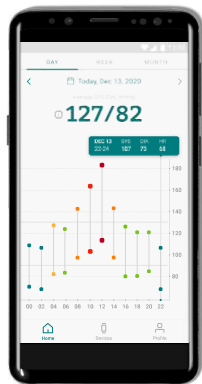


AKTİA

Bracelet G1

EN–User Manual



ENGLISH

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1 Introduction

Aktiia Bracelet is the smart way to track your Blood Pressure over days and nights without any effort. Aktiia Bracelet 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 app.



Please read this User Manual carefully to gain a complete understanding of the device's functions and safety-related information. In case you have any additional questions, you encounter any issue, or you would like to suggest some improvements, please contact Aktiia's Customer Service at support@aktiia.com or visit our website at www.aktiia.com

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

Aktiia Bracelet G1 is indicated for monitoring of adult patients in home use.

4 Contraindications

Aktiia Bracelet G1 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 65 y.o.

5 Clinical benefits

Aktiia Bracelet G1 enables long-term unbiased blood pressure monitoring (e.g. free from whitecoat effect, masked hypertension effect).



Aktiia Bracelet G1 does not provide any diagnosis of your blood pressure.

Consult your physician for an appropriate analysis of your blood pressure data for diagnosis.

6 Technological characteristics

Aktiia Bracelet uses PPG technology (Photoplethysmography) to acquire optical data on your wrist. The PPG data are then transferred through the Aktiia App to a secured cloud server on which Aktiia's algorithms estimate your blood pressure through advanced processing of the optical data. 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.

7 Important safety information

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

Warnings



The “WARNING” sign in this user manual indicates a potentially hazardous situation which, if not avoided, could result in serious injury or death.



Your Aktiia Bracelet Pod is small enough to be swallowed by a young child.
To prevent risk of suffocation, never leave your Pod unattended!



No modification of the equipment is allowed.

Cautions



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.



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. Avoid wearing the Bracelet in case of known allergy to silicone.
In case of skin irritation, stop wearing your Aktiia Bracelet immediately and consult your doctor.

8 Package contents

Your Aktiia Bracelet is supplied in a box containing the following items:

1 Aktiia Bracelet with Pod and Strap	 A black wristband with a silver buckle and a central pod containing a green LED display.
1 Charging station + 1 USB cable	 A black charging dock with a red base and a black USB cable with a USB-A connector.
1 User Manual	Latest version of Aktiia Bracelet user manual can also be found online at: www.aktiia.com/ifu

9 Operating requirements

In order to use Aktiia Bracelet you need to download the free Aktiia app from the Apple App Store or Google Play. Creation of a user account and login are requested to operate Aktiia Bracelet.

Access to the Internet is required to:

- Download the Aktiia App;
- Set up your Aktiia user account;
- Update Aktiia Monitor's firmware;
- Visualize your new Blood Pressure data;
- Receive insights on your Blood Pressure readings

10 Authorized accessories and compatible devices

Your Aktiia Bracelet G1 requires initialization and periodic re-initialization. This procedure must be realized with an authorized compatible accessory referred to in this manual as Aktiia Cuff. Aktiia Cuff is an oscillometric device provided by Aktiia in a separate package.

Aktiia Bracelet works with mobile devices operating and Wi-fi or 3G/4G/5G connection.

For more details on the authorized accessories and compatible devices, please refer to www.aktiia.com/support/compatible_devices.

11 Set up and initialization procedures



1. Charge Bracelet before First Use.

Connect the charging station to a USB port using the charging cable provided, and place Aktiia Bracelet on the station. A red light at the bottom of the charger will start blinking. When charge is completed, the indicator light is a steady red color.

2. Download Aktiia App.

Scan the QR code on this page or go to the Google Play store or Apple App Store, then 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 Aktiia Bracelet on the charging station and enable Bluetooth connection on your mobile device. Wait until pairing is confirmed by Aktiia App.

5. Pair your Aktiia Cuff with your mobile device.

Switch ON the Aktiia Cuff by acting on the toggle button. A blue light should start blinking. Wait until pairing is confirmed by Aktiia App and the light indicator is a steady blue. For further information on Aktiia Cuff operation, please refer to its user manual.

6. Fit your Aktiia Bracelet on your wrist.



For optimal measurement by Aktiia Bracelet, please carefully read the instructions in the "Correct Aktiia Bracelet positioning" section of this user manual.

7. Fit your Aktiia Cuff on the opposite arm.

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



The accuracy of blood pressure measurement done by Aktiia Cuff depends on the right Cuff positioning. Please carefully read the instructions in the section "Correct Aktiia Cuff positioning" of this user manual.

8. Initialize your Aktiia Bracelet.

On the Aktiia App, carefully follow the instructions on the screen to start the initialization procedure. The 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" of this user manual.

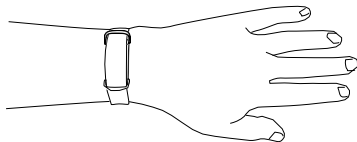
Congratulations! Your Aktiia Bracelet is now initialized and ready to track your blood pressure!



