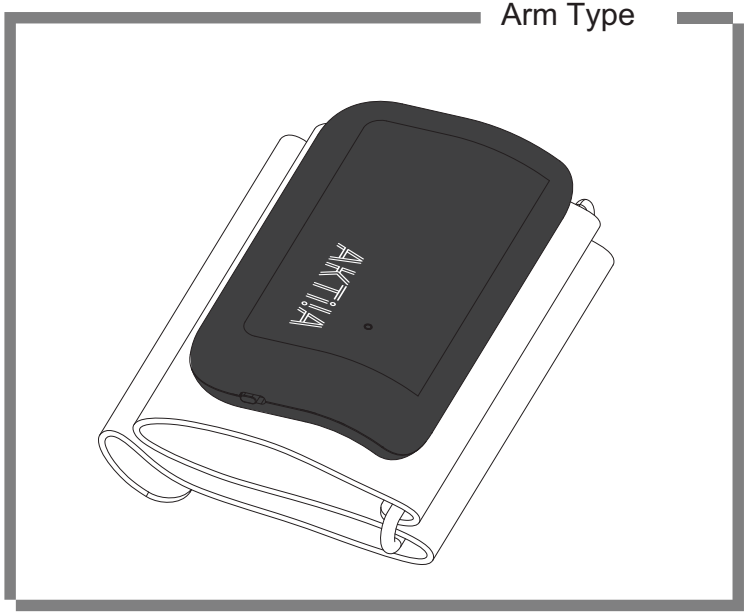
User Manual

Blood Pressure Monitor AKTIIA INIT I1

AKTiiA

Arm Type



- Thank you very much for selecting AKTIIA Blood Pressure Monitor AKTIIA INIT I1.
- Please read the user manual carefully and thoroughly to ensure the safe usage of this product. Keep the manual for your further reference in case you have problems.

Table of Contents

General Description

Thank you for selecting AKTIIA arm type blood pressure monitor (AKTIIA INIT I1). The monitor features blood pressure measurement, pulse rate measurement and the result storage. The design provides you with two years of reliable service.
Readings taken by this mornitor 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

Indications for Use

The AKTIIA Blood Pressure Monitor is a digital monitor intended for use in measuring blood pressure and and heart rate in adults with arm circumference ranging from 22cm to 42cm about 8¾″-16½″). It is intended for indoor use only.

Contraindications

1.The device should not be used by any person who may be suspected of, or is pregnant .
2.The device is not suitable for use on patients with implanted, electrical devices, such as cardiac pacemakers, defibrillators.

Measurement Principle

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. Then it starts inflating the arm cuff, meanwhile, the unit detects pressure oscillations generated by beat-to-beat pulsatile, which is used to determine the systolic and diastolic pressure, and also pulse rate.

Safety Information

The signs below might be in the user manual, labeling or other component. They are the requirement of standard and using.

	Symbol for “THE OPERATION GUIDE MUST BE READ”		Symbol for “TYPE BF APPLIED PARTS”
CE 0123	Symbol for “COMPLIES WITH MDD 93/42/EEC REQUIREMENTS”		Symbol for “ENVIRONMENT PROTECTION - Electrical waste products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice”
	Symbol for “MANUFACTURER”		
SN	Symbol for “SERIAL NUMBER”		
	Symbol for “DIRECT CURRENT”	EC REP	Symbol for “Authorised Representative in the European Community
	Symbol for “MANUFACTURE DATE”		Caution: These notes must be observed to prevent any damage to the device.
	Symbol for “RECYCLE”		The Green Dot is the license symbol of a European network of industry-funded systems for recycling the packaging materials of consumer goods.

