ActivInsights

GENEActiv (1.2) with Software

Instructions for Use

GENEActiv®

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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 that 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 the 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.

i. Intended Use/Purpose

GENEActiv is an active device, that is worn on the wrist or other parts of the body for quantification and recording of movement (through acceleration), near-body temperature and environmental light levels at defined time intervals.

ii. Indications for Use

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

iii. Intended Users

Healthcare professionals and Researchers.

iv. Use Environment

Participant's natural environment and Professional healthcare.

v. Patient Population

All ages, from studies in small infants to multiple studies in school-age children, adults, and older adults.

vi. Contra-Indications

A tight wrist strap can cause skin redness as from normal watch wear, when the GENEActiv is worn by people with abnormal skin irritation or an ongoing health condition, consider applicability and tolerance levels. Other wrist straps and fabrics are available.

vii. Contact with Patient

Uninjured skin only.

viii. Device Lifetime in use

The device is reusable with a lifetime of 50 charging cycles or 2 years from the date of purchase.

ix. Shelf Life

Two Years.

x. Clinical Benefits and Performance Claims

There are no direct clinical benefits to the patient from data collection by the GENEActiv. However, there are multiple examples of clinical conditions where the GENEActiv may provide an indirect health benefit, either via lifestyle benefits or interventions, or by facilitating deeper understanding and clinical implications of an intervention.

xi. Warning

Not to be used in a shielded environment.

b) About GENEActiv Charging Cradle

i. Intended Use/Purpose

The GENEActiv Charging Cradle allows for charging of the GENEActiv and connection of GENEActiv to the computer via USB port.

ii. Intended Users

Healthcare professionals and Researchers.

iii. Use Environment

Healthcare professional environment.

iv. Patient Population

Healthcare professionals.

v. Contact with Patient

No contact with the patient.

vi. Device Lifetime in use

Two years.

vii. Shelf Life

Two years.

viii. Clinical Benefits and Performance Claims

No medical.

c) 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 (IP68 – 1m 24hrs)
Material Ingress	Dust tight (IP68)
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	Full 3 hours
Data Download Time	For SN starting 00 approximately up to 20 minutes for 4 concurrent units. For SN starting 02 under 10 minutes for 4 concurrent units
Radio and Wireless Signals	
Neither the GENEActiv nor the Charger Cradle receive or transmit any radio frequencies or wireless signals	

Getting Started

a) System Requirements

To run the GENEActiv PC software you must have the following Windows PC and Apple Mac specifications:

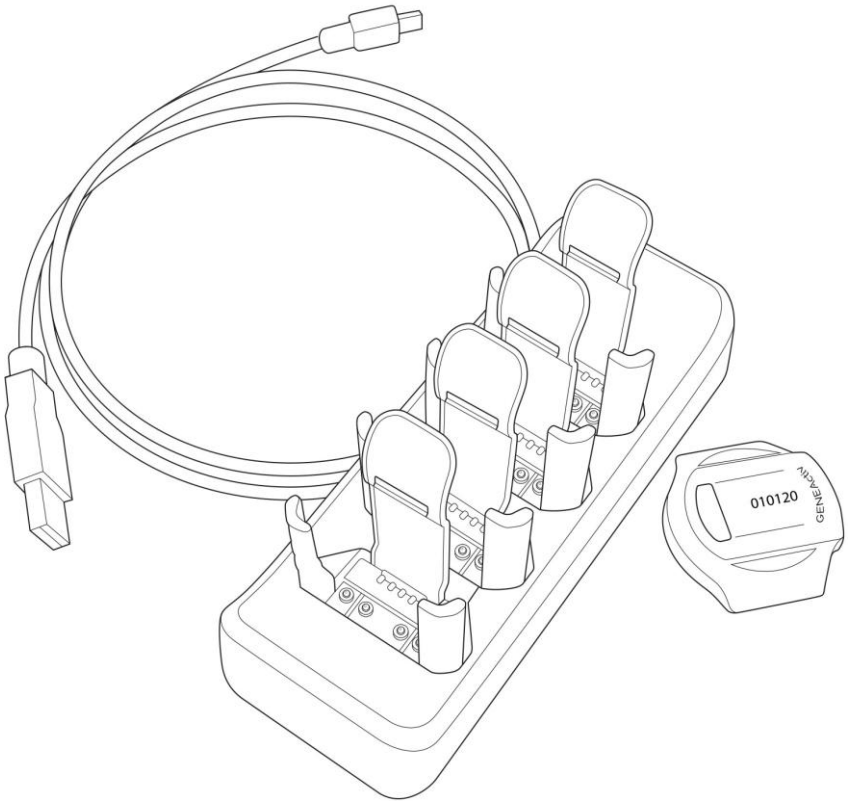
- PC with Intel Core i3 Processor, 2GB Memory
- Windows 10/11 Intel x64
- Apple MacOS 12 (Monterey)
- NET Framework 4.7.2

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.



