AKTiiA

Init I1

EN – User Manual

ENGLISH

Content

1 Introduction

Thank you for selecting Aktiia arm type blood pressure monitor (Aktiia Init I1). The monitor features include blood pressure measurement and pulse rate measurement. The monitor is designed for at least two years of reliable service.

Readings taken by the Aktiia Init I1 are equivalent to those obtained by a trained observer using the cuff and stethoscope auscultation method.
This manual contains important safety and care information and provides step-by-step instructions for using the product.
Please read the manual thoroughly before using the product.

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 Init I1 is an oscillometric (cuff-based) blood pressure monitor intended to measure blood pressure and heart rate of a user.

3 Indications for use

Aktiia Init I1 is indicated to be used for measuring blood pressure and heart rate in adults with arm circumference ranging from 22cm to 42cm (about 8¾″-16½″). Aktiia Init I1 is indicated for home use.

4 Contraindications

Aktiia Init I1 should not be used by any person who is pregnant or may possibly be pregnant.

Aktiia Init I1 is not suitable for use on patients with implanted electrical devices, such as cardiac pacemakers or defibrillators.

Aktiia Init I1 is not suitable for use neonatal patients, children, patients with pre-eclampsia, premature ventricular beats, atrial fibrillation, peripheral arterial disease, and patients undergoing intravascular therapy or arterio-venous shunt, or people who have received a mastectomy.

Please consult your doctor prior to using the device if you have one of these listed conditions.

5 Technological characteristics

This product uses the Oscillometric Measuring method to detect blood pressure. Before every measurement, the unit establishes a “zero pressure” equivalent to the atmospheric pressure. With inflation of the arm cuff, the unit detects pressure oscillations generated by the brachial artery pulsatility, which are used to determine the systolic and diastolic pressure, as well as pulse rate.

6 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 Init I1 should be reported to Aktiia and the competent authority of the Member State in which the user and/or patient is established.

6.1 Warnings

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

- Keep the device out of reach of young children to avoid swallowing of small parts.
- This device is intended for non-invasive measuring and monitoring of arterial blood pressure.
  It is not intended for use on extremities other than the arm or for functions other than obtaining a blood pressure measurement
- If you are taking medications, consult your physician to determine the most appropriate time to measure your blood pressure.
  Never change a prescribed medication without consulting your physician.
- Do not apply the cuff over a wound, otherwise it can cause further injury.

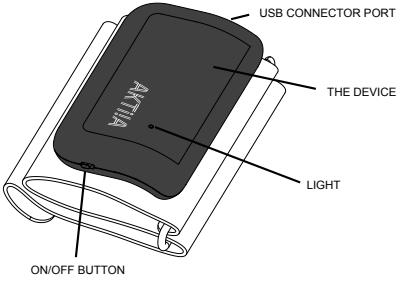
6.2 Cautions

The “Caution” sign throughout 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 be used only for the purpose described in this manual. The manufacturer cannot be held liable for damage caused by incorrect application.
- Do not inflate the cuff on the same limb which other monitoring equipment is applied simultaneously.
  This could cause temporary loss of function of the monitoring equipment that is being simultaneously used.
- On the rare occasion of a fault causing the cuff to remain fully inflated during measurement, open the cuff immediately. Prolonged high pressure (cuff pressure > 300mmHg or constant pressure < 15mmHg for more than 3 minutes) applied to the arm may lead to an ecchymosis.
- Check that operation of the device does not result in prolonged impairment of the patient's blood circulation. Too frequent and consecutive
  measurements could cause disturbances in blood circulation and injuries.
- This device comprises sensitive components and must be treated with caution. Observe the storage and operating conditions described in this manual.
- Do not realize servicing/maintenance while the device is in use. It is recommended that the performance should be checked every 2 years, as well as after maintenance and repair. Contact the manufacturer for such operation.
- If you are allergic to polyester, nylon or plastic, don't use this device.
- Check the device before use, do not use the device if it is damaged in any way. The use of a damaged unit may cause injury or improper results.
- The service life of the cuff may vary by the frequency of measurement and cleaning and storage state. The typical service life is 10,000 measurements.
- Please dispose the device and associated accessories according to local disposal guidelines.
- Dust may affect the performance of the unit. Please use the soft cloth to clean the whole unit before and after use. Don't use any abrasive or volatile cleaners.
- Don't open or repair the device by yourself in the event of malfunctions. The device must only be serviced, repaired and opened by individuals at authorized sales/service centers.
- Please use accessories and detachable parts specified/authorised by the manufacturer. Otherwise, it may cause damage to the unit or danger to the user.