⚠ CAUTION

* This device is intended for adult use in homes only.
* The device is not suitable for use on neonatal patients, pregnant women,patients with implanted, electronical devices, patients with pre-eclampsia, premature ventricular beats, atrial fibrillation, peripheral, arterial disease and patients undergoing intravascular therapy or arterio-venous shunt or people who received a mastectomy. Please consult your doctor prior to using the unit if you suffer from illnesses.
* The device is not suitable for measuring the blood pressure of children. Ask your doctor before using it on older children.
* The device is not intended for public use.
* 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.
* Do not confuse self-monitoring with self-diagnosis. This unit allows you to monitor your blood pressure.Do not begin or end medical treatment without asking a physician for treatment advice.
* If you are taking medication,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 take any therapeutic measures on the basis of a self measurement. Never alter the dose of a medicine prescribed by a doctor. Consult your doctor if you have any question about your blood pressure.
* When the device is used to measure patients who have common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, the results might be inaccurate. Please consult your physician about the result.
* When using this device, please pay attention to the following situation which may interrupt blood flow and influence blood circulation of the patient, thus cause harmful injury to the patient: consecutive multiple measurements; the application of the cuff and its pressurization on any arm where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present; inflating the cuff on the side of a mastectomy.
* Warning: Do not apply the cuff over a wound;otherwise it can cause further injury.
*Do not inflate the cuff on the same limb which other monitoring ME equipment is applied around simultaneously, because this could cause temporary loss of function of those simultaneously-used monitoring ME equipment.
*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.
*Please check that operation of the device does not result in prolonged impairment of patient blood circulation.
* When measuring, please avoid compression or restriction of the connection tubing.
* The device cannot be used with HF surgical equipment at the same time.

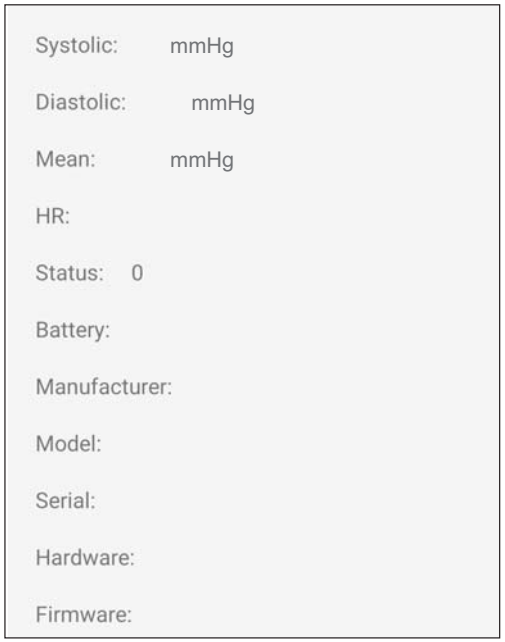
⚠ CAUTION

* The ACCOMPANYING DOCUMENT shall disclose that the SPHYGMOMANOMETER is clinically investigated according to the requirements of ISO 81060-2:2013.
* To verify the calibration of the AUTOMATED SPHYGMOMANOMETER, please contact the manufacturer.
* This device is contraindicated for any female who may be suspected of, or is pregnant. Besides providing inaccurate readings, the effects of this device on the fetus are unknown.
* Too frequent and consecutive measurements could cause disturbances in blood circulation and injuries.
* This unit is not suitable for continuous monitoring during medical emergencies or operations.Otherwise, the patient's arm and fingers will become anaesthetic, swollen and even purple due to a lack of blood.
* When not in use, store the device with the adapter in a dry room and protect it against extreme moisture, heat, lint, dust and direct sunlight. Never place any heavy objects on the storage case.
* This device may be used only for the purpose described in this booklet. The manufacturer cannot be held liable for damage caused by incorrect application.
*This device comprises sensitive components and must be treated with caution. Observe the storage and operating conditions described in this booklet.
* The maximum temperature that the applied part can be achieved is 42.5℃ while the environmental temperature is 40℃.
* The equipment is not AP/APG equipment and not suitable for use in the presence of a flammable anesthetic mixture with air of with oxygen or nitrous oxide.
* Warning: No servicing/maintenance while the ME equipment is in use.
* The patient is an intended operator.
* The patient can measure data and charge power under normal circumstances and maintain the device and its accessories according to the user manual.
* To avoid measurement errors, please avoid the condition of strong electromagnetic field radiated interference signal or electrical fast transient/burst signal.
* The blood pressure monitor, its adaptor, and the cuff are suitable for use within the patient environment. If you are allergic to polyester, nylon or plastic, please don't use this device.
* During use, the patient will be in contact with the cuff. The materials of the cuff have been tested and found to comply with requirements of ISO 10993-5:2009 and ISO 10993-10:2010. It will not cause any potential sensization or irritation reaction.
* Adaptor is specified as a part of ME EQUIPMENT.
* If you experience discomfort during a measurement, such as pain in the arm or other complaints, press the START/STOP button to release the air immediately from the cuff. Loosen the cuff and remove it from your arm.
* When the cuff pressure reaches 40 kPa (300 mmHg), the unit will automatically deflate. If the cuff not deflate when pressure reaches 40 kPa (300 mmHg), detach the cuff from the arm and press the START/STOP button to stop inflation.
* Before use, make sure the device functions safely and is in proper working condition. Check the device, do not use the device if it is damaged in any way. The continuous use of a damaged unit may cause injury, improper results, or serious danger.