IMPORTANT MESSAGE

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Charging & Storing

a) Charging

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

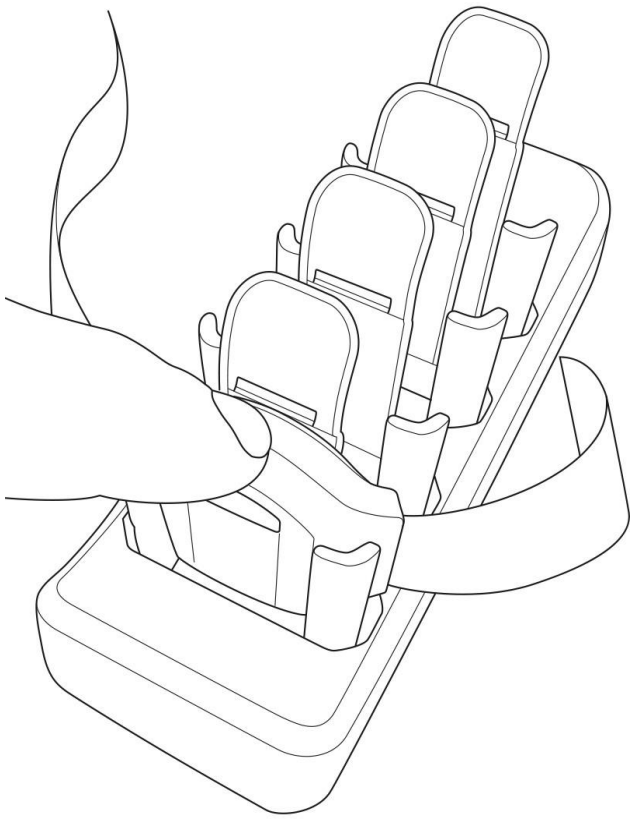
This can be done via the USB port on your computer or using a USB wall plug. We recommend using a wall plug when charging your devices so that it does not interfere with the GENEActiv software. It is essential that the power supply provides 500mA on every port to ensure the devices fully charge.

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 MESSAGE

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, before deployment. When devices are not in use, they should be fully charged **for a full 3 hours** every 6 months. This will ensure good battery health.

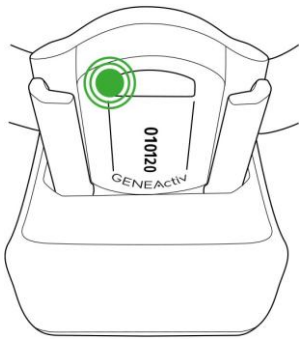


b) LED Signals

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

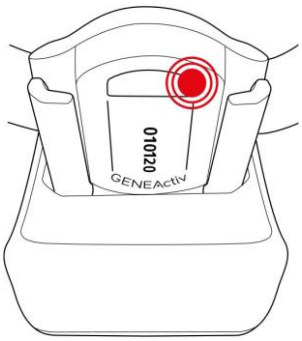
A green flash indicates that the device is OK to go into storage if it is no longer in use. A red flash or no flash at all means that the device should be charged (this function is not always available if a device has been configured to record).

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.

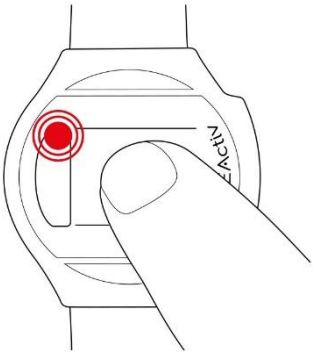


Green Flashing = Check the battery level in the software (after 3 hours of charge)

Short Green Flash (when unconfigured) = Battery good for storage/configuration
Long Green Flash (On Button Press Mode) =recording started



Red Flashing = Charging
Constant Red = Communicating



Red Flashing (when unconfigured) = Battery needs charging

Device Setup & Configuration

a) Installing Software

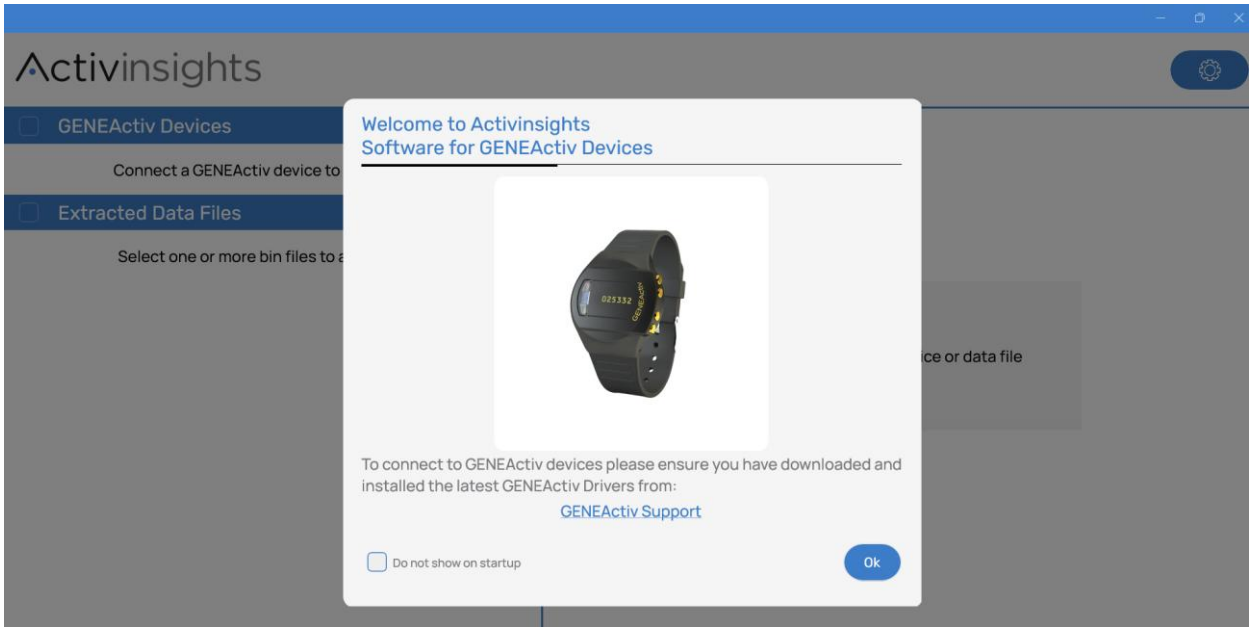
i. Installing Software for Windows

The software can be downloaded from the Microsoft Store. 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.

