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ActivInsights

GENEActiv

GENEActiv®

Instructions for Use

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Overview

a) About GENEActiv

Device Name	Device Description	Product Code
GENEActiv	GENEActiv (Original) Single Unit Pack	GATV04M
GENEActiv 4-Way Station	GENEActiv 4-way Download/Charger Cradle	GATV05

The 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 on other 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 the GENEActiv records the occurrence and degree of motion. The device's relative movement data is stored internally. The captured data shall be downloaded through the charging cradle and the software. The GENEActiv also incorporates a light sensor to record luminous intensity (lux) of white light and a near body temperature sensor.

i. Intended Use/Purpose

GENEActiv is an active device, that is worn on the wrist or other part 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, across any indication, disease state or therapeutic area.

iii. Intended Users

Healthcare professionals

iv. Use Environment

Clinical settings, laboratories and the participant's natural environment

v. Participant Population

All demographics, including small infants, school-age children, and adults of all ages.

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 ongoing health conditions, consider applicability and tolerance levels. Other wrist straps and fabrics are available.

vii. Contact with Participant

Uninjured skin only

viii. Duration of use

14 to 60 days Would it be better to say – Up to 60 days depending on logging configurations.

ix. Device Lifetime in use

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

x. Shelf Life

Two Years

xi. Clinical Benefits and Performance Claims

There is no direct clinical benefit to the participant from wearing the GENEActiv. Indirect, but possibly significant, health benefits may be derived from an increased understanding of the participant's lifestyle; that is their physical activity, sedentary behaviour patterns and sleep, examples of clinical conditions where GENEActiv may provide an indirect health benefit, either via lifestyle benefits or interventions or by facilitating deeper understanding and clinical implications of an intervention. Examples in the published literature include:

- Cancer
- Parkinson's disease
- Bone health
- Type 2 diabetes
- Cardiovascular disease
- Mental health
- Gait and balance conditions
- Respiratory disease
- Sleep disorders

xii. Warnings and Precautions

- 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.
- We advise not to wear GENEActiv in sauna and other heat aggressive environments
- Not to be used in a shielded environment

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 (IP68 – 1m 24hrs)
Material Ingress	Dust tight (IP68)
Operating Temperature	5 to 40 deg C
Mechanical Impact	0.5m drop resistant
Measurement Capabilities	
Memory	Versions 1.2 & 1.3 : 2.0 Gb non-volatile, version 1.1 : 1.0 Gb non-volatile
Logging Frequencies	Selectable 10-100Hz
Maximum Logging Periods	60 days @20hz, 14 days @100hz (see table below)
Internal Clock	
Type	Quartz Real Time Clock
Frequency	32.768kHz
Accuracy	Versions 1.2 & 1.3 : +/- 20ppm (+/- 1.7s per day), version 1.1 : +/- 20ppm (+/- 1.7s per day)
Acceleration Measurements	
Sensor Type	MEMS
Range	+/- 8g
Resolution	12 bit (3.9mg)
Light Measurements	
Sensor Type	Versions 1.2 & 1.3: digital, version 1.1: analogue
Peak wavelength	Versions 1.2 & 1.3: 560nm, version 1.1: 900nm
Range (typical)	Version 1.3: 0–50,000 Lux, version 1.2: 0–40,000 Lux, version 1.1: 0–2,000 Lux
Resolution (typical)	Versions 1.2 & 1.3: 3-48 Lux dynamic, version 1.1: 5 Lux
Accuracy	+/- 30% @ 1000 Lux calibration
Event Logger	
Sensor Type	Mechanical membrane switch
Temperature Measurements	
Sensor Type	Digital Temperature Sensor
Range	0 to 60 °C
Resolution	0.25 °C
Accuracy	Versions 1.2 & 1.3: +/- 1 °C, version 1.1: +/- 2 °C
Measurement Frequency	Every 30s minimum
USB Connection	
Device USB	Versions 1.2 & 1.3: USB High Speed, version 1.1 : USB Full Speed
Charging Cradle	Format 4 unit cradle USB 2.0 High Speed
Charge Time	4 hours
Data Download Time	For SN starting 00 up to 20 minutes for 4 concurrent units. For SN starting 02 under 10 minutes for 4 concurrent units
Radio and Wireless Signals	
GENEActiv 1.3 has a Bluetooth module which is qualified Bluetooth 4.2 (2.4 GHz band) Charger Cradle does not receive or transmit any wireless signals.	