⚠ CAUTION

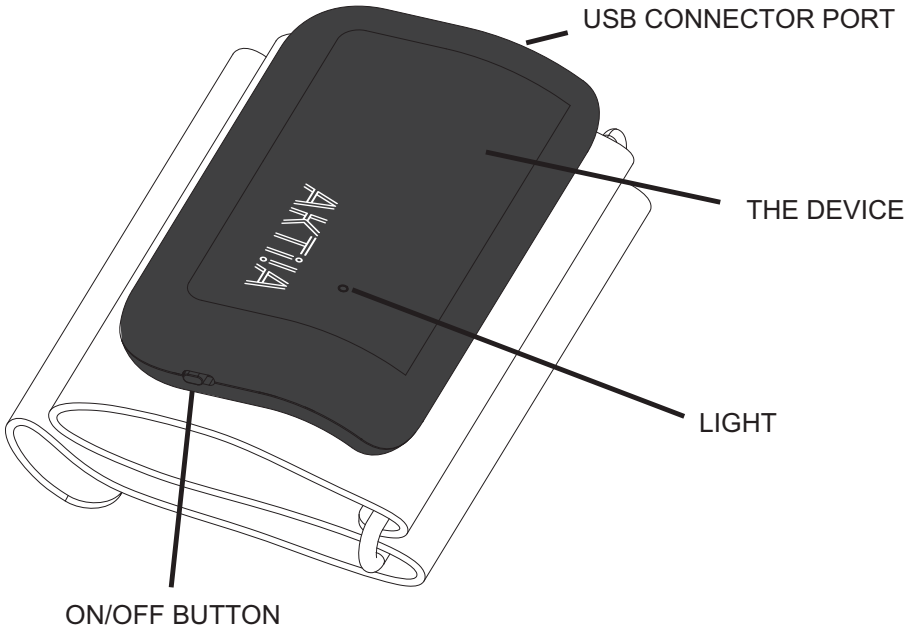
* Do not wash the cuff in a washing machine or dishwasher!
* The service life of the cuff may vary by the frequency of washing, skin condition, and storage state. The typical service life is 10000 times.
* It is recommended that the performance should be checked every 2 years and after maintenance and repair, by retesting at least the requirements in limits of the error of the cuff pressure indication and air leakage (testing at least at 50mmHg and 200mmHg).
* Please dispose of ACCESSORIES, detachable parts, and the ME EQUIPMENT according to the local guidelines.
* Manufacturer will make available on request circuit diagrams, component part lists, descriptions, calibration instructions,etc., to assist to service personnel in parts repair.
* The plug/adapter plug pins insulates the device from the main supply. Do not position the device in a position where it is difficult to disconnect from the supply mains to safely terminate operation of ME equipment.
* The operator shall not touch output of batteries /adapter and the patient simultaneously.
* Cleaning: Dust environment 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.
* The device doesn’t need to be calibrated within two years of reliable service.
* If you have any problems with this device, such as setting up, maintaining or using, please contact the SERVICE PERSONNEL of AKTIIA. 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 report to AKTIIA if any unexpected operation or events occur.
* Keep the unit out of reach of infants, young children or pets to avoid inhalation or swallowing of small parts. It is dangerous or even fatal.
* Be careful to strangulation due to cables, particularly due to excessive length.
* At least 30 min required for ME equipment to warm from the minimum storage temperature between uses until it is ready for intended use. At least 30 min required for ME equipment to cool from the maximum storage temperature between uses until it is ready for intended use.
* This equipment needs to be installed and put into service in accordance with the information provided in the ACCOMPANYING DOCUMENTS;
* Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance d away from the equipment. The distance d is calculated by the MANUFACTURER from the 80 MHz to 5.8 GHz column of Table 4 and Table 9 of IEC 60601-1-2:2014, as appropriate.
* Please use ACCESSORIES and detachable parts specified/ authorised by MANUFACTURER. Otherwise, it may cause damage to the unit or danger to the user/patients.
* There is no luer lock connectors are used in the construction of tubing.If there has, there is a possibility that they might be inadvertently connected to intravascular fluid systems, allowing air to be pumped into a blood vessel.
* Please use the device under the environment which is provided in the user manual. Otherwise, the performance and lifetime of the device will be impacted and reduced.

