

MiBloodPressure Plus

Arm Blood Pressure Monitor Model: AES-U214 1 Year Warranty

User Manual



1. To use the monitor correctly and safely, please read the manual thoroughly before operating it

2. Please store this manual for future reference.

Version: 1.0 Date Modified: 2023-03-15

Intended Use /Indications for Use

The Arm Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of person via non-invasive oscillometric technique in which an inflatable cuff is wrapped around the upper arm. It can be used at medical facilities or at home. The intended upper arm circumference is 22-42cm. Suitable for adults and adolescents who over the age of 12.

Package Contents

1 x Arm Cuff

1 x Type-C Charging Cable 1 x User Manua

Explanation of Marks or Symbols

The below signs might be in the user manual, labeling or other components.

	They are the requirements of standard use.					
	③	Follow instructions for use.				
	∱	IMPLICATION OF SYMBOL Type-BF applied part.				
	\triangle	Caution: Consult accompanying documents.				
Transport package Do not roll		Transport package shall be kept away from rain.				
		Do not roll				
	杰	Transport package shall not be exposed to sunlight.				
Contents of the transport pac shall be handled with care. Indicates temperature limits of the transport pace.		Indicates correct upright position of the transport package.				
		Contents of the transport package are fragile therefore it shall be handled with care.				
		Indicates temperature limits within which the transport				

USER 1	User 1
SET	Set
USER 2	User 2
IP21	IP21: Protected against solid foreign objects of 12,5 mm Ø and greater,Protection against vertically falling water drops.
SN	Serial Number
LOT	Production lot number
М	Production date
***	Manufacturer
Σ	The device should not be used after the end of the shown or the day
•	Warning: The device is MR Unsafe.
0	Plastics recycling
43	Paper recycling



(01) · DI(Device Identification)

7):Expiration Date 1):Production Date

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Specification

Name	Arm Blood Pressure Monitor
Model	AES-U214
Measurement mode	Oscillography
Operating conditions	5°C-40°C, 15%-80%RH, 70-106kPa
Storage & transportation Condition	-20°C-+55°C, 15% -93% RH, 70-106kPa
Display range	0-290mmHg (0-39kPa)
Measurement range	Diastolic: 30-200mmHg, Systolic: 60-255mmHg Pulse: 40-199 pulses/min
Measurement accuracy	Pressure: ±3mmHg (±0.4kPa), Pulse: ±5% of reading
Dimensions	126*115*71mm
Weight	About 283g
Power supply	3.7 V, 1100 mAh Li-ion battery
Type-c power supply	DC 5V, 1A
Switch off	Automatically turns off after 60 seconds
Cuff size is suitable for arm size	About 8.6-16.5 inches (22-42 cm)
Product life	5 years or 10000 measurements under normal use
Adapter	Input:100-240VAC,50/60Hz 0.5A(MAX) output:5V == 1A which should be applied to IEC60601-1

Know Your Unit

 Δir lack Air Plug

(C) Air Tub

Arm Cuff

(E) Display Screen F TYPE-C Power Socke

© User 2 (H) Settings

(I) User 1



Blood Pressure Level Indication

(K) Low Battery Symbol

Heartbeat Icon

M High Pressure Value (Systolic Pressure)

N Low Pressure Value (Diastolic Pressure) Number of User Groups

(P) Cuff Detection

Pulse Rate Display

Mobile Communication Symbol

§ Mobile Communication Card Slot

(777)

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Start the Measurement

1. Before you take your first reading, decide if you will be USER 1 or USER 2. It is important to always use the same USER button for every reading because each USER button keeps track of the testing history for each USER in the device's memory.

- 2. Apply the arm cuff to your left upper arm.
- 3. Press your assigned USER button. The monitor will reset to zero and start the measurement process. If the arm cuff is applied correctly, "OK" will be displayed on the screen. If the arm cuff needs to be adjusted, "NO" will be displayed on the screen. Remove the arm cuff and reapply to your upper arm until you see the "OK" message.
- 4. During the inflation process, the monitor will detect pulse rate. Please do not move until the entire measurement process is completed. As the arm cuff deflates, decreasing numbers will appear on the display. The heartbeat symbol will flash at the same time. When the measurement is complete, the arm cuff deflates automatically, and the blood pressure values and pulse rate appears on the display.
- 5. When your health data has been successfully transmitted, the wireless communication symbol flashes and then lights up



point, the monitor will automatically re-inflate to about 40mmHg higher than the initial inflation, and then re-measure, without affecting the measured value.

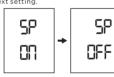
7. After you finish the measurement, the blood pressure value and pulse rate will display on the screen. Press the button to turn the monitor off. Or the monitor will automatically switch off after about 60 seconds of inactivity.

