AKTiA

Bracelet G1

EN – User Manual
FR – Manuel d'utilisation
DE – Bedienungsanleitung
IT – Manuale d'uso

ENGLISH

Content

1 Introduction

The Aktiia Bracelet G1 is the smart way to track your Blood Pressure over days and nights without any effort. The Aktiia Bracelet G1 is designed to be discreet, with no lights or alarms bothering you during your daily life. With its accuracy and ease of use, Aktiia is the perfect solution to track your blood pressure 24/7.

Aktiia offers a new way to monitor your heart health that easily integrates into your life. Our device tracks your Blood Pressure through unnoticeable measurements performed multiple times per day. All you need to do is to wear the bracelet. You can access your data anytime by simply looking at the Aktiia mobile application.

	Please read this User Manual carefully to gain a complete understanding of the device's functions and safety-related information.

Support : In case you have any additional questions, you encounter any issue, or you would like to suggest some improvements, please contactAktiia's Customer Service at **support@aktiia.com** or visit our website at **www.aktiia.com.**

Incident and Adverse Event : For any incident or event, please contact immediately Aktiia at **support@aktiia.com** with mention of Incident or Adverse Event in the email content or title.

2 Intended purpose

Aktiia Bracelet G1 is a non-invasive blood pressure (BP) monitor intended to measure optical Photoplethysmography (PPG) signals on the user's wrist and to calculate blood pressure values using a Pulse Wave Analysis (PWA) technique, following a calibration process using an oscillometric blood pressure monitor.

Aktiia Bracelet G1 can also calculate heart rate based on the same measurement and analysis technology.

3 Indications for use

The Aktiia Bracelet G1, referred to as the Aktiia bracelet, is indicated for monitoring of adult patients for home use only.

4 Contraindications

The Aktiia bracelet **IS NOT INTENDED** to be used:

- on patients suffering from sustained cardiac arrhythmias that can lead to weak or unstable pressure pulses including tachycardia (heart rate at rest > 120bpm) and atrial fibrillation;
- on patients suffering from pathologies that systematically reduce peripheral perfusion including Raynaud's disease, diabetes, renal dysfunctions (eGFR < 60mL/min/1.73 m2), hyper-/hypothyroidism, pheochromocytoma or arteriovenous fistula;
- on pregnant women;
- on damaged/injured skin;
- on patients below 21 y.o. and above 85 y.o.

5 Intended population

The Aktiia Bracelet G1 is intended to be used on and by adult population, aged between 21 and 85 years old. There are no restrictions related to the user's sex and ethnicity.

6 Intended clinical benefits

The Aktiia system enables long-term unbiased blood pressure and heart rate monitoring. This clinical benefit to the user stems from the acceptable accuracy, stability and automaticity of the blood pressure and heart rate estimation in compliance with the requirements of the relevant standards, ISO 81060-2 Non-invasive sphygmomanometers -- Part 2: Clinical investigation of intermittent automated measurement type and 80601-2-61 Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.

⚠	Aktiia Bracelet does not provide any diagnosis of your blood pressure. Consult your physician for an appropriate analysis of your blood pressure data for diagnosis.

7 Technological characteristics

The Aktiia bracelet uses PPG technology (Photoplethysmography) to acquire optical data on your wrist. The PPG data are then transferred through the Aktiia mobile application to a secured cloud server on which Aktiia's algorithms estimate your blood pressure through advanced processing of the optical data. The Aktiia bracelet detects if the user is moving before initiating a PPG measurement and will provide blood pressure measurement only when the user is still.

This product is licensed under patents owned by CSEM SA, Switzerland.

8 Important safety information

Please read the important safety information in this user manual before using the device. Any serious incident occurring in relation to the Aktiia bracelet should be reported to Aktiia and the competent authority of the Member State in which the user and/or patient is established.