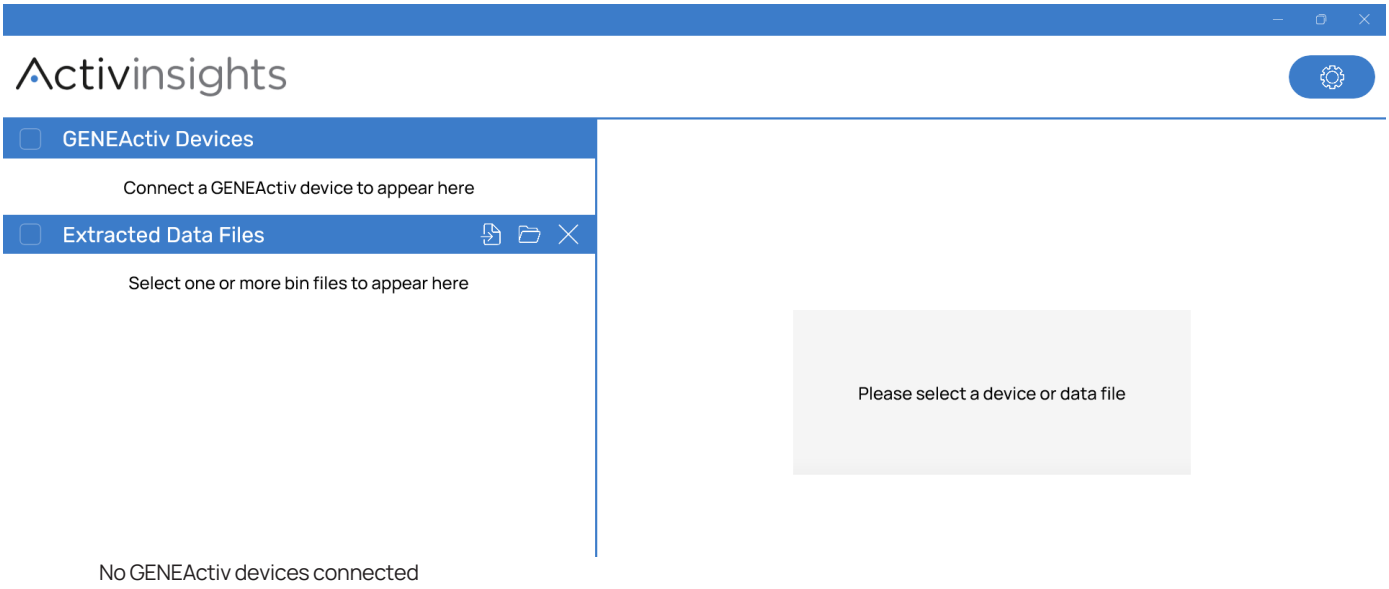


ii. Installing Software for Mac

GENEActiv software supports Apple MacOS 12 (Monterey) or later, on Intel and Apple Silicon-based Mac computers. It may be installed from the App Store

