



Electronic Instructions for Use

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Overview

a) About GENEActiv





Device / controlled item	Regulatory and functional description	Identification
GENEActiv	Body-worn, reusable active medical device for recording movement (acceleration), near-body temperature and environmental light at defined time intervals. EU MDR Class IIa under Annex VIII Rule 10.	Product code: GATV04M UDI-DI: 5065009840007 Basic UDI-DI: 5065009840GATV04M9K
GENEActiv firmware incorporated into GATV04M	Software component incorporated into GENEActiv (GATV04M) for unit control, data acquisition, internal storage and communication. It has no independent medical intended purpose or independent MDR classification. It is IEC 62304 Class A.	No independent UDI-DI. Version and build are controlled through the Software Configuration Index and product release records.
GENEActiv 4-Way Station	Separately identified accessory under Regulation (EU) 2017/745 Article 2(2), assessed in its own right. It provides charging of compatible GENEActiv units and wired data communication to an authorised host only. It has no participant contact, measurement, data-interpretation, treatment or independent clinical function.	Product code: GATV05 UDI-DI: 5065009840014 Basic UDI-DI: 5065009840GATV05YL
GENEActiv SDK	Controlled host-side supporting software for device identification and configuration, source-data extraction and defined file conversion. It has no independent medical intended purpose and no independent MDR classification. IEC 62304 Class A is a software-safety classification, not an MDR device class.	No independent UDI-DI. Version and build are controlled through the Software Configuration Index and release history.

GENEActiv is a body-worn accelerometer and data logger. It records raw movement (acceleration), near-body temperature and environmental light at defined time intervals during daily living and sleep. The measurements are stored internally and are extracted through the GENEActiv 4-Way Station using compatible software. GENEActiv does not diagnose, provide alarms, interpret clinical significance or recommend treatment. Clinical or research interpretation remains the responsibility of an appropriately qualified healthcare professional or investigator.

Device, software and supply configuration

GENEActiv (GATV04M) is the primary medical device. The GENEActiv 4-Way Station (GATV05) is a separately identified accessory under Regulation (EU) 2017/745 Article 2(2), assessed in its own right. Its intended purpose is to charge compatible GENEActiv units and provide wired data communication to an authorised host. It has no medical indication, participant-measurement function, diagnostic interpretation, treatment function or independent clinical purpose. Use GENEActiv only with the GENEActiv 4-Way Station (GATV05), cables, power sources and compatible software configurations specified or authorised by ActivInsights. GATV05 identification, UDI, classification and conformity route are controlled through the Regulatory Master Data Register and the applicable Declaration of Conformity.

GENEActiv firmware is incorporated into GENEActiv (GATV04M) and is limited to device control, data acquisition, internal storage and communication. The GENEActiv SDK is a controlled host-side supporting software component used within compatible management applications for device identification and configuration, source-data extraction and defined file conversion. Neither the firmware nor SDK has an independent medical intended purpose or provides diagnostic interpretation, treatment recommendations, alarms or immediate clinical decision support. Neither is independently classified under MDR Annex VIII Rule 11. The GENEActiv embedded firmware and the GENEActiv SDK are IEC 62304 Class A; that designation is a software-safety classification and not an MDR device class.

GENEActiv units may be supplied singly or as multiple devices to one healthcare organisation or study site. The GENEActiv 4-Way Station (GATV05), USB cable and access to compatible software may be supplied separately or with a consignment. No combination with another medical device is intended unless that combination has been specifically assessed, validated and authorised by ActivInsights.

This IFU is supplied electronically instead of in paper form and is intended exclusively for healthcare



professionals, trained investigators and trained site personnel. No paper IFU is routinely included with the device package. Access the current controlled eIFU using the electronic address identified on the label or packaging or through www.activinsights.com, and verify document number GA-MDF-LBL-001, revision and issue date before use. This English master and all required national-language translations are controlled under Commission Implementing Regulation (EU) 2021/2226, as amended by Commission Implementing Regulation (EU) 2025/1234. Where requested, ActivInsights will provide a paper copy free of charge within seven calendar days, as required by the eIFU regulation; use the contact details in the support section.

i. Intended Use/Purpose

GENEActiv is intended to be worn on the wrist or another specified body location to quantify and record movement through acceleration, near-body temperature and environmental light at defined time intervals for subsequent review by healthcare professionals or investigators. It is not intended to diagnose a disease, provide an alarm, direct treatment or support an immediate clinical decision.

ii. Indications for Use

Acquisition of movement-related data during daily living and sleep in clinical studies, healthcare assessment and research where such data are relevant. Individual suitability, placement, strap, recording duration and configuration are determined by the responsible healthcare professional or investigator.

iii. Intended Users

Healthcare professionals, trained investigators and trained site personnel. This eIFU is addressed exclusively to those professional users. Participants may wear or remove a configured device and may perform only the limited actions instructed by the responsible professional; they do not configure, service, recondition, extract or independently interpret device data. The responsible professional provides participant-facing wear, skin-check, removal and safety instructions in an appropriate accessible format before use.

iv. Use Environment

Clinical settings, laboratories and the participant's natural environment, within the specified operating, storage, electromagnetic and ingress-protection conditions. The GENEActiv 4-Way Station (GATV05) is for indoor use by trained personnel in a dry professional environment and is not intended for participant contact.

v. Participant Population

Participants of all ages, including infants, children, adults and older adults, provided the responsible healthcare professional or investigator has assessed suitability, selected an appropriate strap and wear location, and defined the necessary supervision. Children and persons unable to recognise or communicate discomfort require responsible adult supervision.