7 Package content

Your Aktiia Init I1 is supplied in a box containing the following items:

1x Aktiia Init I1	1x USB cable	1x User Manual
		Latest version of Aktiia Init I1 user manual can also be found online at: **www.aktiia.com/ifu**

8 Power supply and charging

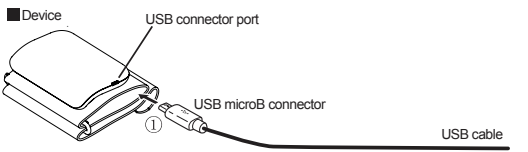
The battery of Aktiia Init I1 is a built-in rechargeable li-polymer battery. The battery capacity is 1000 mAh.
If charging for the first time (immediately after purchase or after not having used it for a long time), or if the battery stops working while using the device, make sure to charge it fully.

To charge your device:

1. **Switch on** your AKTIIA Init I1.
2. Connect the USB microB connector of the USB cable to the device's USB connector port.
3. Connect the USB A connector of the USB cable to the USB ports noted below.

Charge the battery under following circumstances:

- When the red light is flashing, the battery power is low.
- When powering on the monitor, the light doesn't light up



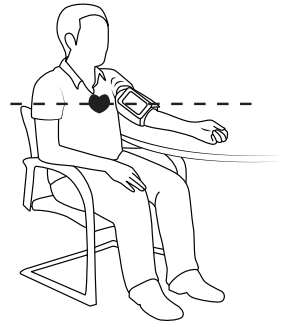
Note: Charge at least once every three months. If the battery completely loses all charge, it may not be rechargeable anymore.

⚠ Batteries shall not be exposed to excessive heat such as direct sunshine, fire, or other similar situations. The battery could explode causing injury or death.

⚠ Do not attempt to replace the device battery: it is built-in and not changeable. Only charge the battery in accordance with the user instructions supplied with the device. Do not use the blood pressure monitor while charging. Do not clean the blood pressure monitor when it is being charged.

9 Correct Aktiia Init I1 positioning

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. 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 Init I1 is at the same height as your heart. Your Aktiia Init I1 is positioned on the inner side of your arm, over the artery and the logo is towards your elbow joint.



10 Body posture during measurement

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

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 up in front of you on a flat surface such as a desk or a table.
3. The middle of the Aktiia Init I1 should be placed as the same level as your heart.
4. Do not move or tense your arm muscles during measurement.
5. Relax, and do not talk.

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

11 Start the measurement

1. **Download the free Aktiia App.**
   Scan the QR code below or go to the Google Play store or Apple App Store, then download and install the Aktiia App.

2. **Create a user account on Aktiia App (or login to your existing user account).**
   Open the Aktiia App on your mobile device and follow the instructions to register and set up your personal account.

3. **Unplug Aktiia Init I1 from the charger and switch it ON by acting on the ON/OFF toggle button.**
   A blue light should start blinking.

4. **Pair your Aktiia Init I1 with your mobile device.**
   Press the “START PAIRING” button on your Aktiia app to start the pairing procedure.
   Wait until pairing is confirmed by Aktiia App and the light indicator is a steady blue.

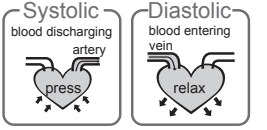
5. **Fit your Aktiia Init I1 on your arm and prepare for measurement.**
   Follow the procedure described in §7 and §8.

6. **Press on “START INITIALIZATION” to start the measurement.**
   Follow the instructions on screen

7. **Switch OFF and store your Aktiia Cuff.**

12 Important facts about Blood Pressure measurement

Blood pressure is the pressure applied by circulating blood on the walls of blood vessels. Blood pressure is mainly due to the work of the heart pumping blood through the circulatory system. When the ventricles contract and pump blood out of the heart, the blood pressure reaches its maximum value in the cardiac cycle, which is called systolic pressure. When the ventricles relax, the blood pressure reaches its minimum value in the cycle, which is called diastolic pressure.



Individual blood pressure naturally varies through regular daily life. Some circumstances have a larger impact on your blood pressure variation and may bias the measurement.

Measurements may be inaccurate if taken in the following circumstances:

Within 1 hour after dinner or drinking

Immediate measurement after tea, coffee, smoking

Within 20 minutes after taking a bath

When talking or moving your fingers

In a very cold environment

When you want to discharge urine

13 How to evaluate your Blood Pressure

⚠ Aktiia Init I1 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 and diagnosis based on your personal 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 readings 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.

13.1 United States of America

The American Heart Association (AHA) has created the following guide for classifying blood pressure values.