Getting Started

a) System Requirements

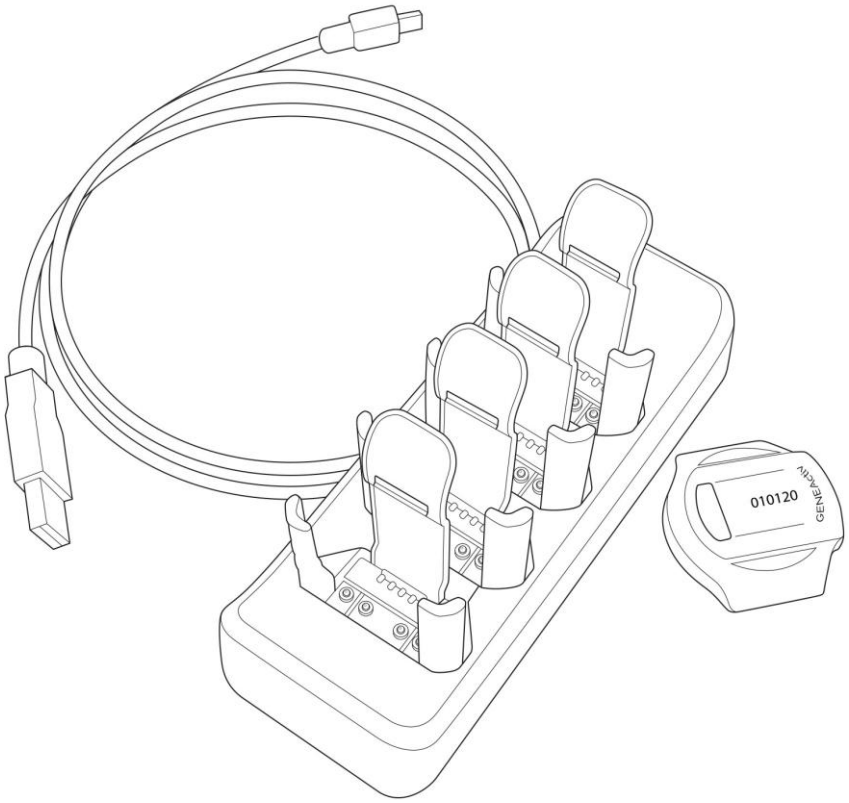
Software applications that integrate the GENEActiv SDK support computing devices with the minimum specifications listed below. Bluetooth 5 is required for adherence data extraction:

- PC with x64 processor, 2GB Memory running Windows 11 or Windows 10 version 1903 (10.0.18362) or higher
- Apple mac computer with Intel or Apple Silicon running macOS 12 or later (Monterey)
- Apple iOS device running iOS version 15 or later (adherence data only supported)
- Android device running Android 6 or later

b) GENEActiv Hardware

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

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



c) GENEActiv Body Straps

Body Strap	Wear Location	Product Code	Diameter (mm)	
			Min.	Max.
Standard resin	wrist	GATV07	161	217
Fabric	wrist	GATV06	171	246
Tyvek single use	wrist, ankle	GATV16	132	217
Thigh strap	thigh	GATV15	400	800
Upper arm / ankle strap	upper arm, ankle	GATV11	170	360
Chest strap	chest	GATV13	650	1600
Waist belt	waist	GATV14	650	1600

IMPORTANT MESSAGE

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could cause an increase in 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 4 hours** before configuring with software.