Symbols meaning



SYMBOL	DESCRIPTION	EXPLANATION
Systolic	Systolic Blood Pressure	High blood pressure
Diastolic	Diastolic Blood Pressure	Low blood pressure
Mean	Mean arterial pressure	The average value of arterial blood pressure during a cardiac cycle
HR	Heart rate	Blood pressure monitor is detecting a heartbeat during measurement.

Monitor Components

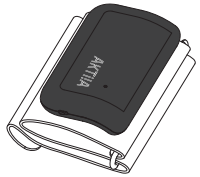


Component list of pressure measuring system

1 PCBA
2 Air pipe
3 Pump
4 Valve
5 Cuff

List

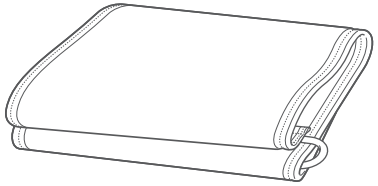
1.Blood Pressure Monitor
(AKTIIA INIT I1)

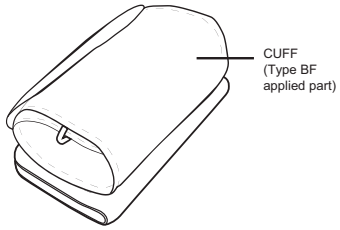


2.USB Cable

3.User Manual

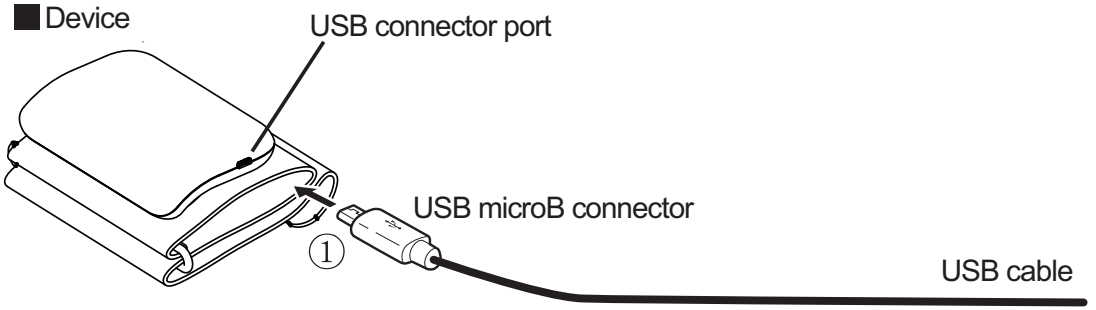
4. Cuff (22cm-42cm) (Type BF Applied Part)(Please use AKTIIA authorized cuff.
For the size of the actual cuff, please refer to the label on the attached cuff.



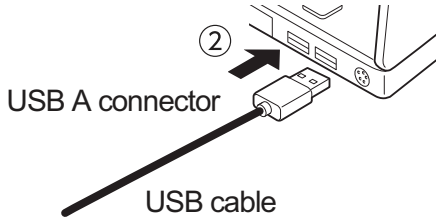


Power Supply and Charging

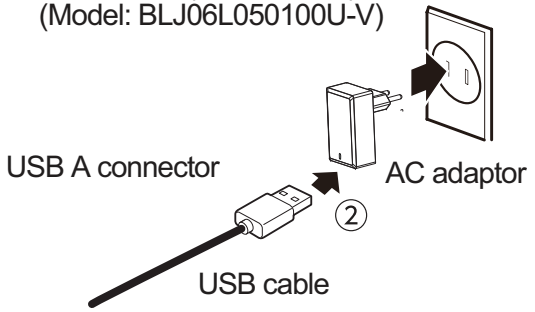
1. The battery of AKTIIA INIT I1 is built-in rechargeable li-polymer battery, the battery current is 1000 mAh.
2. If charging for the first time (immediately after purchase or after not having used it for a long time), or if the battery stops working while using the device, make sure to charge it fully.
    1. Connect the USB microB connector of the USB cable to the device's USB connector port.
    2. Connect the USB A connector of the USB cable to the USB ports noted below.