BLOOD PRESSURE CATEGORY	**SYSTOLIC BP mmHg**		**DIASTOLIC BP mmHg**	**COLOR INDICATOR**
NORMAL	LESS THAN 120	AND	LESS THAN 80	Dark Green
ELEVATED	120-129	AND/OR	LESS THAN 80	Yellow
HIGH BLOOD PRESSURE STAGE I	130-139	AND/OR	80-89	Orange
HIGH BLOOD PRESSURE STAGE 2	140 OR HIGHER	AND/OR	90 OR HIGHER	Light Red
HYPERTENSIVE CRISIS	HIGHER THAN 180	AND/OR	HIGHER THAN 120	Dark Red

13.2 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

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.

14 Some frequently asked questions

Why does my blood pressure measurements differ throughout the day?
Individual blood pressure naturally varies through regular daily life (see §10). It is also affected by the way you tie your cuff and your measurement position, so please try take the measurements under the same conditions. If you are under prescription drugs, your blood pressure may vary more.

Why do I get a different blood pressure at home compared to the hospital?
The blood pressure is different even throughout the day due to weather, emotion, exercise, etc. Also, there is a phenomenon known as "white coat" effect; evidence shows that blood pressure usually increases in clinical settings, due to stress, anxiety, or other causes.

What you need to pay attention to when you measure your blood pressure at home?
- The cuff is tied properly.
- The cuff is not too tight or too loose.
- The cuff is tied on the upper arm.
- You are relaxed. Waiting for 5 minutes and taking deep breaths before beginning will yield a more accurate measurement.

Is the result the same if measuring on the right arm?
- It is ok to measure on either arm, but the results may vary for different people.
- We suggest you measure on the same arm every time.

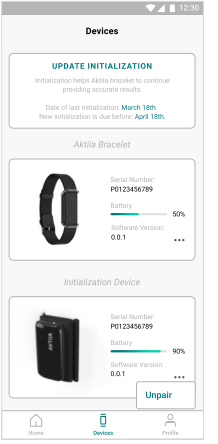
15 Unpair your device

During the pairing procedure, the Aktiia Init I1 is linked to your Aktiia 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 Init I1 need to be linked with a new user account.
Note: Unpairing is not needed if a new mobile device is used with the same user account.



16 Care and maintenance

To obtain the best performance, please follow the instructions below.

- Store in a dry place and avoid sunshine.
- Avoid intense shaking, or collisions.
- Use a slightly damp cloth to remove any dirt or dust.
- Avoid immersing in the water. Clean with a dry cloth if wet.
- Avoid dusty environments or fluctuating temperatures.
- Avoid washing the device other than with a damp cloth (per above).

17 Troubleshooting

Problem	Symptom	Check this	Solution
No power	The status LED is not on	The battery is empty	Recharge the device
		The side button is on the OFF position	Switch the button to the ON position
Battery low	Status LED flashing red	Battery is low	Recharge the device
Measurement error	The mobile application displays the message “Recording failed”	Cuff not tight or inflated properly, talk or walk while measuring and the measurement is out of range.	Adjust the cuff, hold still, and measure again.
SW issue	The status LED is on with a white/light blue color	Check this: On the mobile application the “Update FW” message is shown	Contact our customer support
Cuff cannot be paired	Error message “Pairing failed”	The status LED is blinking green or solid green	Unplug the cuff from power supply and try again

18 Warranty

Your Aktiia Init I1 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. The warranty extends only to the end user. We will, at our option, repair or replace without charge Aktiia Init I1 covered by the warranty. Repair or replacement is our only responsibility and your only remedy under the warranty.

Do not attempt to disassemble the device as this will result in permanent damages and will void your warranty.

19 Specifications

Power supply	3.7V 1000mAh Built-in rechargeable Power supply li-polymer battery, 5V 1A AC Adaptor (Optional)
Measurement mode	Oscillometric testing mode
Measurement range	Rated cuff pressure: 0mmHg~299mmHg (0kPa ~ 39.9kPa) Measurement pressure: SYS: 60mmHg~230mmHg (8.0kPa~30.7kPa) DIA: 40mmHg~130mmHg (5.3kPa~17.3kPa) Pulse value: (40-199)beat/minute
Accuracy **(according to the clinical evaluation)**	Aktiia Init I1 complies with the accuracy requirements of ISO 81060-2 Blood Pressure: Mean error ± 5mmHg / Standard deviation ± 8mmHg Pulse value: ± 5%
Normal working condition	A temperature range of: +5°C to +40°C A relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa An atmospheric pressure range of: 700 hPa to 1060 hPa
Storage & transportation condition	Temperature: -5°C to +50°C A relative humidity range of ≤ 93%, non-condensing, at a water vapour pressure up to 50hPa
Measurement perimeter of the arm	About 22cm-42cm (8 ¾ to 16 ½ inches)