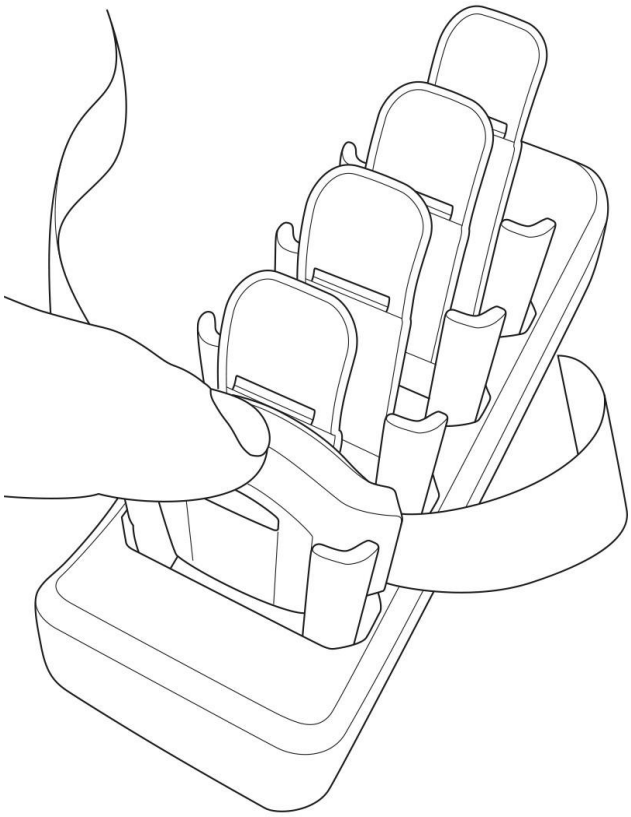
This can be done via the USB port on your computer or using a USB wall plug. We recommend using a wall plug when charging your devices so that it does not interfere with software. It is essential that the power supply provides 500mA on every port to ensure the devices charge fully.

A red light on the device will indicate that the device is charging. After 4 hours, once a green light flashes, this indicates that the device can be checked in 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 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 **4 hours** at a time.

Following a full 4-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 4 hours** every 6 months. This will ensure good battery health.

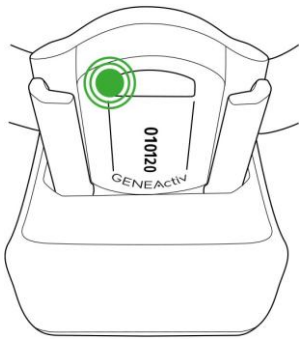


b) LED Signals

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

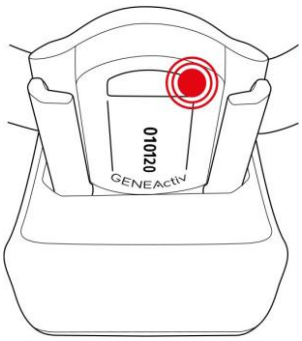
A green flash indicates that the device is OK to go into storage if it is no longer in use. A red flash or no flash at all means that the device should be charged (this function is not available if a device has been configured to record).

To ensure that a device is fully charged, it must be left in the cradle for a full 4 hours before deployment. To check the battery level, connect the device to software. It should show at least a 90% battery level before deploying.

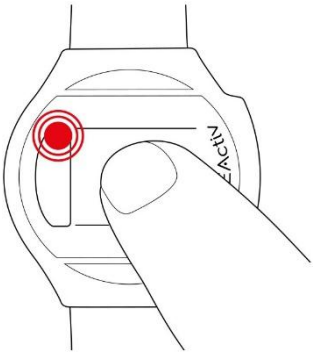


Green Flashing = Check the battery level in the software (after 4 hours of charge)

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) Device Management Software

GENEActiv devices are managed with software applications providing access to the principal functions of the device. These applications integrate the GENEActiv Software Development kit ("GENEActiv SDK"), which exposes functions for the software to use for device configuration, data extraction and data-file conversion, and will be incorporated within the application. Applications may take many different forms such as a graphical user-interface or command-line application running on a general computing platform.

Software should be installed according to the requirements of the chosen application. This installation will include the GENEActiv SDK automatically as part of the application.

b) Software Operation Overview

Once installed, running the application provides access to common functionality of the GENEActiv SDK. Whichever application is used, a similar process is followed:

- Connect one or more devices via the cradle – these will then be detected by the application which may display device information including the device type, serial number, length of data recorded and frequency, and the battery charge level. The application may also display details on the device configuration.
- Set up devices to record new data, erasing any existing data on the device; or
- Extract data previously recorded on the device.

c) Device Setup

Device "configuration" is the process of erasing all existing data from a device, then setting it up to begin a new recording when the device is disconnected, or at a later date, depending on the options chosen.