vi. Contra-Indications

There are no known medical contraindications when used as intended. Do not apply the device or strap over injured, broken or infected skin. Do not continue use where the participant cannot tolerate the device materials, develops persistent redness, swelling, pain or irritation, or where safe placement and supervision cannot be maintained. The responsible healthcare professional shall assess individual suitability.

vii. Contact with Participant

Intact skin only. The GENEActiv 4-Way Station and USB cable have no participant contact.

viii. Duration of use

Up to 60 days per recording, depending on the GENEActiv version, measurement frequency, delayed-start setting, battery condition and approved configuration. The responsible healthcare professional or investigator shall define wear breaks and skin checks appropriate to the participant.

ix. Device Lifetime in use



GENEActiv is reusable within its declared lifetime of 50 charging cycles or 2 years from the date of purchase, whichever occurs first, subject to inspection, cleaning, correct battery maintenance and continued functional suitability. Remove the device from service at the end of its declared life or earlier if damaged or malfunctioning.

x. Shelf Life

Two years when stored and maintained within the specified conditions. Do not deploy a device beyond the controlled expiry/service-life status shown in the organisation's equipment record.

xi. Clinical Benefits and Performance Claims

GENEActiv provides objective, time-stamped acquisition of acceleration, near-body temperature and environmental light for subsequent analysis. There is no direct clinical benefit from wearing the device. GENEActiv does not diagnose, predict deterioration, recommend treatment or generate an alarm. Any clinical conclusion requires professional review together with other relevant information.

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.

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

Published work may use GENEActiv source data in studies of activity, sleep and other research questions. Such use does not establish a GENEActiv disease-specific benefit, diagnosis, treatment effect or validated algorithmic outcome. The controlled clinical evaluation and literature review determine which device-specific performance claims are supported; professional or investigator interpretation remains outside the device function.

The GENEActiv 4-Way Station (GATV05) and GENEActiv SDK have no independent clinical benefit or performance claim. Embedded firmware remains within GATV04M.

xii. Warnings and Precautions

- ☐ Use GENEActiv only for the intended purpose and within the specified configuration. Do not use its output as the sole basis for diagnosis, treatment, an alarm or an immediate clinical decision.
- ☐ Children and persons unable to recognise or communicate discomfort require responsible adult supervision and an individual suitability assessment before use.
- ☐ Apply only to intact skin. Check the skin and fit at intervals appropriate to the participant. Stop use and seek professional review if persistent redness, swelling, pain, pressure injury or irritation occurs.
- ☐ Select the correct strap and body location. A strap that is too tight may cause discomfort or skin injury; a loose, reversed or incorrectly positioned device may produce incomplete or misleading data.
- ☐ Near-body temperature is not core body temperature and shall not be used to diagnose fever or other clinical conditions. Environmental light readings depend on sensor exposure and may be affected by clothing or orientation.
- ☐ Before deployment, verify the device serial number, participant/study assignment, measurement frequency, start mode, start time, time zone, recording duration, battery level and wear location. Incorrect configuration or assignment can cause incomplete, mistimed or misattributed data.
- ☐ Configuration erases existing data. Extract, identify, back up and verify all required files before reconfiguration. Do not return a configured device to the station during data collection because this stops recording.



- ❑ Bluetooth adherence information is supplementary and is not guaranteed to be continuous or complete. Range, interference, host-device settings, application status and connectivity may delay or prevent transfer. Absence of adherence data shall not be interpreted by itself as proof that the participant is not wearing the device.
- ❑ Use only compatible application, SDK and firmware versions that have been released or authorised for the intended configuration. Verify successful extraction, file identity, completeness and expected timestamps before the data are used or the device is erased.
- ❑ Minimise personal data stored on the device. Protect exported files against unauthorised access, loss, alteration and incorrect participant linkage in accordance with the organisation's approved data-protection and backup controls.
- ❑ Use only the GENEActiv 4-Way Station (GATV05), USB cable and power source specified or authorised by ActivInsights. The power source shall provide at least 500 mA per occupied port. Do not use damaged, modified or incompatible accessories, cables or equipment.
- ❑ Do not wear GENEActiv while it is charging or connected to USB. Keep the GENEActiv 4-Way Station (GATV05) dry, place it on a stable surface with ventilation, and disconnect it from power before cleaning.
- ❑ Do not disassemble, modify or service GENEActiv or the GENEActiv 4-Way Station (GATV05). The device battery is not user-replaceable. Repair, refurbishment, reconditioning and release after reconditioning may be performed only by ActivInsights or an organisation expressly authorised by ActivInsights.
- ❑ Stop using the device or station if it is damaged, unusually warm, swollen, leaking, fails to charge or communicate, or behaves unexpectedly. Isolate it from use and contact ActivInsights.
- ❑ Do not expose the device to excessive force, shock, aggressive chemicals, microwave or conventional ovens, dishwashers, washing machines, external heat sources, saunas or temperatures outside the specified operating and storage limits.
- ❑ Portable RF communication equipment, including antennas and cables, should be kept at least 30 cm from GENEActiv and the GENEActiv 4-Way Station (GATV05). Electromagnetic disturbance may interrupt charging or communication. The system is not evaluated for use in RF-shielded or MRI environments.
- ❑ Do not wear GENEActiv in saunas or other high-temperature environments.
- ❑ Clean the device with a soft moistened cloth. Do not use abrasive cleaners or solvents.

Residual risks and limitations

Residual risks that may remain when the instructions are followed include temporary skin irritation or discomfort; incomplete, lost, delayed or incorrectly assigned data; failed charging, communication or extraction; and inaccurate or unavailable data caused by incorrect placement, configuration, battery condition, environmental exposure, electromagnetic disturbance, software incompatibility or user error. The responsible healthcare professional or investigator shall determine whether the available data are complete and suitable for the intended analysis.