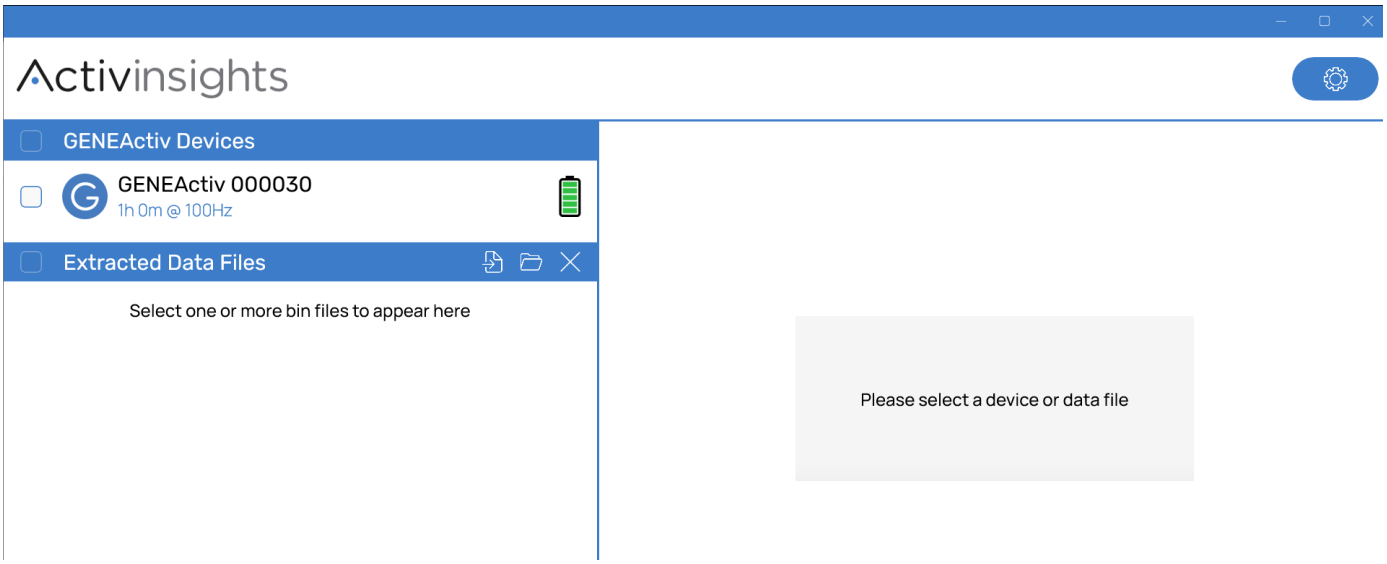
b) Software Overview

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



i. GENEActiv devices

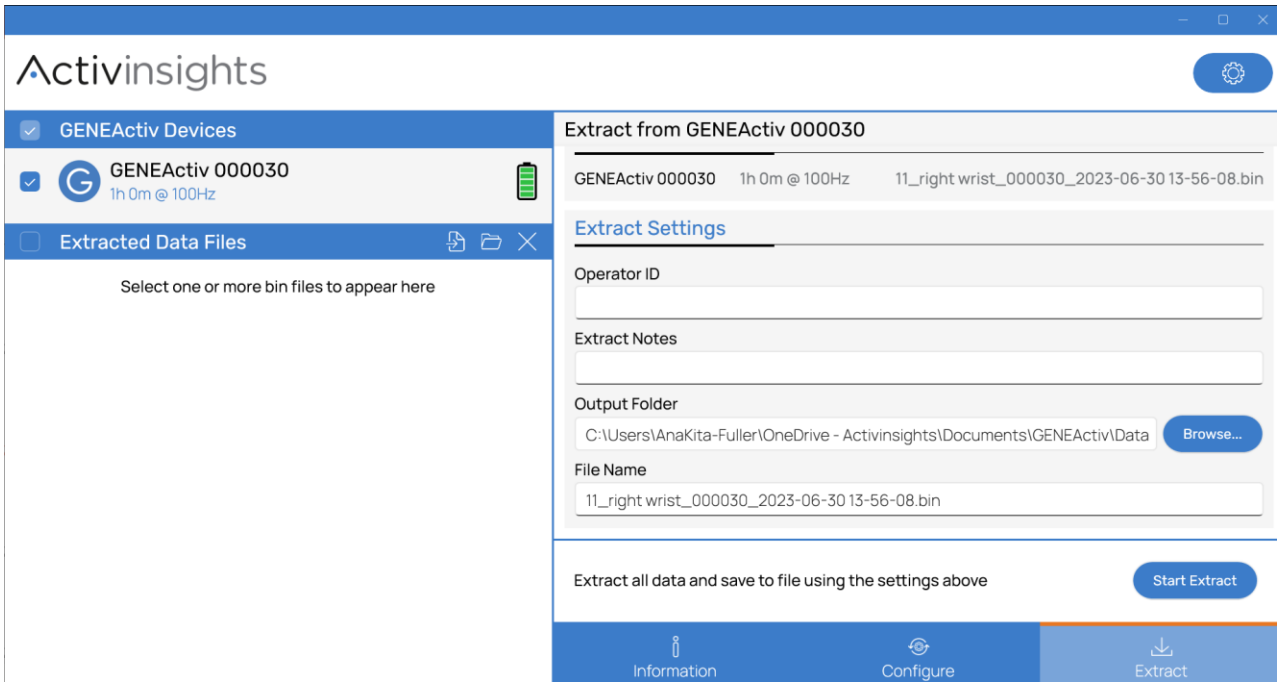
Once the device is connected, you will see the device number(s) displayed in the panel underneath GENEActiv devices section.



Under the device(s) serial numbers are the length of data recorded, frequency and 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.

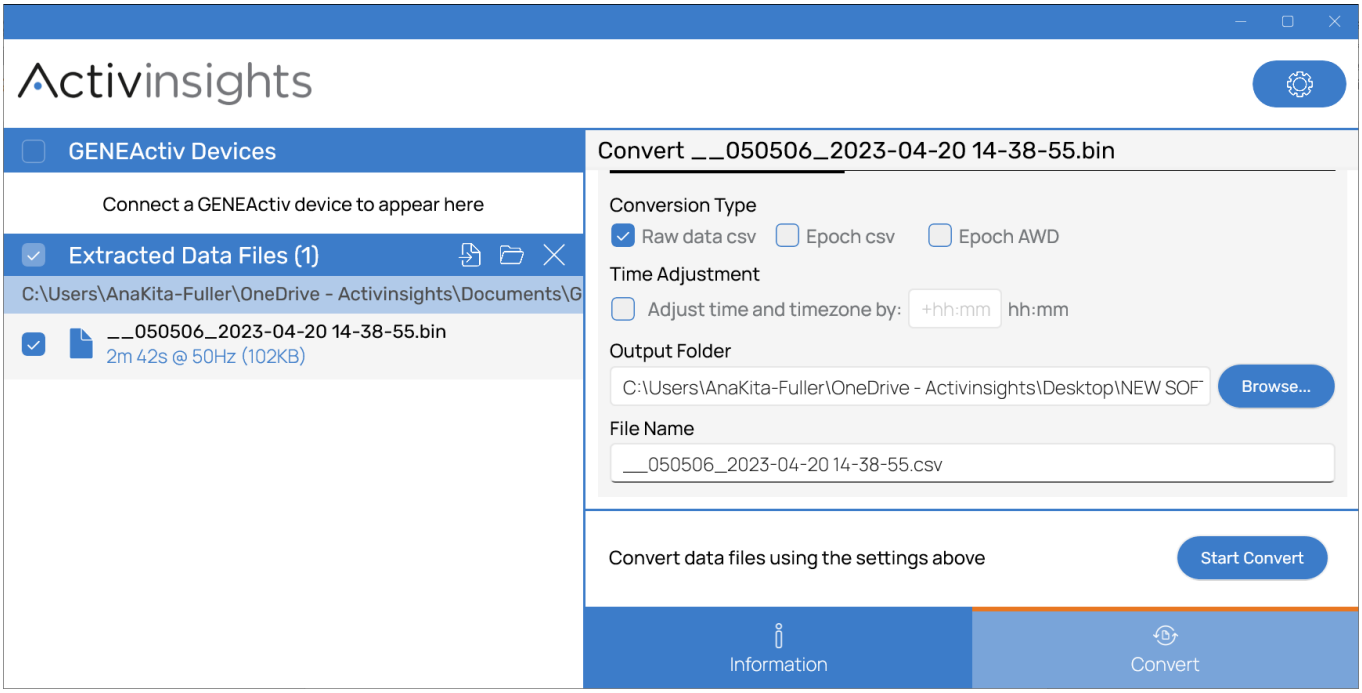
- **INFORMATION:** this is where the device's capabilities will be displayed. This tab displays information about the device(s) connected and existing stored data.
- **CONFIGURE:** this tab allows the GENEActiv device(s) to be configured and details of the trial and test subject to be entered on the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



ii. Extracted Data Files

This panel allows you to convert one or more .bin files into Raw data csv files and Epoch csv files that can be read by Excel. You can use this panel to convert .bin files into AWD can be entered into ActivInsights Sleep Toolkit and Actiware software.