To set up a device, plug one or more into a charging cradle connected to the system running the management application. Once detected by the application, devices may be chosen for configuration. It can be useful to configure multiple devices together when a trial subject will wear several GENEActiv devices on different body locations. Configuration settings encompass:

i. Measurement Frequency

The Measurement Frequency (Hz) should be chosen from the values available on the selected device. The Maximum Measurement Period is dependent on the frequency selected and any delay to start which reduces the achievable measurement time by approximately 5% per week.

Measurement Frequency	Max. Measurement Period (Days)		
	Ver 1.1	Ver 1.2	Ver 1.3
10	30	56	56
20	30	44	44
25	28	38	38
30	21	35	N/A
40	18	30	N/A
50	15	26	26
60	12	24	N/A
66.7	11	22	N/A
75	10	20	N/A
85.7	9	18	N/A
100	7	14	14

ii. Start Mode

The start mode determines when the device will begin recording once it has been unplugged. 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 LED on the device 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.
3. **'At Future Time'** allows the operator to choose a start time up to two 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.

iii. Time Settings

Time settings control the time set on the device, determining the timestamps for the measurement period. Please be aware of the daylight-saving hours changing during the data collection period – the device time will not change automatically if this occurs once it has been configured. Two options are available:

- **'Local Time'** – this is the local time (UTC/GMT time with local time-zone) on the system running the management application.
- **'UTC with Timezone'** – sets the time to the current system UTC/GMT time with a manually-specified time-zone offset.

iv. Study, Trial and Participant Settings

Any required information related to the trial/study and participant may be entered including information on Study, Site, Visit and Investigator.

Participant information can be entered but we do not recommend entering personal data, such as name or date of birth, to reduce privacy risks from directly identifying personal information. This information can be linked post data collection as required. In some jurisdictions, information about device serial number may also need to be removed for onward data sharing.

v. Configuration

Once configuration settings have been selected the device may be configured by software. The configuration process will overwrite any existing data on the device, so it is important that any previous data collected has been successfully extracted. Device configuration will take about 10 seconds after which it will be ready for deployment. The device will record for the given data collection period. Do not charge the device once configured, there is no need for any additional charging.

If the application supports configuration confirmation over Bluetooth, it may provide feedback to confirm that the device has been successfully configured after being removed from the charger cradle.

IMPORTANT MESSAGE

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.

Adherence Data Extraction (GENEActiv 1.3)

Adherence data extraction is performed by an application running on a general computing platform with Bluetooth 5 capability. This will typically be an application that runs in the background with minimal user interaction required once the application has been installed.

Once a device has started recording, it will attempt to initiate a Bluetooth connection periodically to provide adherence data. When a connection attempt is detected by the application, it will communicate with the device to extract and then erase the available adherence data. This data will be stored by the application for further processing. The process will typically repeat at roughly five-hour intervals, supporting the provision of near real-time adherence information.

Data Extraction and Conversion

Data extraction is the process of reading recorded data from a device at the end of a recording and saving it to a GENEActiv .bin file. A recording ends at the time determined by the original configuration settings, or if the device is plugged in to the cradle prematurely. Data conversion is the process of reading a previously extracted .bin file and converting this into a different file format.

a) Extracting data

To extract data from a device, plug one or more into the charging cradle. Once detected by the application, devices may be chosen for extraction. In addition to selecting the .bin file output filename, extract options allow the Investigator ID and Extract Notes fields to be entered and saved in the .bin file.

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. Do not remove or add devices to the cradle while devices are extracting.

b) Reading and Converting data

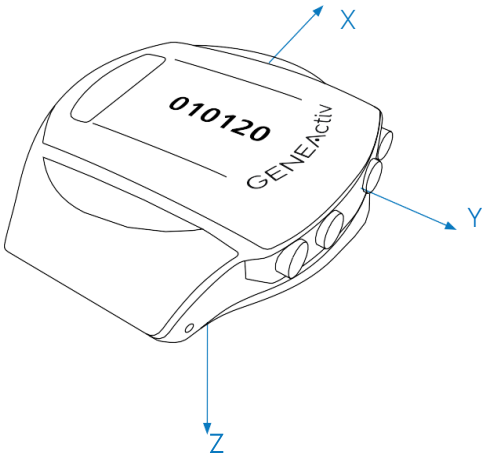
The management application may allow a previously extracted .bin data file to be read and converted into a different format. Once one or more .bin files have been loaded into the application, one or more of these may be selected for conversion. Three conversion types are available:

- **Raw data csv** – creates comma-separated value (.csv) files with one row per recorded data point, which can be read by Microsoft Excel or other applications. Please note that older versions of Excel cannot handle very large .csv files.
- **Epoch csv** – creates smaller, compressed, .csv files by creating epochs of 1, 5, 10, 15, 30, or 60 seconds based on a user-selected option. The Mean for each parameter and the Sum Vector Magnitude are calculated for each epoch.
- **Epoch AWD** – creates AWD format files that may then be analysed using the ActivInsights Actigraphy Sleep Toolkit or Actiware software. The data is compressed into 15, 30 or 60 second epochs based on a user-selected option.

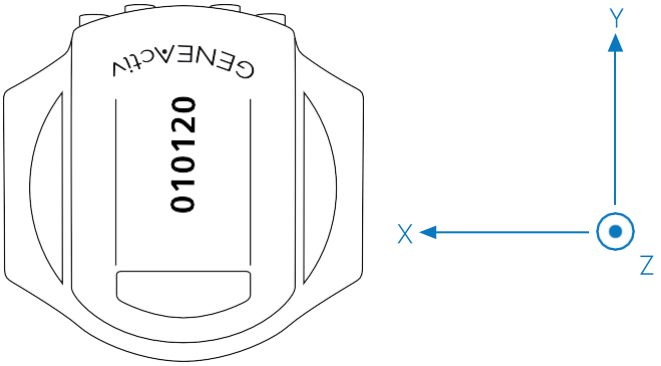
In addition to epoch selection, an option is provided to enable the timestamps from the .bin file to be adjusted by a fixed offset prior to conversion. This allows for correction of recording time if the time set in the initial device configuration was incorrect or set to UTC/GMT.

Sensor Axes & Body Positions

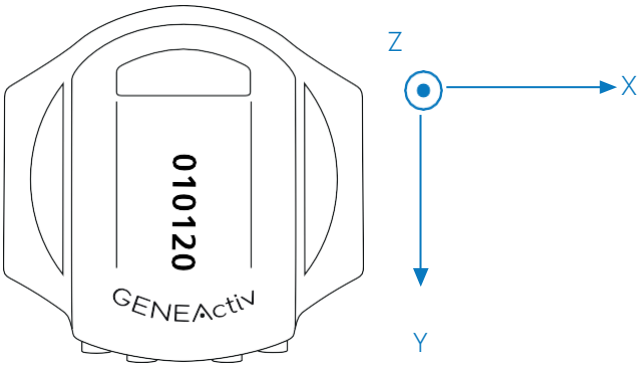
The device should be fitted to the wrist – with the serial number in the correct orientation to be read by the wearer and with the 'crown' to the right – like a watch.



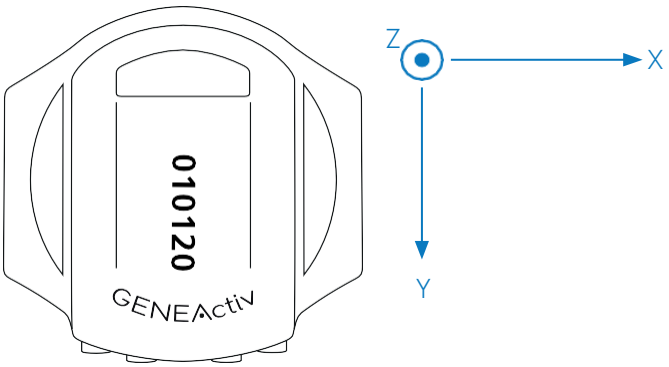
On the right hand, with the arm relaxed to the side, the device will appear to the observer.