Failure of the GENEActiv 4-Way Station (GATV05), embedded firmware, SDK or host application may make data unavailable or may interrupt configuration, transfer or conversion. These components do not provide alarms or independent clinical interpretation. If operation is unexpected, stop the affected workflow, retain the source data where possible, record the event and contact ActivInsights before reuse.



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
GENEActiv 4-Way Station	Four-unit station; 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	
Qualified Bluetooth 4.2 module operating in the 2.4 GHz band. Used only for supplementary communication/adherence-data transfer; host Bluetooth 5 capability is required. The GENEActiv 4-Way Station (GATV05) does not transmit or receive wireless signals.	

Getting Started

a) System Requirements

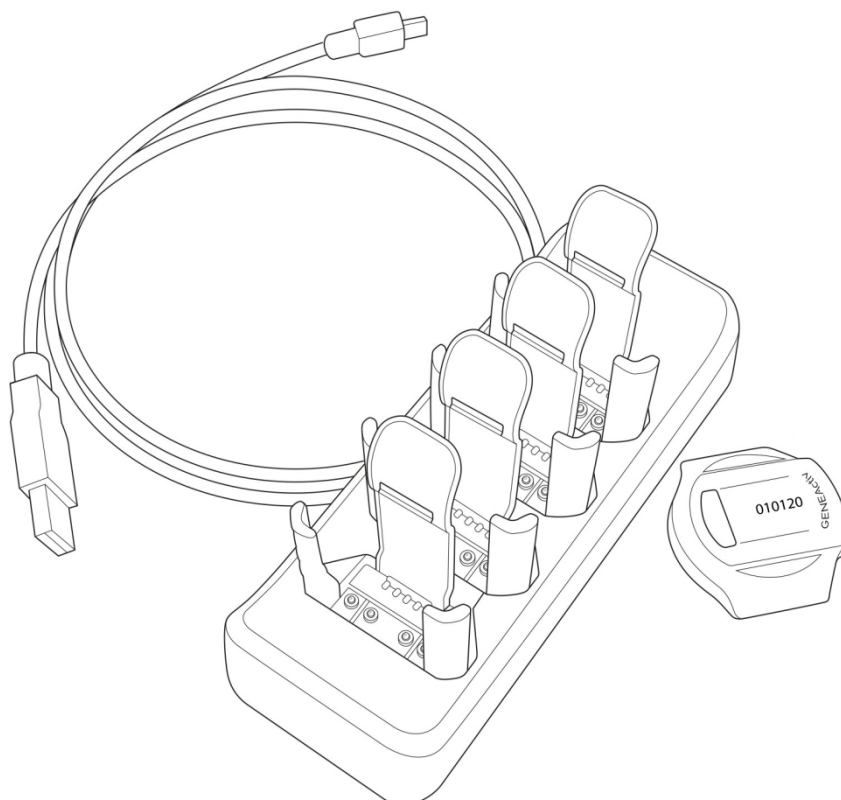
Use only a GENEActiv-compatible software application and version released or authorised for the intended device/firmware configuration. Minimum host requirements are listed below. Bluetooth 5 capability is required on the host platform for adherence-data extraction from Bluetooth-enabled GENEActiv 1.3 devices.

- ☐ 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 unit with black resin wrist strap
- ☐ Spring bar tool with pins
- ☐ GENEActiv 4-Way Station (GATV05) with authorised USB cable

Use the GENEActiv 4-Way Station (GATV05) and supplied or authorised USB cable for charging, wired configuration and end-of-recording data extraction. Do not connect GENEActiv to unapproved charging or communication equipment.





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

Before first configuration and before each deployment, charge GENEActiv in the GENEActiv 4-Way Station (GATV05) for 4 hours. Confirm in compatible software that the battery level is at least 90% and that the correct device serial number is selected.

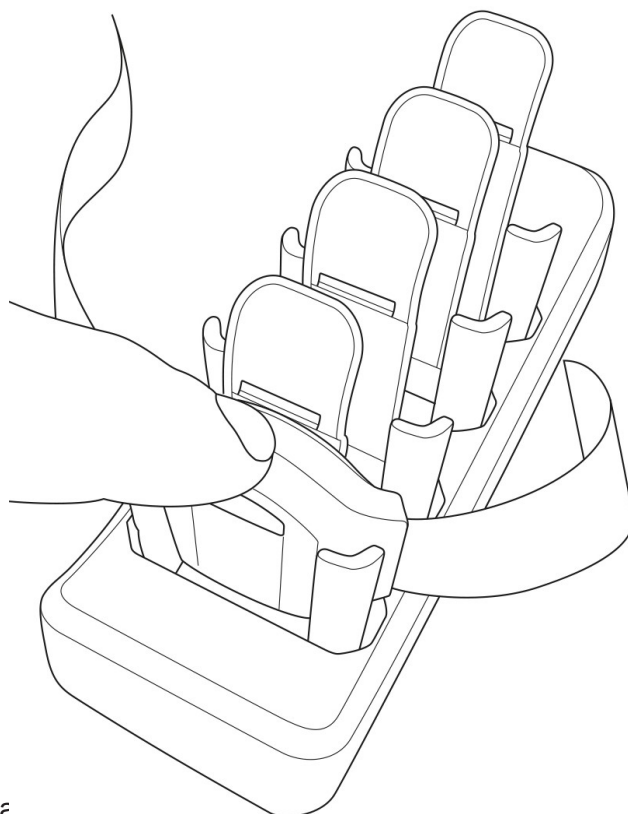
Connect the GENEActiv 4-Way Station (GATV05) to a compatible computer USB port or an authorised USB power supply. The source shall provide at least 500 mA for each occupied port. Place the station on a dry, stable surface with adequate ventilation. Do not use unapproved hubs, cables or adapters.