Warning and Caution symbols definition:

Symbol	Definition	Symbol	Definition
	**The "WARNING" sign in this user manual indicates a potentially hazardous situation which, if not avoided, could result in serious injury or death.**		**The "CAUTION" sign in this user manual indicates a potentially hazardous situation which, if not avoided, could result in minor injury to the user or patient or damage to the equipment or other property.**

Important safety information, including residual risk and side effect, about Aktiia Bracelet:

Important warning information:

	A risk of swallowing and suffocation has been identified as residual risk: The pod on your Aktiia bracelet is small enough to be swallowed by a young child. To prevent risk of suffocation, never leave your Aktiia bracelet unattended!
	No modification of the equipment is allowed.

Important caution information:

	This device may only be used for the purposes described in this User Manual. Aktiia cannot be held liable for damage or injury caused by incorrect use. Always follow the operating procedures described in this User Manual to measure your blood pressure accurately and safely.
	Aktiia Bracelet is designed as a device for personal use (single user) only. Do not share your device with others as it may result in inaccurate blood pressure readings.
	The strap of your Aktiia Bracelet contains silicone material. A side effect of skin irritation and reaction has been identified. Avoid wearing the Bracelet in case of known allergy to silicone. In case of skin irritation or reaction, stop wearing your Aktiia Bracelet immediately and consult your doctor.

9 Package contents

Make sure to remove all components from the packaging and inspect for damage. If the Aktiia packaging or any other components are damaged, do not use and contact Aktiia's Customer Service. Your Aktiia bracelet is supplied in a box containing the following items:

1 Aktiia Bracelet G1 with pod and strap	
1 Charging station + **1 USB cable**	
1 User Manual	Latest version of Aktiia Bracelet user manual can also be found online at: **www.aktiia.com/ifu**

Note: If the packaging or any other components are damaged, do not use and please contact Aktiia Customer Service.

10 Operating requirements

To use the Aktiia bracelet you need to download the free Aktiia mobile application (Aktiia app) from the Apple App Store or Google Play.
Creation of a user account via the Aktiia app is required to make use of the Aktiia bracelet.

Access to the Internet is required to:

- Download the Aktiia app
- Create and access your Aktiia user account
- Update the Aktiia device firmware
- Visualize your new Blood Pressure data
- Receive insights on your Blood Pressure readings

11 Authorized and compatible devices

Your Aktiia bracelet requires initialization and periodic reinitialization. This procedure must be realized with an authorized compatible device, the Aktiia Init I1 - referred to as the Aktiia cuff. The Aktiia cuff is an oscillometric blood pressure monitor provided by Aktiia in a separate package.

12 Set up and initialization procedures

1. Charge the Aktiia bracelet and the Aktiia buff before first use.
Connect the provided charging station to a USB port using the charging cable and place the Aktiia bracelet on the charging station, making sure to remove the plastic cover from the bottom of the Aktiia bracelet. A red light at the bottom of the charger will start glowing. When the charge is completed, the indicator light stays a steady red color.

	To charge the Aktiia Cuff, please refer to the provided Aktiia Init I1 user manual for operating information.

2. Download the Aktiia app.
Scan the QR code or go to the Apple App Store or Google Play to download and install the Aktiia app.

3. Create a user account on Aktiia app.
Open the Aktiia app on your mobile device and follow the instructions to register and set up your personal account.

4. Pair your Aktiia bracelet with your mobile device.
Place the Aktiia bracelet on the charging station, follow the on-screen instructions to enable the appropriate permissions and to pair with your mobile device. Wait until pairing is confirmed by Aktiia app.

5. Pair your Aktiia cuff with your mobile device.
Unplug the Aktiia cuff from the charging cable and power **ON** using the toggle switch. When a blue light begins to blink, follow the cuff pairing instructions in the Aktiia app.

6. Fit your Aktiia bracelet on your wrist.

	Follow the Aktiia app on-screen instructions or carefully read the instructions in the “Correct Aktiia bracelet positioning” section (§12) of this user manual.

7. Fit your Aktiia cuff on the opposite arm.

Follow the on-screen instructions, noting the Aktiia cuff must be placed on the opposite arm as the Aktiia bracelet, i.e., if you wear the Aktiia bracelet on your RIGHT wrist, place the Aktiia cuff over your LEFT arm and vice versa.