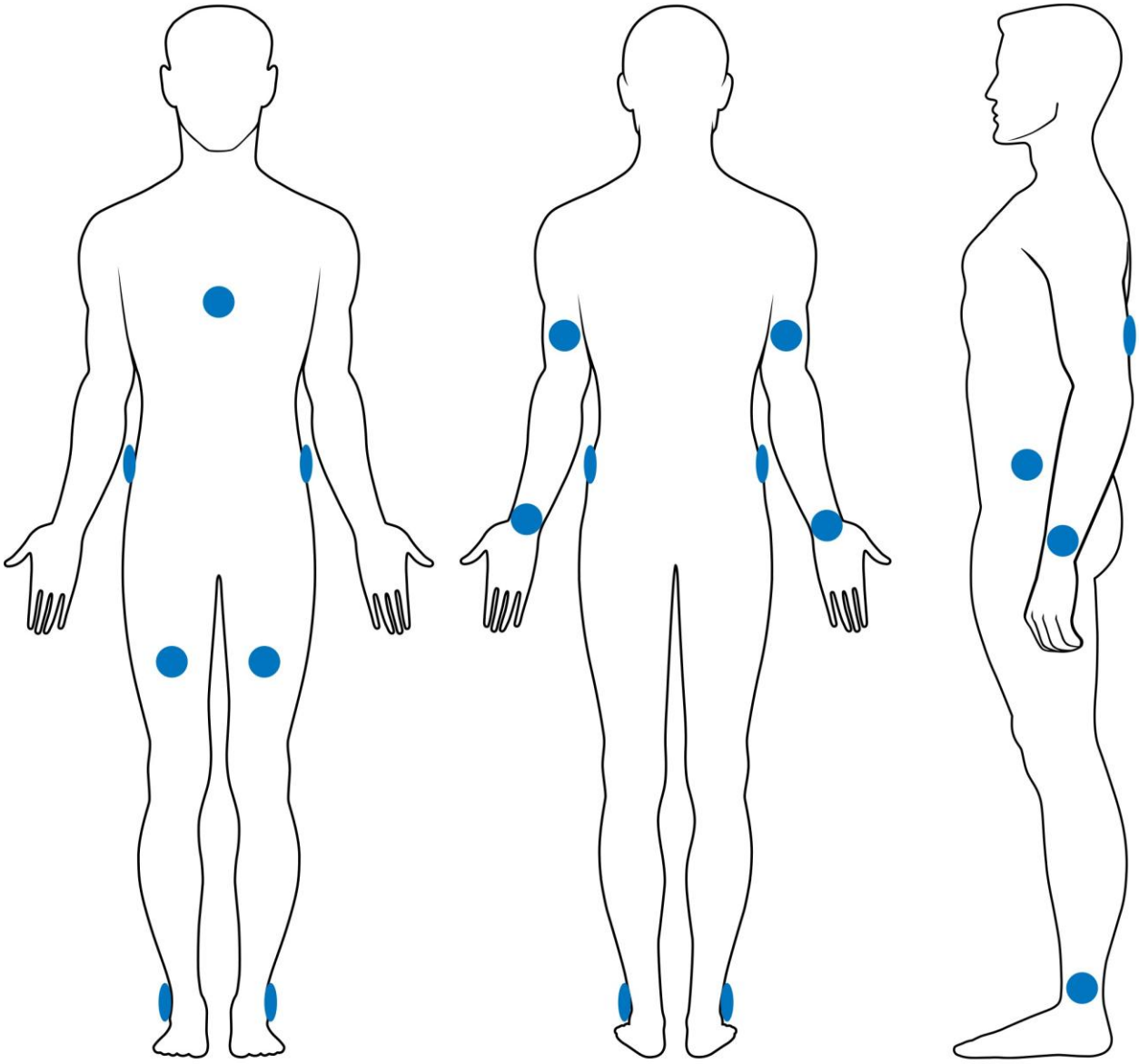


On the left hand, with the arm relaxed to the side, the device will appear to the observer:



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





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 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 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 the charging cradle.

b) Storing

GENEActiv units should be stored at temperatures between 5-45 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 4 hours to maintain good battery health.

If devices are exposed to a storage temperature above 45deg °C they should not be used and returned to ActivInsights for recycling. If devices are exposed to a storage temperature below 5 deg °C, contact ActivInsights and a 14 days test should be completed prior to deployment.

Regulatory Compliance

European Compliance

GENEActiv is a Class IIa Medical Device based on Rule 10 & 11 from Annex VIII of the EU MDR (EU) 2017/745 Medical Devices Regulations for the Medical Devices, conforming to the General Safety & Performance Requirements. The application of the classification rules is governed by the intended purpose of the device.