Click the icons to the right of **Extracted Data Files,** 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) you would like to configure. 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 three different start modes:

1. **'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.
2. **'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.
3. **'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. The option of "UTC with Timezone" provides the user with a drop-down list of GMT +/- options.

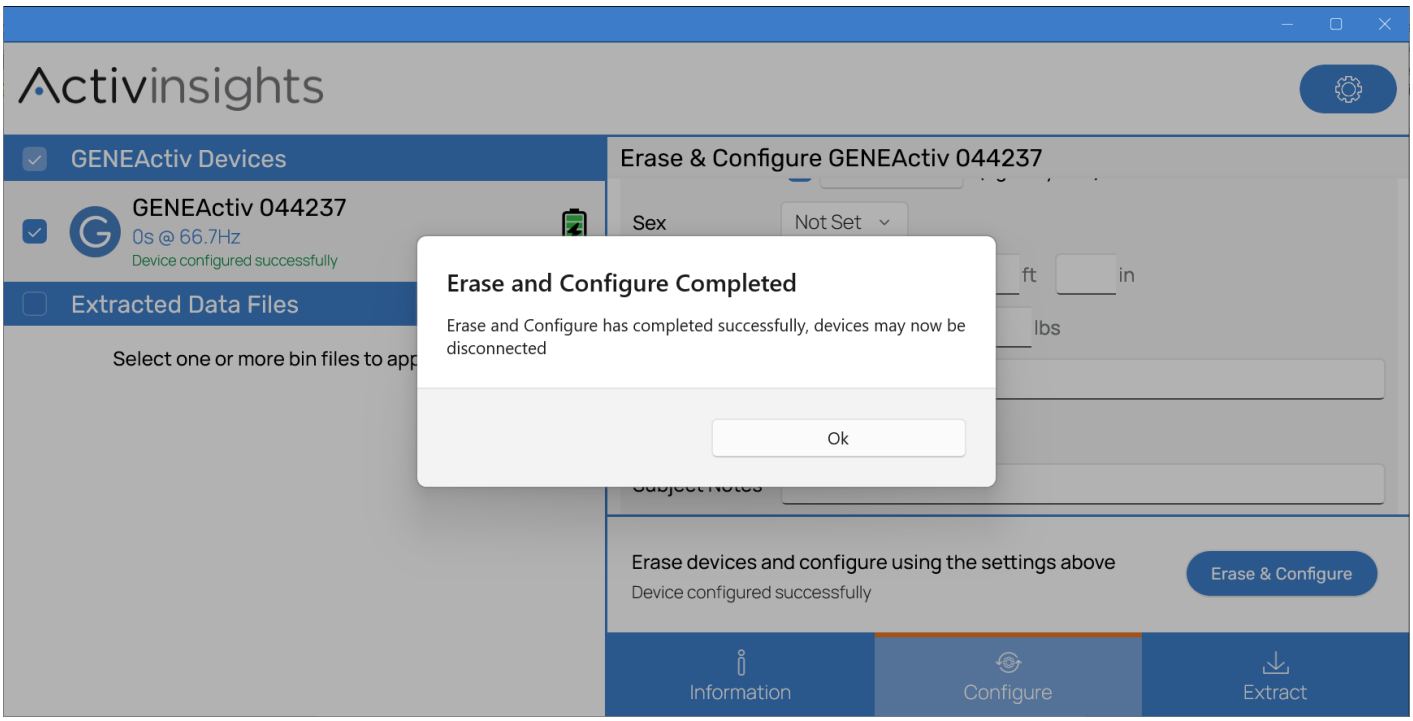
iv. Trial Settings

Enter any relevant information related to the trial/study.

v. Study Settings

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.

This section is optional. 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.



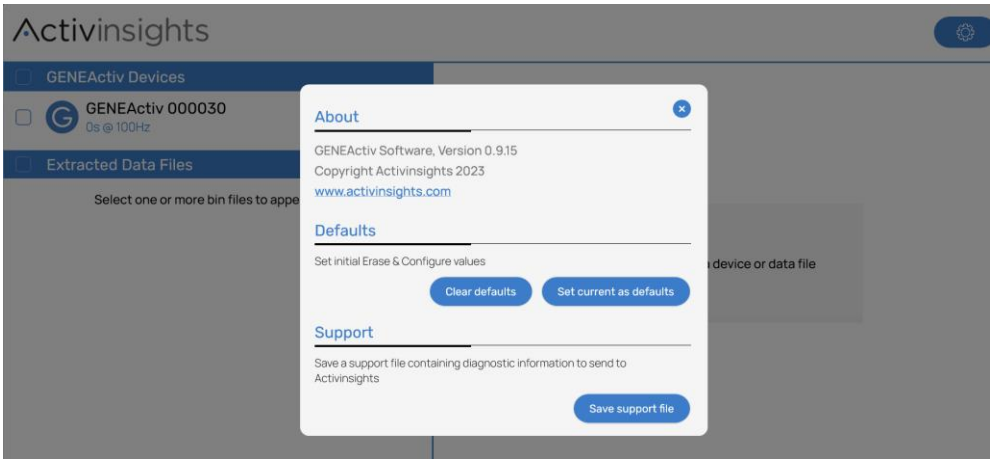
IMPORTANT MESSAGE

Once the configuration of the device is complete, the device must not be 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