A red device light indicates charging. After the 4-hour charge, check the battery level in compatible software; the LED is only a visual indicator and is not a reliable battery-capacity measurement. When the battery is confirmed at 90% or above, remove the device from the station. Do not leave devices charging for more than 4 hours at a time.

IMPORTANT MESSAGE

DO NOT leave GENEActiv units 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

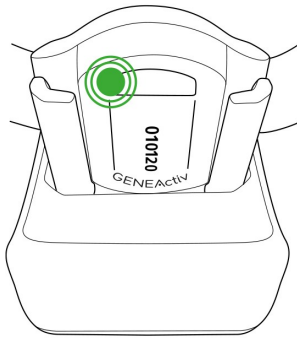
When not recording, the battery level is indicated by the LED. See the diagram below for LED indicators.

button on the device. See

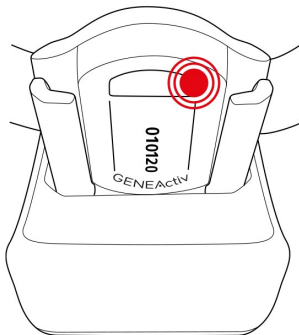
A **green** flash indicates that the device is OK to go into storage if it is no longer in use. A **red** flash or no flash at all means that the device should be charged (this function is not available if a device has been configured to record).

To ensure that a GENEActiv unit is fully charged, it must be left in the GENEActiv 4-Way Station (GATV05) for a full 4 hours before deployment. To check the battery level, connect the device to software. It should show at

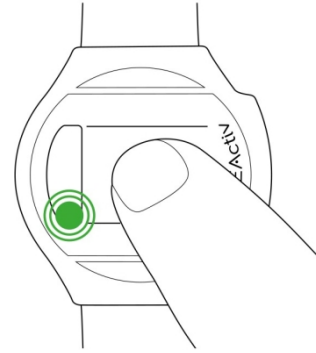
least a 90% battery level before deploying.



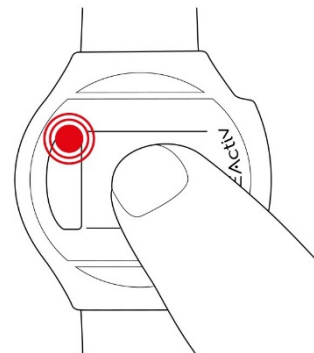
Green Flashing = Check the battery level in the software (after 4 hours of charge)



Red Flashing = Charging
Constant Red = Communicating



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



Red Flashing (when unconfigured) = Battery needs charging



Device Setup & Configuration

a) Device Management Software

GENEActiv is operated with compatible software applications that incorporate the controlled GENEActiv SDK. The application may provide a graphical or command-line interface for device identification, configuration, data extraction and file conversion. Embedded firmware controls device operation, acquisition, storage and communication.

Install and maintain only a software application/version released or authorised for the intended GENEActiv and firmware configuration. Follow the application supplier's installation instructions and the organisation's access-control, cybersecurity, backup and change-control procedures. Do not use an unverified update or unsupported operating-system/software combination.

b) Software Operation Overview

Before use, confirm the application identity/version and the connected device serial number and firmware/configuration status. The usual controlled workflow is:

- ☐ Connect one or more GENEActiv units through the GENEActiv 4-Way Station (GATV05) – 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 GENEActiv units to record new data, erasing any existing data on the device; or
- ☐ Extract data previously recorded on the device.

c) Device Setup

Device configuration erases existing data and assigns the settings for the next recording. Extract, identify, back up and verify all required data before configuring the device. Record the device serial number and participant/study linkage in the authorised study or equipment record.

To set up a device, plug one or more into a GENEActiv 4-Way Station (GATV05) 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 units 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 GENEActiv 4-Way Station (GATV05) 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 GENEActiv unit is removed from the GENEActiv 4-Way Station (GATV05). 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 determine measurement timestamps. Verify the host clock, time zone, daylight-saving implications and scheduled start before configuration. The configured device time does not automatically change when daylight-saving time changes. Any later timestamp correction shall be documented and traceable to the original file.

- ☐ **'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

Enter only the study, site, visit and investigator information necessary for the authorised purpose. Confirm the correct device-to-participant assignment before deployment and again at extraction.

Do not enter directly identifying personal data, such as name or date of birth, unless specifically authorised and protected. Maintain the linkage key separately under controlled access.

v. Configuration

After selecting and independently checking the required settings, configure the device. Configuration overwrites all existing device data. Confirm successful configuration, serial number, start mode/time, measurement frequency, duration and battery status before deployment. Do not return the configured device to the station until data collection is complete because connection to the station stops recording.

Where the authorised application supports Bluetooth configuration confirmation, treat the confirmation as an additional check only. If confirmation is inconsistent or associated with the wrong serial number, do not deploy the device until the configuration has been verified through the approved workflow.

IMPORTANT MESSAGE

Once the configuration of the device is complete, it is important that the device is not returned to the GENEActiv 4-Way Station (GATV05) at any point, until after data collection. If the device is returned to the GENEActiv 4-Way Station (GATV05) 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 available only for Bluetooth-enabled GENEActiv 1.3 and requires an authorised application on a compatible Bluetooth 5 host. Keep the application active and configured as instructed. Bluetooth adherence transfer is supplementary and does not replace end-of-recording extraction from the device.