■ If connecting to a computer, just like the following picture:
USB 2.0 or USB 3.0 for computers conforming to IEC60601-1



■ If connecting to the AC adapter, just like the following picture:
AC adapter (Not included)
(Model: BLJ06L050100U-V)



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

Charging the power under following circumstances:

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

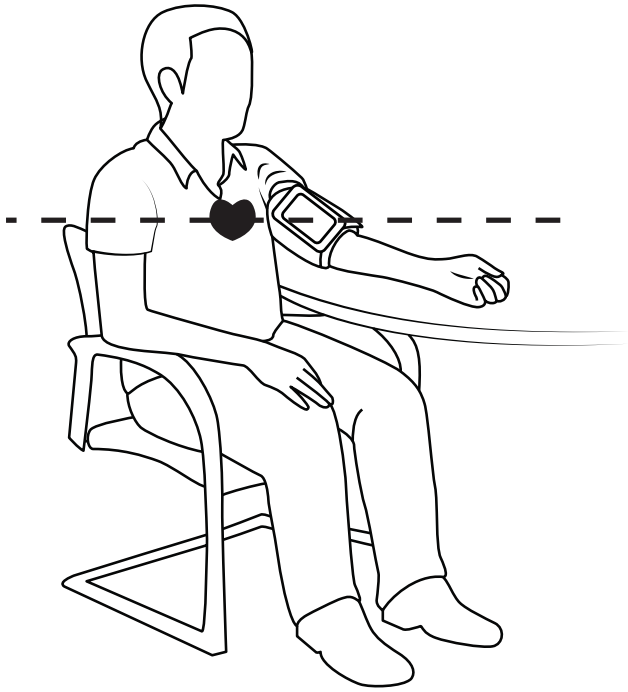
* The battery of AKTIIA INIT I1 is built-in rechargeable lithium-ion battery, please do not disassemble it by the unauthorized maintenance personel.
* Under normal usage, it can charge power about 300 times, if the battery cannot charge the power normally or the blood pressure monitor cannot be used normally, please connect with the authorized maintenance personel.If measured three times per day, and the battery is fully charged, it can be used for about 23 days.
* Store and use the blood pressure monitor in a cool, dry and ventilated environment. Avoid to approach to fire and heat sources or the battery may explode.
* Only AKTIIA's authorized AC Adaptor can be used (Model: BLJ06L050100U-V) (Not included) to charge the power. You cannot use the blood pressure monitor during the process of charging.
* During the process of charging, the light turns green, it means the charging is finished, please pull the plug.
* When charging, shall not touch charging connector and the patient simultaneously.
* Do not attempt to replace your blood pressure monitor’s battery. It is built-in and not changeable.
* Only charge the battery in accordance with the user instructions supplied with the blood pressure monitor.
* Avoid charging your blood pressure monitor in extremely high or low temperatures.
* Do not use your blood pressure monitor while you are charging it.
* Do not attempt to disassemble the blood pressure monitor or force open the built-in battery.
* Do not clean the blood pressure monitor when it is being charged. Always unplug the charger first before cleaning the blood pressure monitor.
* Do not dispose of your blood pressure monitor in a fire. The battery could explode causing injury or death.
* Batteries (battery pack or batteries installed) shall not be exposed to excessive heat such as sunshine, fire or the like.
Charge at least once every three months. If the battery loses all its charge, it may not be rechargeable.

PROBLEM	SYMPTOM	CHECK THIS	REMEDY
No power	The light is not on.	The battery is empty	Recharge the battery.
		The button is in the “OFF” side.	Switch the button on the “ON” side.
Low batteries	Red light flashing.	The battery is low.	Recharge the battery.
Measurement error	APP displays "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.

