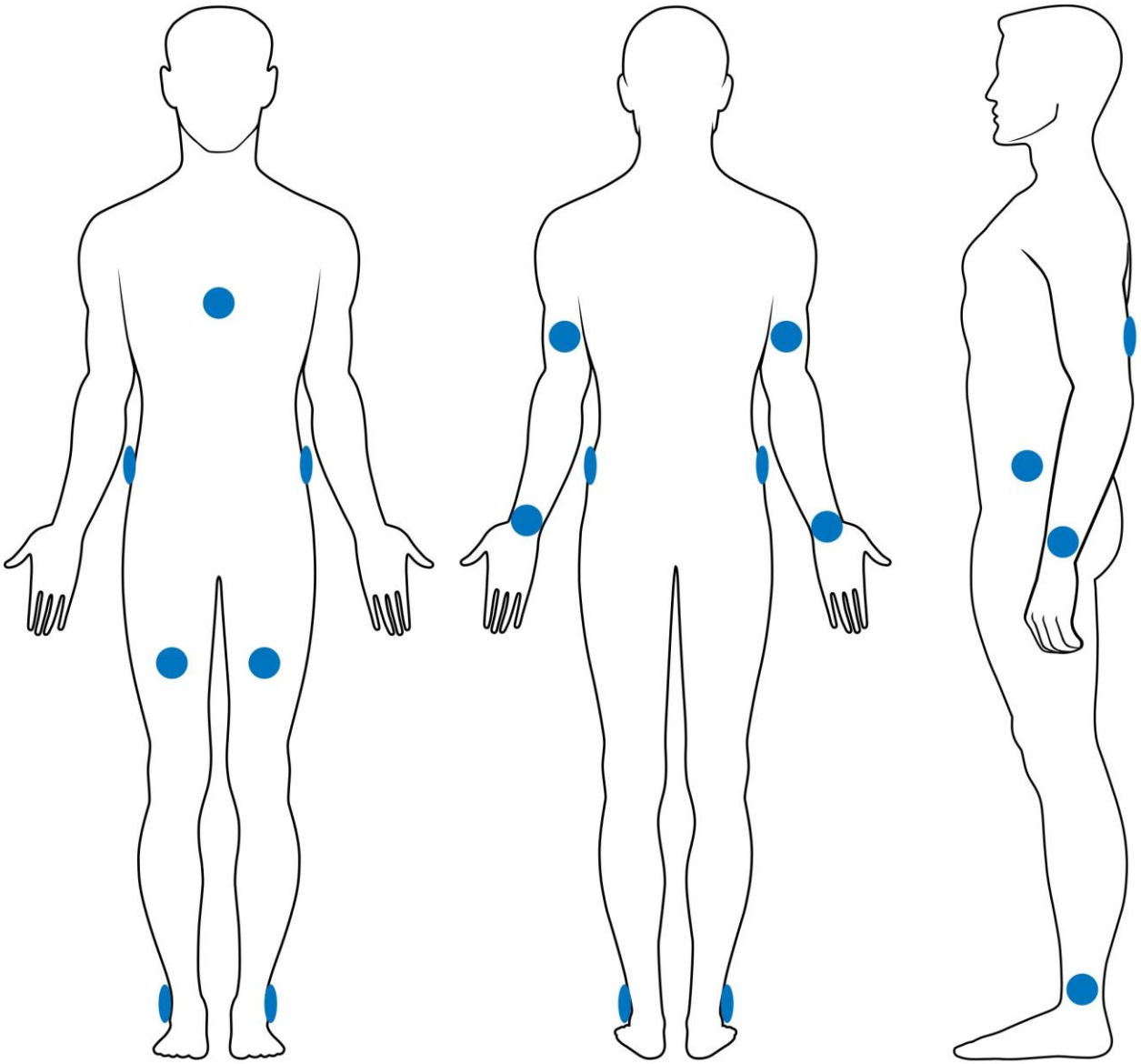


On the left hand, with the arm relaxed to the side, the device will appear to the observer:



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




Front
Back
Side

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 6 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 1.2. 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's life, please return it to your issuing authority.

Getting More Help and Support

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

www.activinsights.com

Please create a support file containing diagnostic information using our settings tab together with a short description of the reason to contact us and email it to: info@activinsights.com

For further information or assistance, please contact:

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