During recording, the device periodically attempts a Bluetooth connection to transfer the available adherence. Transfer timing depends on range, radio conditions, host settings and application availability. Gaps or delays in adherence data do not by themselves establish non-wear. Confirm final recording data by wired extraction through the GENEActiv 4-Way Station (GATV05).

Data Extraction and Conversion

Data extraction reads the completed recording from GENEActiv and saves it as a GENEActiv .bin file. Connecting the device to the station before the planned end stops recording. Data conversion creates a derived output from an extracted .bin file; retain the original .bin file as the source record.

a) Extracting data

Before extraction, confirm the device serial number and intended participant/study linkage. Connect the device to the GENEActiv 4-Way Station (GATV05), select a controlled destination and filename, and perform extraction using an authorised application. Do not add or remove devices during extraction. After completion, verify that the .bin file exists, is readable, has the expected identity/time range and is backed up before erasing or reconfiguring the device.

Please note: Data extraction will take up to approx. 20 minutes for GENEActiv 4-Way Stations starting with SN 00; and under 10 minutes for GENEActiv 4-Way Stations starting with SN 02. Do not add or remove GENEActiv units while extraction through the GENEActiv 4-Way Station (GATV05) is in progress.



b) Reading and Converting data

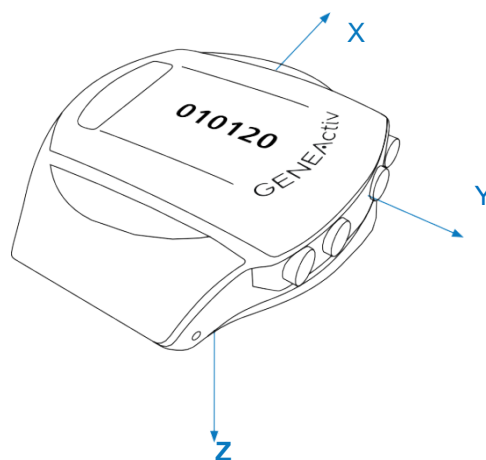
Load only verified source .bin files into an authorised compatible application. Record the application/version, conversion settings, time-offset adjustments and output location where required by the study or quality system. Converted files are derived records; retain the original .bin file. Available conversion types include:

- ☐ **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.

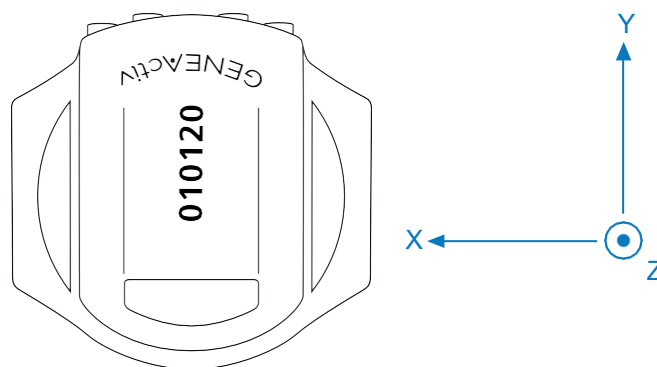
A fixed timestamp offset may be applied during conversion to correct a documented configuration-time error or UTC/local-time difference. Preserve the original .bin file unchanged and document the reason, value, author and date of any offset so the transformation is traceable.

Sensor Axes & Body Positions

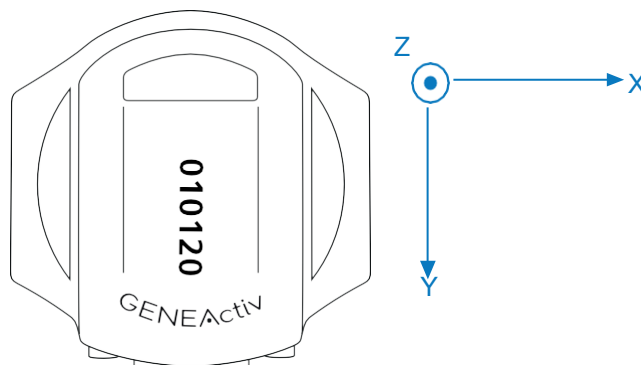
The device should be fitted to the wrist – with the serial number in the correct orientation to be read by the wearer and with the ‘crown’ to the right – like a watch.



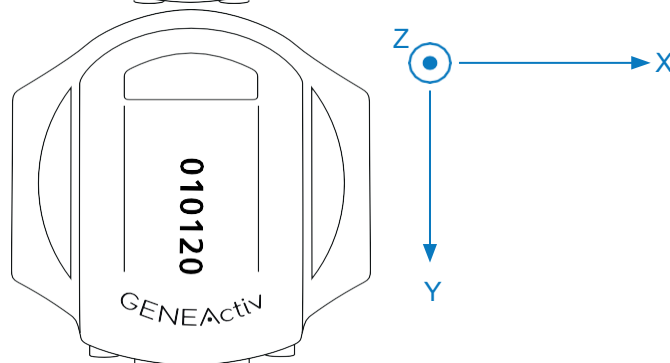
On the right hand, with the arm relaxed to the side, the device will appear to the observer:

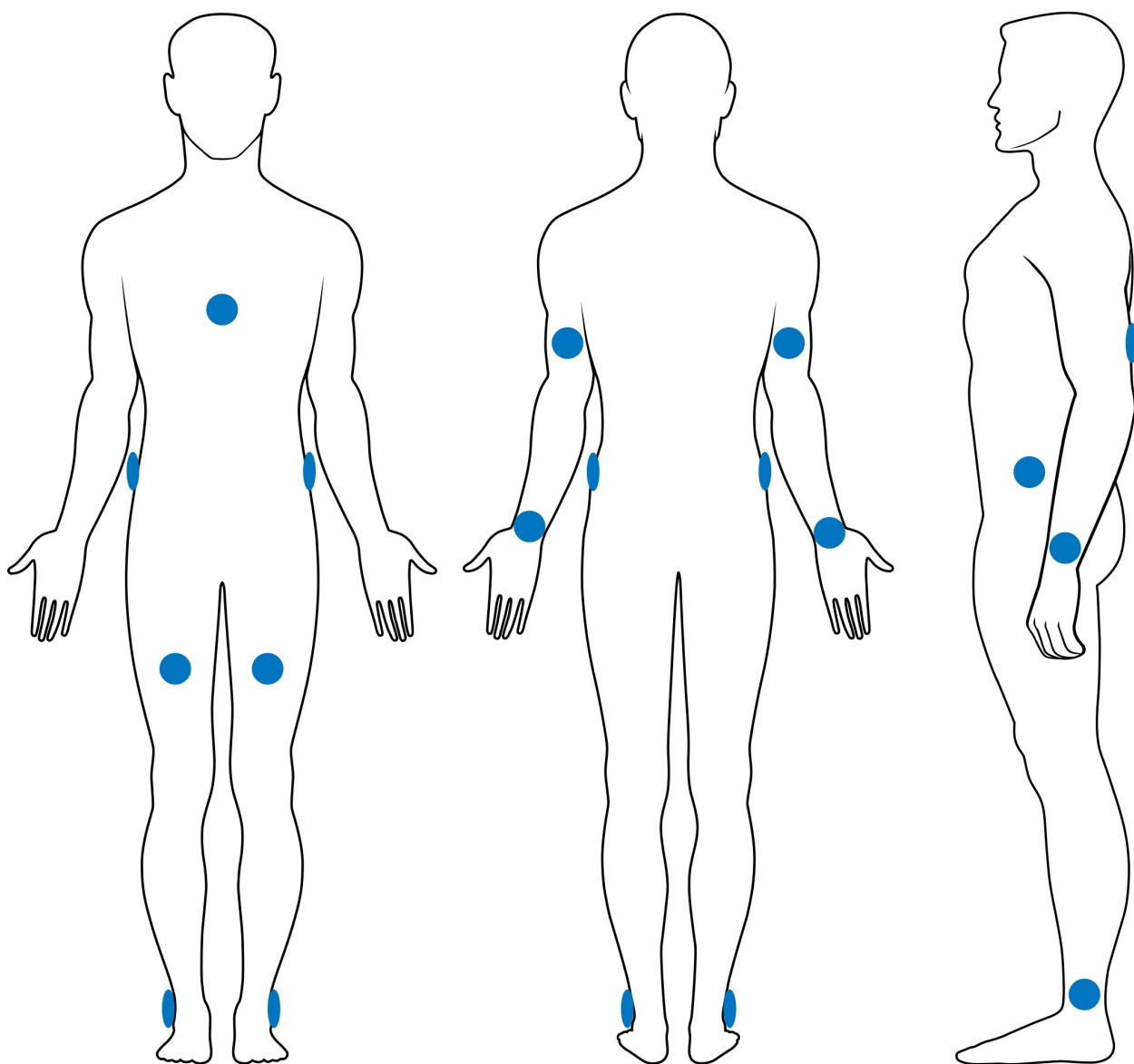


On the left hand, with the arm relaxed to the side, the device will appear to the observer:



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







Cleaning & Storing

a) Cleaning the Device

Clean GENEActiv after each participant use and whenever visibly soiled. Wipe with a cloth or soft-bristle brush using warm soapy water or a mild detergent solution, then allow it to air dry completely. Do not immerse a damaged device.

For disinfection between participants, use a Clinell Universal Wipe or an equivalent product validated by the responsible organisation for the device materials. Wet all external surfaces for the disinfectant manufacturer's required contact time, then allow the device to air dry completely. Replace a wipe if dry or soiled and dispose of it appropriately.

Disconnect the GENEActiv 4-Way Station (GATV05) from USB/power before cleaning. Wipe the external surfaces with a dry or lightly dampened lint-free cloth. Do not immerse the station, permit liquid to enter it or apply disinfectant directly to connectors.

If excessively soiled, remove the strap and clean the device and strap separately using the applicable instructions. Replace worn, cracked, stretched or contaminated straps. Do not deploy a device until it and the selected strap are clean, dry, intact and correctly assembled.

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 GENEActiv 4-Way Station (GATV05).

b) Storing

Store clean, dry GENEActiv units at 5 °C to 45 °C, protected from moisture, direct sunlight, impact and contamination. Recharge unused devices for 4 hours every 6 months. If exposed above 45 °C, remove from service and return to ActivInsights. If exposed below 5 °C, contact ActivInsights and complete the manufacturer-specified 14-day check before deployment.

Installation, inspection and preventive maintenance

No fixed installation or user servicing is required. Before first use, place the GENEActiv 4-Way Station (GATV05) on a dry, stable, ventilated surface; connect only the authorised USB cable and compatible host/power source; install an authorised software application; and confirm that the application, SDK, firmware and device configuration are compatible.