Weight	Approx.271g
External dimensions	Approx.74.3mm×28.2mm×133mm
Attachment	USB Cable and user manual
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Protection against ingress of water	IP22: The first number 2: Protected against solid foreign objects of 12,5mm Φ and greater. The second number: Protected against vertically falling water drops when enclosure titled up to 15º. Vertically falling drops shall have no harmful effects when the enclosure is titled at any angle up to 15º on either side of the vertical.
Device classification	Battery Powered Mode: Internally Powered Medical Electrical Equipment AC Adaptor charged Mode: Class II Medical Electrical Equipment (the optional AC Adaptor shall comply with the requirement of IEC 60601-1 or 60950)
Data transfer	Bluetooth Low Energy (BLE) Operating Frequency: 2402 MHz – 2480 MHz Type of Modulation: GFSK Transmission power: max. 4 dBm

20 EMC and RF statements

Aktiia Init I1 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 device is suitable for home healthcare environments.

Aktiia Init 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 .

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.

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 the device, 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.

21 Electromagnetic compatibility information

Guidance and manufacture's declaration - electromagnetic emissions		
Aktiia Init is intended for use in the electromagnetic environment specified below. The user of Aktiia Init should ensure that it is used in such an environment. Aktiia Init 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	Aktiia Init 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	Class A	—
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Compliant	

Guidance and manufacturer's declaration - electromagnetic immunity		
Aktiia Init is intended for use in the electromagnetic environment specified below. The user of Aktiia Init should ensure that it is used in such an environment. Aktiia Init 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 level**
Electrostatic discharge (ESD) 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
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV signal input/output 100 kHz repetition frequency	± 2 kV for power supply lines ± 1 kV signal input/output 100 kHz repetition frequency
Surge IEC61000-4-5	± 0.5 kV, ± 1 kV differential mode ± 0.5 kV, ± 1 kV, ± 2 kV common mode	± 0.5 kV, ± 1 kV differential mode ± 0.5 kV, ± 1 kV, ± 2 kV common mode
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°.0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0°.0 % UT; 250/300 cycle	0 % UT; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°.0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0°.0 % UT; 250/300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz

Conduced RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
Note: UT is the a.c. mains voltage prior to application of the test level.		

Guidance and manufacturer's declaration - electromagnetic immunity							
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Modulation (W)	Distance (m)	Immunity Test Level (V/m)
	385	380-390	TETRA 400	Pulse modulation b) 18Hz	1.8	0.3	27
	450	430-470	GMRS 460, FRS 460	FM c) ± 5 kHz deviation 1 kHz sine	2	0.3	28

	710	704-787	LTE Band 13,17	Pulse modulation b) 217Hz	0.2	0.3	9
	745						
	780						
	810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18Hz	2	0.3	28
	870						
	930						
	1720	1700-1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1,3,4,25, UMTS	Pulse modulation b) 217Hz	2	0.3	28
	1845						
	1970						
	2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
	5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
	5500						
	5785						

22 CE compliance

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

EU RED STATEMENT: Hereby, Aktiia SA, declares that the device is compliance with the essential requirements and other relevant provisions of RE Directive 2014/53/EU.

EN 60601-1:2006+A1:2013/ IEC 60601-1:2005+A1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015/ IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6:2010+A1:2015/IEC 60601-1-6:2010+A1:2013 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 60601-1-11:2015/ 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
IEC 80601-2-30:2009+A1:2013 Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
EN 1060-3:1997+A2:2009 Non-invasive sphygmomanometers – Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems
IEC 62366-1:2015 Medical devices – Part 1: Application of usability engineering to medical devices
EN 62304:2006/AC: 2008 / IEC 62304: 2006+A1:2015 Medical device software - Software life-cycle processes
ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

23 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.

24 Safety information

The signs below might be in the user manual, labeling or other component with your Aktiia Init I1.

	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 “STORAGE AND TRANSPORTATION ENVIRONMENT – TEMPERATURE LIMITS”		Symbol for “SERIAL NUMBER”
	Symbol for “STORAGE AND TRANSPORTATION ENVIRONMENT – HUMIDITY LIMITS”		Symbol for “SINGLE PATIENT - MULTIPLE USE”
	Symbol for “European authorized representative”		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 “Australian representative/sponsor”		Symbol for “TYPE BF APPLIED PART”
			Symbol for “STORAGE AND TRANSPORTATION ENVIRONMENT – PRESSURE LIMITS”

25 Network security recommendations

The following warnings detail security measures that Aktiia users should follow to ensure appropriate protection of their personal data.
Failure to comply with these warnings 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.

Version 14 – 21.09.2021

MD

Aktiia Init I1
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

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