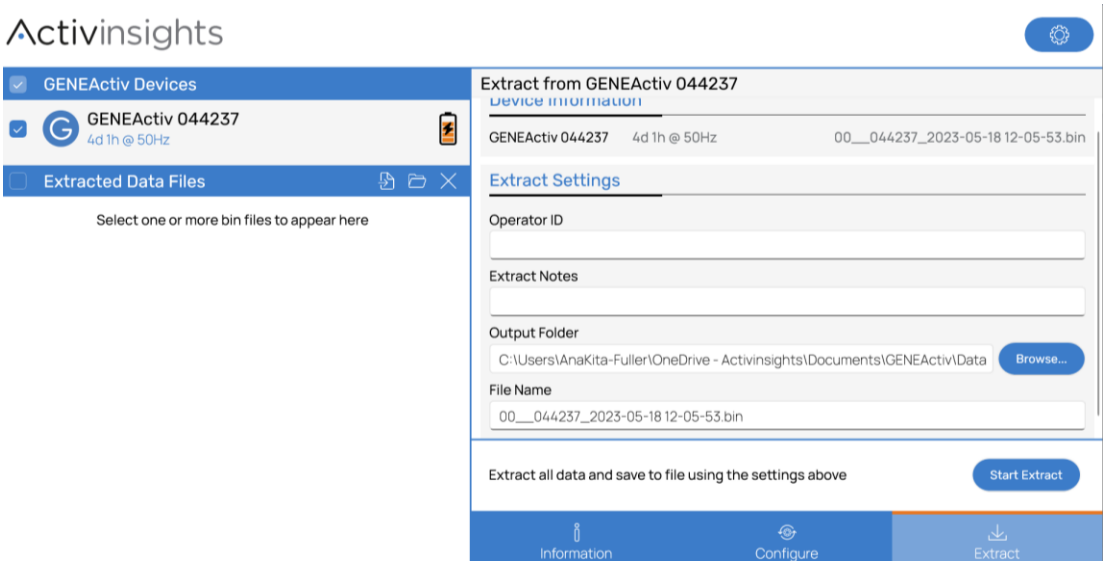
If you are configuring multiple devices with the same settings, you can set default Erase and Configure values. Click the Settings icon at the top right corner of the page and click Set current as default. You can change this at any point by clicking Clear defaults.



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 CSV and AWD.
- Click the '**Start Extract**' button.



Please note: Data extraction will take up to approx. 20 minutes for charging cradles starting with SN 00; and under 10 minutes for charging cradles starting with SN 02.

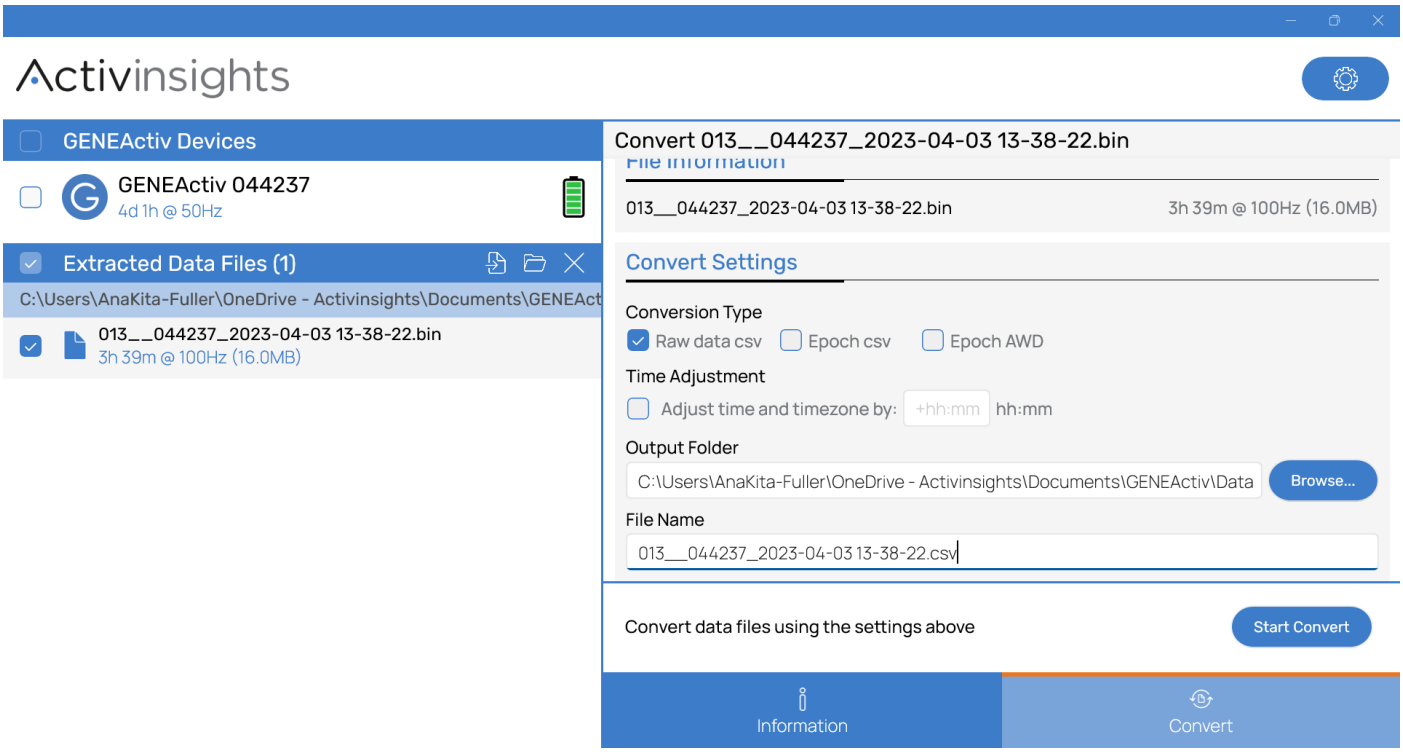
A pop-up will confirm success.