- ☐ Before every deployment: inspect the enclosure, lens, contacts, button, strap and station for damage or contamination; confirm legible device identification; clean/disinfect as required; charge for 4 hours; and verify in software the serial number, battery level of at least 90%, date/time and intended configuration.
- ☐ After every deployment: confirm the recording has stopped as expected; extract, identify, verify and back up the source .bin file; clean/disinfect the device and strap; inspect for wear or damage; and update the equipment record.
- ☐ During storage: recharge each unused device for 4 hours every 6 months and record the maintenance. Inspect the station, cable and contacts before each charging session.
- ☐ No user calibration is permitted. Sensor calibration and performance are established under the manufacturer's controlled processes. If output appears implausible, incomplete or outside the stated specification, quarantine the device, retain the relevant data and contact ActivInsights for assessment.
- ☐ No additional scheduled servicing is required within the declared service life unless specified by ActivInsights. Do not open the enclosure or replace the battery. Repair, calibration, refurbishment and reconditioning are manufacturer-controlled activities.



Reuse and reconditioning

Routine reuse between participants is permitted only after the device has been cleaned/disinfected, inspected and confirmed functional in accordance with this IFU. User cleaning is not reconditioning. A returned, damaged, out-of-tolerance or end-of-life device shall not be reused unless ActivInsights, or an organisation expressly authorised by ActivInsights, has reconditioned it under manufacturer responsibility and formally released it as meeting the applicable general safety and performance requirements.

IFU supply, language and document control

Check the document number, revision and issue date in the footer before use. This is the electronically controlled IFU; no routine printed IFU accompanies the device package. The English master is translated, reviewed and approved before electronic supply where a national language is required. ActivInsights maintains current and superseded eIFU versions and applicable website/retention controls. Do not use or distribute an obsolete, uncontrolled or locally modified copy. Report suspected eIFU errors, inaccessible content, missing pages or unavailable translations to ActivInsights. A required paper copy may be requested free of charge using the support contact details.

IMPORTANT MESSAGE

When not in use it is important that GENEActiv units 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-day check should be completed prior to deployment.



Regulatory Compliance

European Compliance

GENEActiv (GATV04M) is a Class IIa medical device under Regulation (EU) 2017/745, Annex VIII, Rule 10, based on its intended purpose of recording physiological/biomechanical parameters. Conformity is assessed using the applicable MDR conformity-assessment procedure. The CE marking is accompanied by the identification number of the Notified Body: CE 0476.

GENEActiv embedded firmware and the GENEActiv SDK have no independent medical intended purpose and do not provide diagnostic interpretation, therapeutic decision support, patient-management recommendations or alarms. MDR Annex VIII Rule 11 is not independently applicable to those software components. The GENEActiv embedded firmware and the GENEActiv SDK are IEC 62304 Class A; this is a software-safety classification and not an MDR device class.

The GENEActiv 4-Way Station (GATV05) is a separately identified accessory under MDR Article 2(2), assessed in its own right. It provides charging and wired data-transfer support only, has no participant contact or measurement function, and does not alter or interpret recorded data. UDI-DI 5065009840014 and Basic UDI-DI 5065009840GATV05YL apply. Its classification and conformity route are controlled through GA-MDF-TFI-003, the Regulatory Master Data Register and the applicable Declaration of Conformity.

United States and FDA Compliance

For United States supply, GENEActiv is listed under FDA product code IKK, Isokinetic testing and evaluation system, Class II and 510(k) exempt under 21 CFR 890.1925. Commercial distribution remains subject to current establishment registration, device listing, applicable FDA general and special controls, and US labelling requirements. FCC radio/emissions statements in this IFU apply only to the corresponding tested configuration. This IFU does not itself constitute FDA clearance or approval.

Applicable Standards

The standards and specifications below are referenced through the current controlled GSPR Checklist and standards gap assessment. A standard is claimed as applied only to the extent, edition and configuration documented in the supporting Technical File evidence; inclusion in this IFU does not by itself demonstrate conformity.

Applicable Standards	Description
EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes.
EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices.
EN IEC 62366-1:2015/A1:2020	Medical devices - Application of usability engineering to medical devices.
EN 62304:2006/A1:2015	Medical device software - Software life-cycle processes.
IEC 60601-1 and applicable amendments	Medical electrical equipment - General requirements for basic safety and essential performance, as identified in the controlled GSPR assessment.
EN IEC 60601-1-2:2015/A1:2021	Medical electrical equipment - Electromagnetic disturbances - Requirements and tests.
EN ISO 10993-1:2020	Biological evaluation of medical devices - Evaluation and testing within a risk-management process.
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer.



EN ISO 15223-1:2021/A11:2021	Medical devices - Symbols to be used with information supplied by the manufacturer.
IEC 60529 and applicable amendments	Degrees of protection provided by enclosures (IP Code).
ETSI EN 300 328; EN 301 489-1; EN 301 489-17	2.4 GHz radio and electromagnetic compatibility requirements applicable to Bluetooth-enabled configurations.
FCC 47 CFR Part 15	US radio-frequency device/emissions requirements applicable to tested configurations.
UN Manual of Tests and Criteria, Part III, 38.3	Transport testing applicable to lithium batteries.
Directive 2014/53/EU; Directive 2011/65/EU; Directive 2012/19/EU	EU radio equipment, restriction of hazardous substances and waste electrical/electronic equipment requirements, as applicable.
Regulation (EU) 2023/1542	EU batteries and waste batteries requirements, as applicable.
Commission Implementing Regulation (EU) 2021/2226, as amended by (EU) 2025/1234	Electronic instructions for use supplied instead of paper for devices intended exclusively for professional users, including risk assessment, access, language, retention, website and paper-copy-on-request controls.



Regulatory Standards

GENEActiv complies with FCC Part 15 for the tested configuration. Operation is subject to the conditions that the device shall not cause harmful interference and shall accept interference received, including interference that may cause undesired operation.