	The accuracy of blood pressure measurement done by Aktiia Cuff depends on the correct Cuff positioning. Please carefully read the instructions in the section “Correct Aktiia Cuff positioning” (§13) of this user manual.

8. Initialize your Aktiia bracelet.

In the Aktiia app, carefully follow the instructions to complete the initialization procedure. The Aktiia cuff will start inflating.

9. Switch OFF your Aktiia cuff.

	The accuracy of the initialization process depends on your body posture during the initialization. Carefully read the section “Body Posture during Initialization Procedure” (§14) of this user manual.

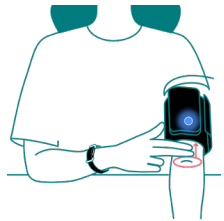
Congratulations! Your Aktiia bracelet is now initialized and ready to track your blood pressure!

	You need to complete an initialization procedure at least once per month, or when prompted by the mobile application. Data obtained outside the initialization period may be inaccurate.

13 Correct Aktiia bracelet positioning

Fasten your Aktiia bracelet around your wrist with the sensor facing toward the skin on top of the wrist. The clasp is on the underside of the wrist. The sensor on the pod should be placed in direct contact with the skin. Tighten the bracelet to be snug but comfortable to ensure that the bracelet does not move around while using your hands.

14 Correct Aktiia cuff positioning



The Aktiia cuff must be placed on the opposite arm with respect to the one wearing the bracelet (i.e., if you wear the Aktiia bracelet on your RIGHT wrist, place the Aktiia cuff over your LEFT arm and vice versa).

1. Remove garments from your upper arm. If you roll up your sleeve, please ensure that the garment is not too tight.
2. Place your bare arm through the cuff to position the cuff 2-3 cm (1") above your elbow joint with the blue light closest to your elbow.
3. Secure and tighten the cuff around your arm so that it fits closely but you can still insert two fingers between your arm and the cuff. Please note that if the cuff is too loose, the measurement will not be accurate.
4. While seated, place your hand, palm side-up in front of you so that it is supported by a flat surface and the Aktiia cuff is at the same height as your heart. Your Aktiia cuff is positioned on the inner side of your arm, over the artery.

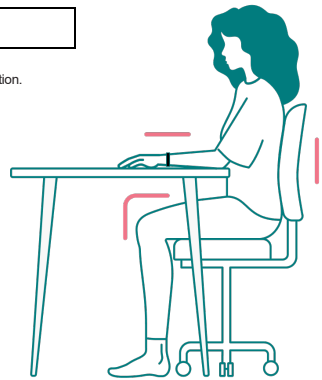
	Please check the Aktiia Init I1 user manual for instructions for use.

15 Body posture during the initialization procedure

⚠	Please sit down and relax for 5 minutes before starting the initialization procedure.

Note: Blood Pressure measurements can be affected by the position of the cuff and your physiological and emotional condition.

1. Sit upright with your back straight and your feet flat on the floor. Do not cross your legs.
2. Place your hand palm-side down in front of you on a flat surface such as a desk or a table.
3. The middle of the Aktiia cuff should be placed at the same level as your heart.
4. Do not move or tense your arm muscles during measurement.
5. Relax, and do not move or talk.



16 Accessing your data

Your Aktiia bracelet automatically tracks your blood pressure. Measurements are triggered every hour, during the day and at night. We use a secured cloud server to store your data, not your Aktiia bracelet or your phone. Therefore, visualizing your data in the Aktiia app requires a working internet connection to synchronize with the Aktiia secure cloud server.

To sync your data

- Enable the Bluetooth and Internet connection on your mobile device. Depending on your Android device version, the location service should be enabled as well.
- Open the Aktiia app to synchronize data from your Aktiia bracelet. The data synchronizes automatically, with a sync indicator showing the status. Depending on how often you open the app and synchronize your data, this might take a few seconds to several minutes.
- In case you do not see a sync view when opening the app, swipe down to manually activate the synchronization.
- Make sure you open the app regularly so that the synchronization is fast, and you avoid losing data. For this reason, synching once a day is recommended.