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

12 Correct Aktiia Bracelet positioning

Make sure to wear your Aktiia Bracelet on the side of your wrist bone that is closer to your forearm (rather than closer to your hand). This ensures that the Bracelet does not move around as much when you are using your hands. The sensing side of the pod should be placed in direct contact with the skin, on the top side of the wrist. The Bracelet should be snug but comfortable.



13 Correct Aktiia Cuff positioning

Aktiia Cuff must be placed on the opposite arm with respect to the one wearing the Bracelet (i.e if you wear Aktiia Bracelet on your RIGHT wrist, place the 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 so that it does not cause any blood flow constriction.
2. Place your bare arm through the Cuff and position the Cuff 1" (2-3 cm) above your elbow joint.
3. Tighten the Cuff around your arm so that it fits closely but you can still insert two fingers between your arm and the Cuff. Secure the Cuff closed with the Velcro fastener.
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 monitor is positioned on the inner side of your arm, over the artery and the logo is at its top.



Please check the instructions for use provided with the Aktiia Cuff calibration accessory (see §10).

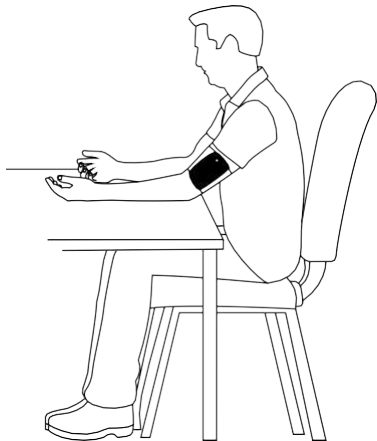
14 Body posture during the initialization procedure



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.
2. Place your hand palm-side up in front of you on a flat surface such as a desk or a table.
3. The middle of the 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 talk.



15 Accessing your data


Your Aktiia Bracelet automatically tracks your blood pressure. Measurements are triggered every hour, at day and at night. To ensure optimal data security, your data are not stored on Aktiia Bracelet or on your phone but on a secured cloud server. Visualizing your data in Aktiia App therefore requires internet connection in order to synchronize with Aktiia secure server.

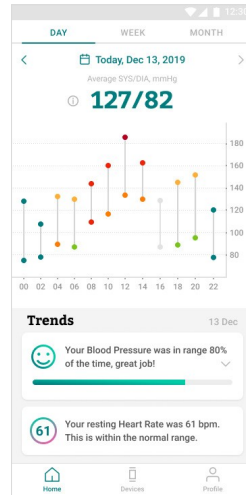
Syncing your data

- Make sure Bluetooth and Internet connection on your mobile device are enabled. If you have an Android device, your location service should be enabled as well.
- Open the Aktiia App to synchronize data from your Aktiia Bracelet. The synchronization is done automatically and a sync view at the top of the screen shows you the sync status. This might take few seconds to several minutes depending on how often you open the app and synchronize your data.
- 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, syncing once a day is recommended.



Visualizing your Blood Pressure data

- Press the Home  button on the Aktiia App to see your blood pressure data in a chart format.
- Every vertical line represents the average of the 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.
- The average Blood Pressure values for the day are shown at the top of the screen.
- Tap the left and right arrows or swipe left and right to navigate through your historical data.



16 How to evaluate your Blood Pressure



Aktiia monitor is not intended to be a diagnostic device. 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 few minutes of rest. It is important to note that Blood Pressure read-ings in normal life conditions might be higher.

These charts are not intended to provide a basis for any type of diagnosis or emergency assessment; these charts only depict 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 1	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.

17 Battery handling and power supply

The battery of Aktiia Bracelet is a built-in rechargeable li-polymer battery.

When the monitor is connected to a mobile device, the battery volume will be displayed in the mobile app, in the Devices section.

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 charger's USB connector port.
2. Connect the USB A connector (the larger side) of the USB cable to a power source.
3. Place Aktiia Bracelet on the charger as depicted below.
A red light on the bottom part of the charger starts blinking when the monitor is charging.
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%.

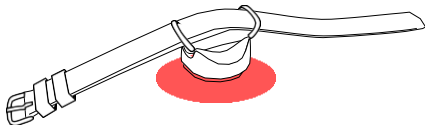
Aktiia Bracelet charger is designed to work when plugged to a constant 5V DC source.



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: Battery life and charge cycles vary by use and settings.

18 Unpair your device

Aktiia Bracelet G1 is designed for personal use (single user) only.

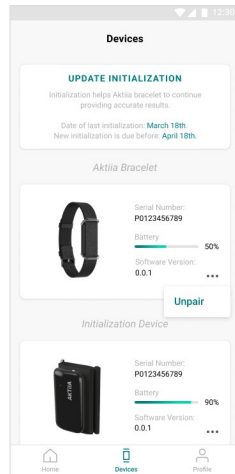
During the pairing procedure, the devices are linked to your account. In case you wish to reset the pairing and allow another person to use the device you must reset the pairing first.