b) Reading Data

i. Converting Data

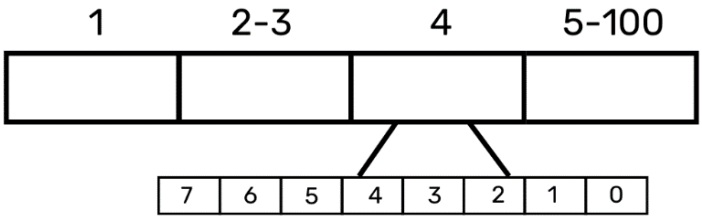
On the Extracted Data Files section, you have the option to select one file or a folder containing one or more .bin files to load. Once you have selected the file, on the right-hand side of the screen, at the bottom of the page, you will see two tabs.

- **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 be entered into the ActivInsights Sleep Toolkit and Actiware software.



ii. Understanding .bin files

Data packets are visualized with first bit on the left with the byte numbers labelled above the row in decimal:



Output values that require interpretation are labelled with an asterisk (*).

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

- Main header (lines 1 to 59)
- Followed by 'pages' of 300 measurements (lines 60 to 69, 70 to 79 etc.)
- Each page will have a sub-header (e.g. lines 61 to 68)
- And a data block (e.g. line 69)

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 basic set-up information.

The timestamp 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.

1	2	3	4	5	6
a		b	c	d	e f

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)

The light sensor outputs a 13-bit value that is compressed into a 10-bit output in the data packet. To decompress this output and obtain the measured light meter reading in lux use the following table:

10-bit data packet *output* value	Calibrated light meter measurement (lux)
Below 256	output * (lux / volts)
Between 256 and less than 512	(output – 128) * 2 * (lux / volts)
Between 512 and less than 768	(output – 320) * 4 * (lux / volts)
Between 768 and less than 1024	(output – 656) * 16 * (lux / volts)
Great than or equal to 1024	5888 * (lux / volts)

where *lux* and *volts* are device calibration parameters reported in lines 54 and 55 of the file.

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.

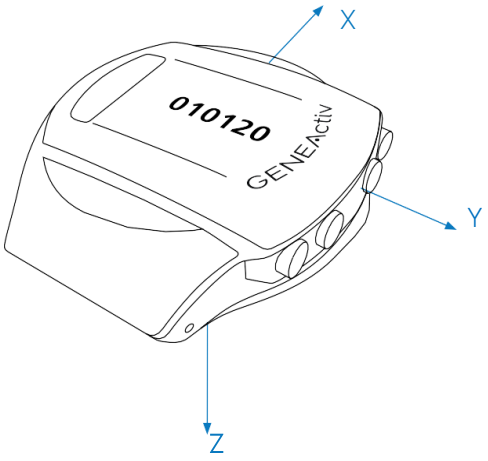
iv. AWD files

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

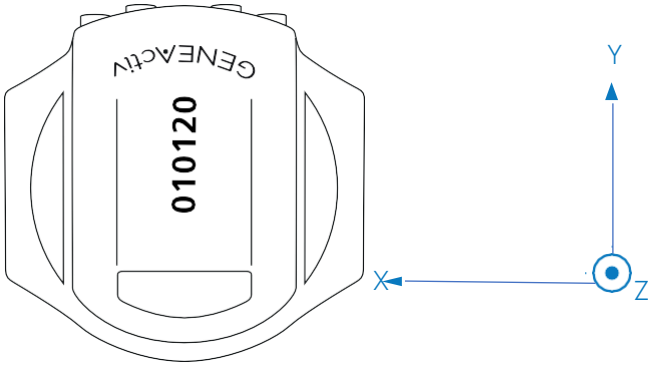
The conversion algorithms and their implementation have been verified and validated by ActivInsights to ensure the approximation is fit for purpose. The algorithm and validation report are available on request. This new functionality will allow sleep clinicians ongoing access to epoch-based sleep analysis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

Sensor Axes & Body Positions

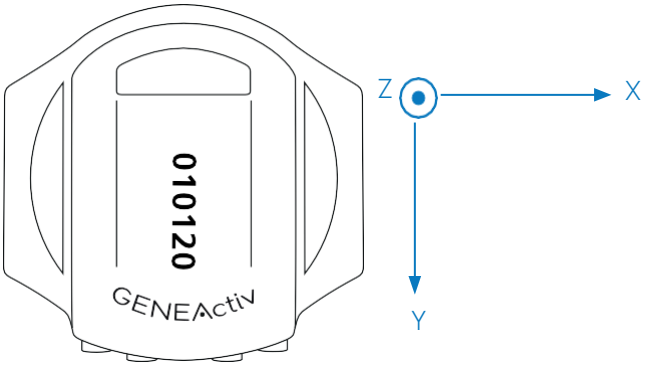
The device should be fitted to the wrist – with the serial number in the correct orientation to be read by the wearer and with the 'crown' to the right – like a watch.



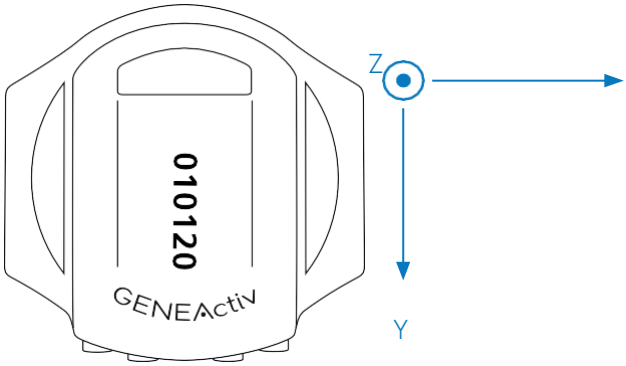
On the right hand, with the arm relaxed to the side, the device will appear to the observer.