Visualizing your Blood Pressure data

- Use the Aktiia app to see your blood pressure data, every vertical line represents the average measurements taken during the displayed period.
- The top endpoint of the line is the systolic (SYS) value, and the bottom endpoint of the line is the diastolic (DIA) value.
- Tap on the line to read the numeric values, hold, and move your finger on the screen to navigate through the values.

17 How to evaluate your Blood Pressure

⚠	The Aktiia app and devices are not intended to be diagnostic devices. Self-diagnosis of measurement results and self-treatment are potentially dangerous. You should always consult your doctor for relevant interpretation of blood pressure results.

The following classifications are based on measurements taken on a seated person after a few minutes of rest.

It is important to note that Blood Pressure readings in everyday life conditions might be higher.

The table is not intended to provide a basis for any type of diagnosis or emergency assessment; the table only depicts different classifications of blood pressure.

Consult your physician for an interpretation and diagnosis based on your personal blood pressure results.

Europe

The European Society of Hypertension (ESH) has created the following guide for classifying blood pressure values.

BLOOD PRESSURE CATEGORY	SYSTOLIC BP mmHg		DIASTOLIC BP mmHg	COLOR INDICATOR
OPTIMAL	LESS THAN 120	AND	LESS THAN 80	Dark green
NORMAL	120-129	AND/ OR	80-84	Light green
ELEVATED	130-139	AND/ OR	85-89	Yellow
HIGH BLOOD PRESSURE STAGE I	140-159	AND/ OR	90-99	Orange
HIGH BLOOD PRESSURE STAGE 2	160-179	AND/ OR	100-109	Light red
HIGH BLOOD PRESSURE STAGE 3	HIGHER THAN 180	AND/ OR	HIGHER THAN 110	Dark red

Note: Various factors such as age, obesity and medical condition should be considered for a correct evaluation.
Consult with your physicians for an accurate assessment and diagnosis of your health condition.

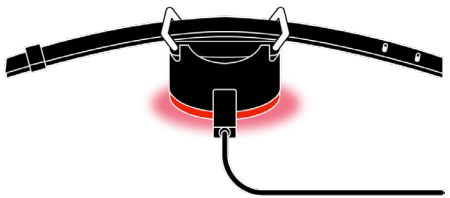
18 Battery handling and power supply

The battery of the Aktiia bracelet is a built-in rechargeable li-polymer battery. Access the current charge of your bracelet via the Aktiia app.
If the battery is lower than 10%, please charge your device:

1. Connect the USB microB connector (the smaller side) of the USB cable to the provided charging station's port.
2. Connect the USB A connector (the larger side) of the USB cable to a power source.
3. Place the Aktiia bracelet on the charging station as shown below. The red light on the bottom part of the charger will start glowing.
4. A steady red light indicates that the device is fully charged.

It is recommended that you charge the battery when the battery is less than 10%.
The Aktiia bracelet charger is designed to work when connected to a constant 5V DC source.

⚠	The battery in this device is a fixed battery and can only be changed by an authorized Aktiia Service agent.
⚠	Should your battery be defective, please contact Aktiia Customer Service for a replacement. Lithium battery replacement by inadequately trained personnel could result in a hazard such as a fire or explosion.



Note: The battery life and charge cycles vary by use and settings.

19 Unpair your device

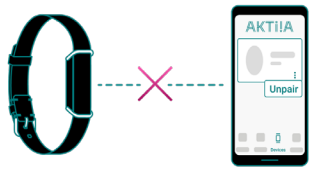
Aktiia bracelet is designed for personal use (single user) only. The in-app pairing process links your device to your account. Suppose you wish to allow another person to use the Aktiia bracelet. In that case, you must unpair the devices from your Aktiia account.

To complete the unpairing procedure you should:

1. Login to your account
2. Tap on the device tab
3. Tap on the button with the three dots
4. Press unpair

Note: Unpairing is needed if the Aktiia bracelet and/or the Aktiia cuff are to be linked with a new user account.

Note: Unpairing is not needed if a new mobile device is used to download the same user account's Aktiia data.