Tie the Cuff

1. Remove all accessories (watch, bracelet,etc) from your arm. If your physician has diagnosed you with poor circulation in your arm, use the other one.
2. Roll or push up your sleeve to expose the skin.
3. Apply the cuff to your arm with your palm facing up.
4. Position the edge of the cuff about 2cm~3cm from elbow.
5. Fasten the cuff around your arm, leaving no extra room between the cuff and your skin. If the cuff is too loose, the measurement will not be accurate.
6. Sit comfortably with your tested arm resting on a flat surface. Place your elbow on a table so that the cuff is at the same level as your heart. Turn your palm upwards. Sit upright in a chair, and take 5-6 deep breaths.
7. Helpful tips for Patients, especially for Patients with Hypertension:

   Rest for 5 minutes before first measuring.
   Wait at least 3 minutes between measurements. This allows your blood circulation to recover.
   Take the measurement in a silent room.
   The patient must relax as much as possible and not move and talk during the measurement procedure.
   The cuff should be maintained at the same level as the right atrium of the heart.
   Please sit comfortably. Do not cross your legs and keep your feet flat on the ground.
   Keep your back against the backrest of the chair.
   For a meaningful comparison, try to measure under similar conditions. For example, take daily measurements at approximately the same time, on the same arm, or as directed by a physician.Take the measurement in a silent room.



Start the Measurement

Before you start the measurement, Download the Aktiia Cuff app from APP Store or Google Play, and turn on the Bluetooth. Install the APP, and register an account. Then set your personal information (Gender, Birthday, Height, Weight, Name and so on).

1.Switch the button to the “ON” side to turn on the monitor,and the blue light will blink.

Note: If the button is on the “OFF” side, there is no reaction when you press any button.

2. Open Aktiia cuff app on your mobile device.

3. Press on “START PAIRING” to launch the pairing procedure.

4. Once the pairing is done, the battery level information will be displayed in the screen.

5. Press on “START INITIALIZATION” to launch the measurement.

6. In case of recording stop or failure during the measurement, press on “TRY AGAIN”.

7. If the recording failed, the possible reasons of failures might be:

- Bad Bluetooth connection
- Bad WiFi connection
- Bad Recording data
- Tried for too many times

In this case, check your connection and try to reconnect to the Aktiia cuff. During the measurement, you should sit or stay still and not move.

Tips for 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

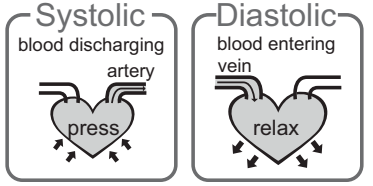
Maintenance

To obtain the best performance, please follow instructions below.

Put in a dry place and avoid the sunshine.
Avoid intense shaking and collisions.
Use the slightly damp cloth to remove the dirt.
Avoid immersing it in the water,Clean it with a dry cloth in case.
Avoid dusty environment and unstable temperature surrounding.
Avoid washing the cuff.

What are systolic pressure and diastolic pressure?

⚠When ventricles contract and pump blood out of the heart, the blood pressure reaches its maximum value in the 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.



1. 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.

⚠ CAUTION

Contact a physician if your blood pressure value has reached a dangerous point

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

1.1 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

1.2 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

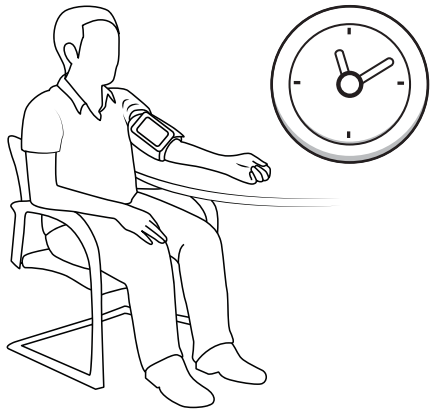
Note: Various factors such as age, obesity and medical condition should be considered for a correct evaluation.Consult with your physicians for an accurate assessment and diagnosis of your health condition.

Why does my blood pressure fluctuate throughout the day?

1. Individual blood pressure varies multiple times everyday. It is also affected by the way you tie your cuff and your measurement position, so please take the measurement under the same conditions.

2.If the person takes medicine, the pressure will vary more.