Bluetooth-enabled GENEActiv 1.3 configurations are assessed under the applicable requirements of Directive 2014/53/EU. The Bluetooth function is limited to communication and supplementary adherence-data transfer; it does not provide a clinical alarm or interpretation.

Electromagnetic compatibility has been evaluated against the editions and configurations identified in the controlled Technical File, including IEC 60601-1-2:2014+A1:2020 / EN IEC 60601-1-2:2015+A1:2021 where applicable. Observe the separation and interference precautions in this IFU.

Electrical and electronic components are controlled against Directive 2011/65/EU (RoHS), as amended, for restriction of specified hazardous substances.

Material and biological-safety claims, including assessment of carcinogenic, mutagenic, reproductive-toxic and endocrine-disrupting substances, are supported and maintained in the controlled biological evaluation and materials documentation.

Under Directive 2012/19/EU on waste electrical and electronic equipment (WEEE), do not dispose of GENEActiv or the GENEActiv 4-Way Station (GATV05) in unsorted municipal waste.

Return end-of-life products to an authorised collection point or to ActivInsights. Separate collection supports safe treatment, recovery and recycling. Contact the relevant local authority or ActivInsights for disposal instructions.

Battery and waste-battery obligations are controlled under Regulation (EU) 2023/1542, as applicable. The internal battery is not user-removable or user-replaceable.

The lithium battery configuration has been assessed against the applicable acceptance criteria in the UN Manual of Tests and Criteria, Part III, subsection 38.3. Use the approved packaging and transport controls when shipping devices.

Symbols

The following symbols may appear on GENEActiv, the GENEActiv 4-Way Station (GATV05), packaging or accompanying information. Interpret each symbol in the context of the item on which it appears.

UNIQUE DEVICE IDENTIFICATION

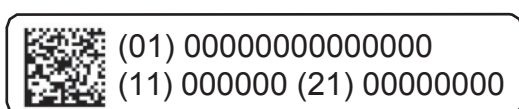
The Unique Device Identification (UDI) supports unambiguous identification and traceability. The UDI carrier and human-readable information shall be interpreted together with the product code and serial number on the applicable label.

The GENEActiv UDI carrier encodes the applicable device identifier and production identifiers, including the date of manufacture and serial number, in the format defined by the controlled labelling specification.

(01) 14-digit GS1 Global Trade Item number.

(11) 6-digit date of manufacture.

(21) 8-digit serial number.



Symbols	Description	Source
	Catalogue Number	EN ISO 15223-1:2021/A11:2021
	Serial Number	EN ISO 15223-1:2021/A11:2021
	Batch No	EN ISO 15223-1:2021/A11:2021
	Unique Device Identifier	EN ISO 15223-1:2021/A11:2021
	Authorised Representative in the European Union	EN ISO 15223-1:2021/A11:2021
	Importer	EN ISO 15223-1:2021/A11:2021
	Date of Manufacture	EN ISO 15223-1:2021/A11:2021
	Manufacturer	EN ISO 15223-1:2021/A11:2021
	Country of Manufacture	EN ISO 15223-1:2021/A11:2021

	Indicate the number of pieces in the package.	ISO 7000
	CE marking of conformity; Notified Body identification number 0476 where applicable	Regulation (EU) 2017/745, Annex V
	Bluetooth	Bluetooth Special Interest Group (SIG)
	Storage Temperature Limit	EN ISO 15223-1:2021/A11:2021
	Humidity	EN ISO 15223-1:2021/A11:2021
	Atmospheric Pressure Limitation	EN ISO 15223-1:2021/A11:2021
	Keep Away from sunlight	EN ISO 15223-1:2021/A11:2021
	Keep Dry	EN ISO 15223-1:2021/A11:2021
	Lithium Ion Battery recycling	ISO 7000 + IEC 62902
	Do not use if the package is damaged	EN ISO 15223-1:2021/A11:2021
	Do not dispose of electronic equipment	ISO 7000 BS EN 50419
	Consult electronic instructions for use (eIFU); use the indicated electronic address and verify the current controlled revision before use.	EN ISO 15223-1:2021/A11:2021; Regulation (EU) 2021/2226 as amended
	Medical Device	EN ISO 15223-1:2021/A11:2021



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

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Intended environments are clinical settings, laboratories and the participant's natural environment within the specified conditions. The GENEActiv 4-Way Station (GATV05) is for dry indoor professional environments. The system is not evaluated for use in RF-shielded or MRI environments.

The GENEActiv system has been evaluated as the defined equipment-under-test configuration. Use only the specified station, cable, power source and compatible software/host configuration; unauthorised substitutions may affect safety, electromagnetic compatibility, charging or data communication.

Electromagnetic disturbance may interrupt charging, Bluetooth communication, wired connection or data extraction. It does not generate a clinical alarm. If operation is affected, move away from the disturbance, verify the device/file identity and data completeness, repeat the approved step where safe, and contact ActivInsights if the problem persists.

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-compatible management application. 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 GENEActiv 4-Way Station (GATV05), 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

Any serious incident that has occurred in relation to GENEActiv or the GENEActiv 4-Way Station (GATV05) shall be reported without undue delay to ActivInsights and or to the competent authority of the Member State in which the user and/or participant is established. Preserve the device, configuration details, software versions and relevant data unless instructed otherwise.

For further information, training or assistance, contact ActivInsights using the details below. Any separately controlled GENEActiv User Guide, GENEActiv Care Card, Product Information Sheet, Participant Information Sheet or Technical Guide, where retained and formally released, is supplementary to this IFU. The current controlled IFU takes precedence if there is any inconsistency.

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