20 Troubleshooting

The Aktiia bracelet is designed to be discreet, with no lights or alarms bothering you during your daily life.

To know if your Aktiia bracelet is **ON**:

1. Take off your Aktiia bracelet.
2. Look at the sensor on the bottom side of the Aktiia bracelet.
3. Double tap the side of the pod (either side is fine), a green light should blink within 5 seconds.

If the green light does not blink, your Aktiia bracelet may be out of power.

Please charge your device with the provided charging station.

Problem	Solution
I don't see a red light when charging my Aktiia bracelet	Verify that the charging station is well connected to a power supply through the USB cable provided. Try replacing the Aktiia bracelet by turning it through 180°. The charging pins on the pod should be aligned with the ones on the charging station. The pod should be magnetically locked on the charging station.

My Aktiia bracelet does not connect to my mobile device	Check that your mobile device Bluetooth is activated and that you enabled permissions for Bluetooth connection and location. If your mobile device Bluetooth is activated but your Aktiia bracelet still does not connect, place your Aktiia bracelet on the charging station to force a reset (you will not lose your personal data or account information). If the problem persists, contact Aktiia Customer Service.
I cannot sync my Aktiia bracelet with the Aktiia app	Check that your Aktiia bracelet is connected in the Devices section. On the Home screen pull down to activate on demand syncing.
I cannot pair my Aktiia bracelet with the Aktiia app	Verify that your Aktiia bracelet is correctly placed on the charger and that a red light is visible at the bottom of the charging station.
The initialization recording failed	Verify that Bluetooth and Location services are enabled, and the devices are connected. Verify that you have a stable internet connection. Verify that the Aktiia bracelet and Aktiia cuff are positioned correctly. Take 5 deep breaths before starting the initialization procedure again, and make sure not to move during recording.
The Aktiia bracelet was not found	Place your Aktiia bracelet on the charging station and connect it to the power supply. Verify that Bluetooth is on and permissions are granted and try again.
There is no reliable measurement data for this period	The Aktiia bracelet only measures your blood pressure while you are at rest. You might not get any measurements during periods of high activity. Please get in touch with our customer support if you don't get any measurements for more than 24 hours and other troubleshooting steps do not resolve this.

21 Care and maintenance

The Aktiia Bracelet G1 does not contain any part or component that requires maintenance operation by the user.

To avoid skin irritation, it is recommended to clean regularly your Aktiia Bracelet G1. Simply wipe your Aktiia Bracelet G1 with soft cloth lightly moistened with water. Then dry your Aktiia Bracelet G1 with a dry cloth.

The Aktiia Bracelet G1 battery can maintain the performance characteristics for a maximum of 300 charge cycles, which corresponds to an expected service life of 3 years.

	Do not attempt to disassemble Aktiia Bracelet G1 as this will result in permanent damages and will void your warranty. If you encounter troubles with your Aktiia Bracelet G1 battery, please contact Aktiia customer support.
	Do not immerse Aktiia bracelet in water and do not expose Aktiia bracelet to water moving with force, such as water running from a tap, ocean waves, or waterfalls.

22 Warranty

Your Aktiia Bracelet G1 is warranted to be free from defects in materials and workmanship within two years from the date of purchase when used in accordance with the provided instructions. Issues related by strap's wearing are not covered by the warranty.
The warranty extends only to the end user. We will, at our option, repair or replace without charge the Aktiia Bracelet G1 covered by the warranty. Repair or replacement is our only responsibility and your only remedy under the warranty.