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 Aktiia Bracelet and/or Aktiia cuff need to be linked with a new user account

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



19 Troubleshooting

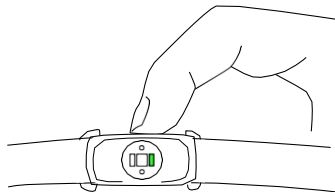
Aktiia Bracelet is designed to be discreet, with no lights or alarms bothering you during your daily life.

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 pod.
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 put your device on the 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 Pod by turning it by 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.

<p>My Aktiia Bracelet does not connect to my mobile device</p>	<p>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.</p>
<p>I cannot Sync my Aktiia Bracelet with the app</p>	<p>Check that your Aktiia Bracelet is connected in the Devices section. On the Home  screen scroll down to activate Sync.</p>
<p>I cannot Pair my Aktiia Bracelet</p>	<p>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.</p>
<p>Initialization recording failed</p>	<p>Verify that Bluetooth and Location services are enabled, and devices are connected. Verify that you have a stable internet connection. Verify that the Aktiia Bracelet and Aktiia Cuff are positioned correctly. Do not move during recording and take 5 deep breaths before starting the initialization procedure again.</p>
<p>Aktiia was not found</p>	<p>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.</p>
<p>There is no reliable measurement data for this period</p>	<p>Aktiia Bracelet only measures your Blood Pressure while you are at rest. You might not get any measurements during periods of high activity. If you don't get any measurements over more than 24 hours, and other troubleshooting steps do not resolve this, please contact our customer support.</p>

20 Care and maintenance

Aktiia Bracelet 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. Simply wipe your Aktiia Bracelet with soft cloth lightly moistened with water. Then dry your Aktiia Bracelet with a dry cloth.

Aktiia Bracelet 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 as this will result in permanent damages and will void your warranty. If you encounter troubles with your Aktiia Bracelet 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.

21 Warranty

Your Aktiia Bracelet 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 Aktiia Bracelet covered by the warranty. Repair or replacement is our only responsibility and your only remedy under the warranty.

22 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)	± 5 mmHg
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	approximately 18g (0.6 ounces).

23 EMC and RF statements

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

Aktiia Bracelet 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.

Aktiia Bracelet 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.

Aktiia Bracelet 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 Aktiia Bracelet.

CAUTIONS:



Aktiia Bracelet should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, it should be observed in order 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.

24 Electromagnetic compatibility information

Guidance and manufacture's declaration - electromagnetic emissions		
<p>Aktiia Bracelet is intended for use in the electromagnetic environment specified below. The user of Aktiia Bracelet should ensure that it is used in such an environment. Aktiia Bracelet 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.</p>		
Emission test	Compliance	Electromagnetic environment - guidance
Conducted emissions CISPR11	Groupe 1	Aktiia Bracelet 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

Aktiia Bracelet is intended for use in the electromagnetic environment specified below. The user of Aktiia Bracelet should ensure that it is used in such an environment. Aktiia Bracelet 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

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

25 CE 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

EN IEC 60601-1:2006 / A1:2013: Medical electrical equipment – Part 1 : General requirements for basic safety and essential performance

EN IEC 60601-1-2:2015: Medical electrical equipment – Part 1-2 : General requirements for basic safety and essential performance –

Collateral Standard: Electromagnetic disturbances – Requirements and tests

EN IEC 60601-1-6:2010 / A1:2015: Medical electrical equipment - Part 1-6 : General requirements for basic safety and essential performance –

Collateral standard: Usability

IEC 60601-1-11:2015: 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, V2.1.1: 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)

26 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.

27 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 (e.g. Google App store).

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.

28 Safety information

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

	Symbol for "IFU are available on www.Aktiia.com/ifu "		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 "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 "THIS EQUIPMENT IS A MEDICAL DEVICE".
	Symbol for "THE INSTRUCTION FOR USE MUST BE READ"		Symbol for "UNIQUE DEVICE IDENTIFIER"
	Symbol for "SERIAL NUMBER"		Symbol for "SINGLE PATIENT - MULTIPLE USE"
	Symbol for "STORAGE AND TRANSPORTATION ENVIRONMENT – TEMPERATURE LIMITS"		The "WARNING" sign in this user manual indicates a potentially hazardous situation which, if not avoided, could result in serious injury or death.
	Symbol for "STORAGE AND TRANSPORTATION ENVIRONMENT – HUMIDITY LIMITS"		Symbol for "TYPE BF APPLIED PART"
	Symbol for "European authorized representative"		Symbol for "STORAGE AND TRANSPORTATION ENVIRONMENT – PRESSURE LIMITS"
	Symbol for "Australian representative/ sponsor"		

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MD

Aktiia Bracelet G1
Blood pressure monitor
www.aktiia.com

CE 0123

EC REP

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