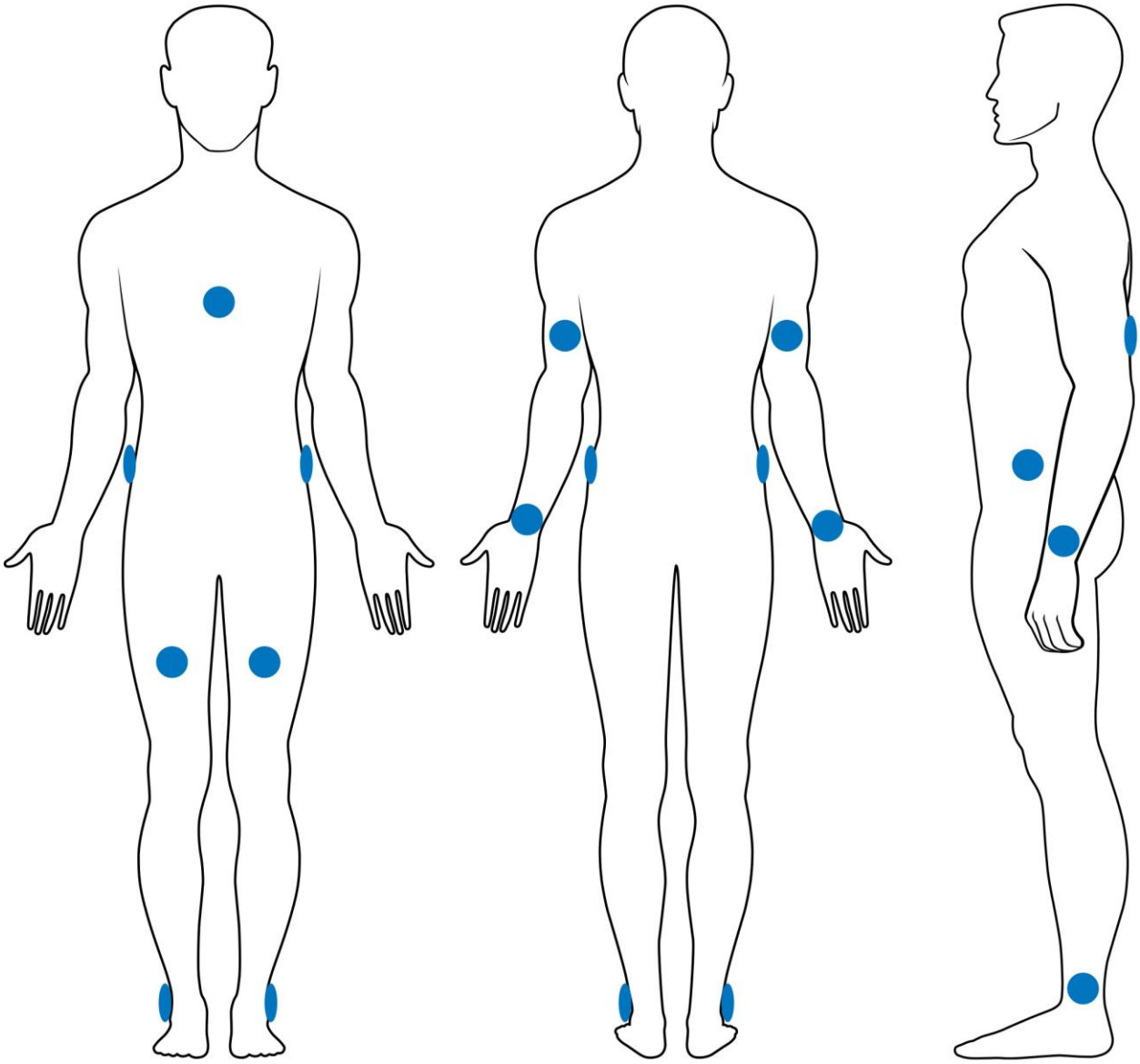


On the left hand, with the arm relaxed to the side, the device will appear to the observer:



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 wet. Ensure the device is allowed 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 MESSAGE

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 MESSAGE

When not in use it is important that GENEActiv devices are charged every 6 months for a full 3 hours to maintain good battery health.

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.

Electrical Safety Statement

Emissions: Class B
Immunity: 240 Vac, 50Hz and 120Vac, 60 Hz
EMC Test Standards
IEC 60601-1-2:2014 +A1:2020 (Ed. 4.1) / EN 60601-1-2:2015 +A1:2021
IEC TR 60601-4-2:2016
FCC CFR 47 15.107 & 15.109
ICES-003 ISSUE 7
Environments for the device to be used in Participants natural environment, Healthcare professional environment and not to be used in shielded location.
The GENEActiv System has been tested as EUT system in EMC testing as per above standards.

If the GENEActiv device is exposed to an Electromagnetic (EM) disturbance, its performance may be impacted, potentially preventing it from connecting to the GENEActiv Software. If you encounter this issue, please contact us at info@activinsights.com for assistance.

IMPORTANT MESSAGE

Improper maintenance of the GENEActiv by regular battery charging, as described in this Instruction for Use, will also result in the GENEActiv not connecting to the GENEActiv Software. Please ensure batteries are properly maintained.

IMPORTANT MESSAGE

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

IMPORTANT MESSAGE

Use of any part of this equipment, including cables and Charger Cradle, within 30cm of any portable Radio Frequency (RF) equipment, including antennas, can affect medical electrical equipment.

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 by clicking the 'Save support file' button in Settings 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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