23 Specifications

Product description	Blood pressure monitor
Model	Aktiia Bracelet G1
Measurement method	Photoplethysmography (PPG)
Sensor to measure PPG	Green light (wave-length 526nm); silicon receiver diode
Measurement accuracy (Blood Pressure)	± 5mmHg
Measurement accuracy (Heart Rate)	± 5 pulse/min
Measurement range	40-250 mmHg for blood pressure, 40-180 beats/min for heart rate
Classifications	Internally powered Applied parts: Pod (type BF). IP33 (protected from spraying water and tools >2.5mm)
Power source	Li-Ion rechargeable battery 3.7 Vdc 55mAh
Communication module	BLE 5.0 Frequency range 2.4 to 2.4835 GHz Modulation GFSK Effective radiated power 0 dBm

Operating conditions	+5°C to 40°C 700hPa to 1060hPa 15% to 90% RH
Storage and transportation conditions	-20°C to +60°C 700hPa to 1060hPa 10% to 95% RH
Aktiia bracelet size	14 cm to 21 cm / 5 ½ to 8 ¼ inches (circumference)
Aktiia bracelet weight	approximatively 18g (0.6 ounces).

24 EMC and RF statements

The Aktiia Bracelet G1 needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the following section.

The Aktiia Bracelet G1 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.

The Aktiia Bracelet G1 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

The Aktiia Bracelet G1 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Interference may occur in the vicinity of equipment marked with the following symbol .

Portable and mobile RF communication equipment (e.g. cell phones) can affect the Aktiia Bracelet G1.

CAUTIONS :

⚠	Aktiia Bracelet G1 should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, it should be observed to verify normal operation in the configuration in which it will be used.
⚠	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.

	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of Aktiia Bracelet, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result."
	Aktiia Init I1 is not suitable for use in MRI (Magnetic Resonance Imaging) environment.

25 Electromagnetic compatibility information

Guidance and manufacture's declaration - electromagnetic emissions		
The Aktiia Bracelet G1 is intended for use in the electromagnetic environment specified below. The user of the Aktiia Bracelet G1 should ensure that it is used in such an environment. The Aktiia Bracelet G1 is suitable for use in "Home Healthcare Environment", i.e. all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
Conducted emissions CISPR11	Groupe 1	The Aktiia Bracelet G1 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Radiated emissions CISPR11	Class B	

Harmonic emissions IEC 61000-3-2	Not Applicable	—
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Not Applicable	

Guidance and manufacturer's declaration - electromagnetic immunity		
The Aktiia Bracelet G1 is intended for use in the electromagnetic environment specified below. The user of the Aktiia Bracelet G1 should ensure that it is used in such an environment. The Aktiia Bracelet G1 is suitable for use in "Home Healthcare Environment", i.e. all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.		
Immunity test	**60601-1-2 test levels**	**Compliance**
Electrostatic discharge IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV in air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV in air
Radiated RF electromagnetic field IEC 61000-4-3	10 V/m 80 MHz à 2.4 GHz 80% MA à 1 kHz	10 V/m 80 MHz à 2.4 GHz 80% MA à 1 kHz

Proximity fields from RF wireless communications equipment IEC 61000-4-3 (interim method)	9 V/m 710 MHz, 745 MHz, 780 MHZ, 5240 MHz, 5550 MHz, 5785 MHz 27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	9 V/m 710 MHz, 745 MHz, 780 MHZ, 5240 MHz, 5550 MHz, 5785 MHz 27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz
Power frequency magnetic field IEC 61000-4-8	30 A/m 50 Hz	30 A/m 50 Hz

26 Compliance

This device complies with the following regulations and normative documents/standards:

2017/745 (EU) Regulation of the European Parliament and of the Council of 5 April 2017 on medical devices, repealing Council Directives 93/42/EEC
2014/53 (EU) Directive of the European Parliament and of the Council of 16 April 2014
EN ISO 10993-5: 2009: Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10: 2010: Biological evaluation of medical devices. Tests for irritation and skin sensitization
IEC 60601-1:2005/A1:2012/A2:2020: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014/A1:2020: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
IEC 60601-1-6:2010/A1:2013/A2:2020: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 60601-1-11:2015/A1:2020: Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN IEC 62471:2008: Photobiological safety of lamps and lamp systems
Draft ETSI EN 301489-1 v2.2.0: ElectroMagnetic Compatibility (EMC) standard for radio equipment and services;
Part 1: Common technical requirements
Draft ETSI EN 301489-17 V3.2.0: ElectroMagnetic Compatibility (EMC) standard for radio equipment and services;
Part 17: Specific conditions for Broadband Data Transmission Systems
EN ETSI 300 328, V2.2.2: Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques
EN 62479 (2010) : Assessment of the compliance of low-power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)

This device contains license-exempt transmitter(s)/receiver(s) that comply with Innovation, Science, and Economic Development Canada's license-exempt RSS(s). Operation is subject to the following two conditions:

(1) This device may not cause interference.