3.Wait at least 3 minutes for another measurement.



Why do I get a different blood pressure at home compared to the hospital?

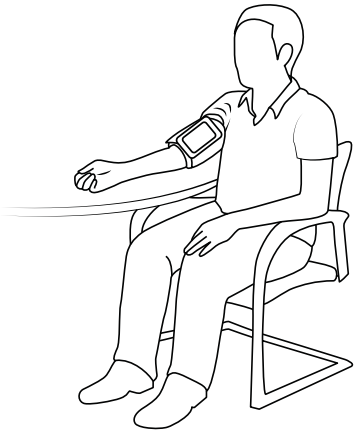
The blood pressure is different even throughout the day due to weather, emotion, exercise, etc. Also, there is the “white coat”effect, which means blood pressure usually increases in clinical settings.

What you need to pay attention to when you measure your blood pressure at home?

If the cuff is tied properly.
If the cuff is too tight or too loose.
If the cuff is tied on the upper arm.
If you feel anxious.
Taking 2-3 deep breaths before beginning will be better for measuring.
Advice: Relax yourself for 4-5 minutes until you calm down.

Is the result the same if measuring on the right arm?

It is ok for both arms, but there will be some different results for different people.
We suggest you measure the same arm every time.



Power supply	3.7V 1000mAH Built-in rechargeable li-polymer battery ,5V ⎓ 1A AC Adaptor(optional)
Measurement mode	Oscillographic 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	Pressure: 5°C-40°C within±3mmHg(0.4kPa) 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:-20°C to +60°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
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.
Software version	A01
Device classification	Battery Powered Mode: Internally Powered ME Equipment AC Adaptor charged Mode: Class II ME Equipment optional AC Adaptor shall comply with the requirement of IEC 60601-1 or 60950

WARNING: No modification of this equipment is allowed.

FCC Statement

FCC ID: OU9TMB1973BS

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Caution: The user is cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-- Reorient or relocate the receiving antenna.
-- Increase the separation between the equipment and receiver.
-- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
-- Consult the dealer or an experienced radio/TV technician for help.

FCC Radiation Exposure Statement: This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

RED Statement:Hereby,Aktiia SA,declares that this AKTIIA INT I1 is compliance with the essential requirements and other relevant provisions of RE Directive 2014/53/EU.A copy of the full DoC is attached.

Complied Standards List

Risk management	EN ISO 14971:2012 / ISO 14971:2007 Medical devices Application of risk management to medical devices
Labeling	EN ISO 15223-1:2016 / ISO 15223-1:2016 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General requirements
User manual	EN 1041:2008 +A1:2013 Information supplied by the manufacturer of medical devices
General Requirements for Safety	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 60601-1-11:2015/ 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
Electromagnetic compatibility	EN 60601-1-2:2015/ IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General require ments for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
Performance requirements	EN ISO 81060-1:2012 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type EN 1060-3:1997+A2:2009 Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems 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
Data transfer	Operating Frequency： 2402 MHz – 2480 MHz Type of Modulation: GFSK Transmission power max. 4 dBm

Clinical investigation	EN 1060-4:2004 Non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers ISO 81060-2:2013 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type
Usability	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 IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices
Software life-cycle processes	EN 62304:2006/AC: 2008 / IEC 62304: 2006+A1:2015 Medical device software - Software life-cycle processes
Bio-compatibility	ISO 10993-1:2009 Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process 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

EMC Guidance

The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments.

Warning: Don’t near activate HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Warning: 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.

Warning: 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.

Warning: 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 equipment AKTIIA INIT I1, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Technical description:
1, all necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the excepted service life.

2, Guidance and manufacturer’s declaration -electromagnetic emissions and Immunity

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	**Compliance**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class [B]
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Comply

Table 2

Guidance and manufacturer's declaration – electromagnetic Immunity		
Immunity Test	**IEC 60601-1-2 Test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4kV, ±8 kV, ±15 kV 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 Not Applicable 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 Not Applicable

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 U_T is the a.c. mains voltage prior to application of the test level.		

Table 3

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) ± 5kHz deviation 1kHz 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 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT;LTE Band 1,3,4, 25; UMTS	Pulse modulation b) 217Hz	2	0.3	28
	2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
	5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9

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