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.

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.

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 10993-1:2020	Biological evaluation of medical devices. Evaluation and testing within a risk management process.
BS EN 20417:2021	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.

ISO 639:2023	Concerned with representation of languages and language groups
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.
EN300 328	Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Tx/RX RSE Only. Single Band e.g. Bluetooth LE
EN 301 489-1 and EN 301 489-17	Broadband Data Transmission Systems AC Fixed Base Device
FCC Part 15 Subpart B	Unintentional emissions, conducted and radiated.
FCC Part 15 Subpart C	Radiated Tx Spurious Emissions - e.g. BT, BLE
ASTM D4169-22	Standard Practice for Performance Testing of Shipping Containers and Systems.
ISTA 3A	Packaged-Products For Parcel Delivery System Shipment 70 Kg (150 Lb) Or Less
BS EN 22248	Packaging - Complete, filled transport packages - Vertical impact test by dropping
BS EN 60068-2-64	Environmental testing. Tests. Test Fh: Vibration, broadband random and guidance
ISO 14155 2020	Clinical investigation of medical devices for human subjects — Good clinical practice
ISO 2859-1:1999+A1:2011	Sampling Procedures for inspection attributes- Part 1 Sampling Schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection.
MEDDEV 2.7.1:2016	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies Under Directives 93/42/EEC and 90/385/EEC
EU Battery Regulation	EU Battery Regulation (2023/1542).

Regulatory Standards

GENEActiv, complies with FCC 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.

GENEActiv does not contain substances that are carcinogenic, mutagenic, CMR or have endocrine disrupting properties

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.

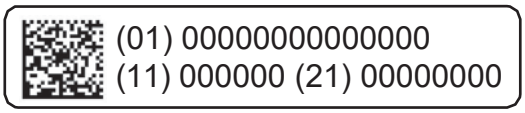
Symbols

The following symbols are used on the GENEActiv

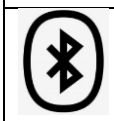
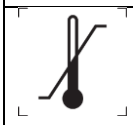
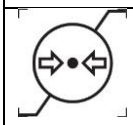
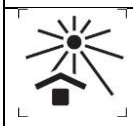
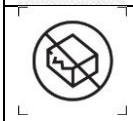
UNIQUE DEVICE IDENTIFICATION
A label required by some countries' regulations regarding identification of medical device also known as Unique Device Identification.

The following information is being coded in the 2-dimensional barcode (GS1 Data Matrix);

(01) 14-digit GS1 Global Trade Item number.
(11) 6-digit date of manufacture.
(21) 8-digit serial number.



Symbols	Description	Source
REF	Catalogue Number	BS EN ISO 15223-1
SN	Serial Number	BS EN ISO 15223-1
LOT	Batch No	BS EN ISO 15223-1
UDI	Unique Device Identifier	BS EN ISO 15223-1
EC REP	Authorised Representative in the European Union	BS EN ISO 15223-1
	Importer	BS EN ISO 15223-1
	Date of Manufacture	BS EN ISO 15223-1
	Manufacturer	BS EN ISO 15223-1
CC	Country of Manufacture	BS EN ISO 15223-1

	Indicate the number of pieces in the package.	ISO 7000
	Certification Mark	EU MDD and EU MDR regulatory requirement (Class I)
	Bluetooth	Bluetooth Special Interest Group (SIG)
	Storage Temperature Limit	BS EN ISO 15223-1
	Humidity	BS EN ISO 15223-1
	Atmospheric Pressure Limitation	BS EN ISO 15223-1
	Keep Away from sunlight	BS EN ISO 15223-1
	Keep Dry	BS EN ISO 15223-1
	Lithium Ion Battery recycling	ISO 7000 + IEC 62902
	Do not use if damage packaging	BS EN ISO 15223-1
	Do not dispose of electronic equipment	ISO 7000 BS EN 50419
	Consult Instructions For Use or consult electronic Instructions For Use (eIFU)	BS EN ISO 15223-1
	Medical Device	BS EN ISO 15223-1

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 Development Kit (SDK). 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.

Getting More Help and Support

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

Please ensure that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or participant are established.

For further information, training, or assistance, please request the Care Card, User Guide, Technical Guide or contact:

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