(2) This device must accept any interference, including interference that may cause undesired operation of the device.

27 Disposal

Actuation of European directives 2002 / 95 / EC, 2002 / 96 / EC and 2003 / 108 / EC, for reduction in use of dangerous substances in the electric and electronic device and for garbage disposal. The symbol applied on the device or its packaging means that at the end of its useful life the product must not be disposed of with domestic waste .

At the end of the device's useful life, the user must deliver it to the able collecting centers for electric and electronic garbage or give back to the retailer when purchasing a new device. Disposing of the product separately prevents possible negative consequences for the environment and for health, deriving from inadequate disposal. It also allows the recovery of materials of which it's made up in order to obtain an important saving of energy and resources and to avoid negative effects to the environment and health. In case of abusive disposal of device by the user, will be applied administrative endorsements in compliance with current standard. The device and its parts are made with regard to disposal, as appropriate, in accordance with national or regional regulations.

This product complies with RoHS Directive 2011/65/EU and Amendment (EU) 2015/863.

28 Network security recommendations

The following recommendations detail security measures that Aktiia users should follow to ensure appropriate protection of their personal data. Failure to comply with these recommendations may lead to user personal data leakage or destruction.

Only use mobile application authorized by Aktiia. Aktiia only makes its mobile application and subsequent updates available on official app stores.

Use unique credentials (username and password) for login to your Aktiia account. Safely store your password so that no other person can access it. It is recommended to regularly update your password, at least once every 3 months.

Do not let other people login to your Aktiia account on your behalf.

29 Safety symbols definitions

The signs below might be in the user manual, labeling or other component with your Aktiia Bracelet G1.

Symbol	Definition	Symbol	Definition
	The “WARNING” sign in this user manual indicates a potentially hazardous situation which, if not avoided, could result in serious injury or death.		The “CAUTION” sign in this user manual indicates a potentially hazardous situation which, if not avoided, could result in minor injury to the user or patient or damage to the equipment or other property.
	Symbol for “IFU are available on www.Aktiia.com/ifu”		Symbol for “THE INSTRUCTION FOR USE MUST BE READ”
CE 0123	Symbol for “COMPLIES WITH MDR EU2017/745 REQUIREMENTS”		Symbol for “ENVIRONMENT PROTECTION - Electrical waste products should not be disposed with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice”
	Symbol for “MANUFACTURER”		Symbol for “SINGLE PATIENT - MULTIPLE USE”
MD	Symbol for “THIS EQUIPMENT IS A MEDICAL DEVICE”.		Symbol for “TYPE BF APPLIED PART”
UDI	Symbol for “UNIQUE DEVICE IDENTIFIER”		Symbol for “STORAGE AND TRANSPORTATIONENVIRONMENT – HUMIDITY LIMITS”
SN	Symbol for “SERIAL NUMBER”		Symbol for “STORAGE AND TRANSPORTATION ENVIRONMENT – PRESSURE LIMITS”
EC REP	Symbol for “European authorized representative”		Symbol for “STORAGE AND TRANSPORTATIONENVIRONMENT – TEMPERATURE LIMITS”
AU REP	Symbol for “Australian representative/ sponsor”		Symbol for “Radio Frequency Radiation (RF)”

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MD

Aktiia Bracelet G1
Blood pressure monitor
www.aktiia.com

CE 0123

EC REP

Medidee Services GmbH
Hohnenweg 9, 78098 Triberg im Schwarzwald, Germany

AU REP

Emergo Australia
201 Sussex Street, Level 20, Tower II Darling Park, Sydney, NSW 2000, Australia

Aktiia SA, Bassin 8a, 2000 Neuchâtel, Switzerland