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Device Settings:

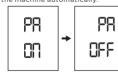
Enabling/Disabling the Voice Feature

When the device is powered off, press and hold the SET button for 10 seconds. The symbol "SP" will appear. Press the USER 2 button to switch the voice feature to "off" or "on", press the USER 1 key to confirm



Choosing the Unit of Measurement

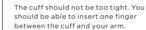
When the symbol "PA" appears, press the USER 2 key to switch the measurement unit. When set to "on", the unit is kPa; when set to "off", the unit is mmHg. After setting the unit, press the USER 1 key to confirm and shut down the machine automatically.

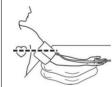


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Apply the Arm Cuff

Place the arm cuff on your upper arm position the tube off-center toward the . inner side of arm in line with the middle finger.





Your arm should be at heart level



Sit comfortably with your left arm resting on a flat surface Rest for 5 minutes before measuring

Wait at least 4 - 5 minutes between measurements. This allows your blood circulation to recover. 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.

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Battery Maintenance, Charging the Battery

The iBloodPressure Plus is equipped with a rechargeable lithium-ion battery Use the included Type-c USB cable to charge the monitor.

will appear on the screen when the monitor needs to be charged.

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1. Insert the USB charging cable into the USB charging socket on the monitor

2. Plug the USB charging cable into a DC 5V, 1A adapter and plug into an outlet

You can also plug the cable into a powered USB outlet. 3. When the blood pressure level indicator

is full grid display, that means the battery is

⚠ Note:

1. Charging may take 3-4 hours.

2. Every 2 months (or when battery life is significantly shorter), fully charge the monitor and then allow the battery to drain until the monitor shuts off. This will optimize battery performance.

3. Battery life depends on the frequency and time of use. If battery life is unusually reduced contact Customer Support.

4. Only use a Type-c USB charging cable to charge the monitor

5. Do not use the monitor while charging.

6. In extreme conditions, the battery may leak corrosive fluid. If this comes into contact with eyes or skin, rinse immediately with water and seek medical

Adapter use (optional)

1. The optional AC adapter should be complied with the requirements of IEC 60601-1. In addition, all configurations should meet the requirements of the medical electrical system (see LEC 60601-1 or Article 16 of IEC 60601-1. respectively). Anyone who connects additional equipment to a medical electrical device configures the medical system and, therefore, the system must comply with the requirements of the medical electrical system. Please note that local laws take precedence over the above requirement If in doubt, please consult your local representative or technical service department

2. To remove the AC adapter, first unplug the adapter from the wall outlet, and then disconnect the power cord from the device. Output voltage: DC 5V

Maximum output current; at least 1A

Note: do not insert the adapter when using the product.

FCC Information

This device complies with Part 15 of the ECC Rules. Operation is subject to the

following two conditions:

(1)This device may not cause harmful interference

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

The subject device 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

The product generates, uses, and can radiate radio frequency energy and, if not installed and used accordance with the instructions, may cause harmful interference to radio communications.

However, there is no guarantee that the interference will not occur in a particular installation. If the product does cause harmful interference to radio or television reception, which can be determined by turning the product on or off, the user is encouraged to try to correct the interference by one or more of the following

a) Regrient or relocate the receiving antenna:

b) Increase the separation between the product and the receiver c) Consult the dealer or an experienced radio / TV technician for help.

d) Connect the equipment into an outlet on a circuit different from that to which

the receiver is connected

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CLIENT: SMART METER

CLIENT CONTACT: Molly McNamee, Marketing Manager Molly.McNamee@iGlucose.com 401-477-9550 (Mobile)

FILE NAME: AES-U214_user_manual_UA2_LED_4G_Li-ion battery_ALICN_031523.ai

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Safety Information

1. General usage

- Do not adjust medication based on measurement values from this blood. pressure monitor. Take medication as prescribed by your physician. Only a physician is qualified to diagnose and treat High Blood Pressure.
- The monitor is not intended to be a diagnostic device.
- · Consult your physician before using the device for any of the following conditions: common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, arterial sclerosis, poor perfusion, diabetes, age, pregnancy, pre-eclampsia renal diseases
- · Note that PATIENT movement, trembling, shivering may affect the measurement.
- Do not use the device on the injured arm or the arm under medical treatment as this can cause further injury
- . Do not apply the arm cuff on the arm while on an intravenous drip or blood transfusion
- · Prolonged over-inflation of the monitor will result in harmful injury to the patient.
- Too frequent measurements can cause injury due to blood flow interference.
- · Consult your physician before using the device on the arm with an arterio-venous (A-V) shunt
- · Do not use the device with other medical electrical (ME) equipment simultaneously.
- · Do not use the device in the area of HF surgical equipment, MRI, or CT scanner, or in an oxygen rich environment
- · Please ask your doctor about your normal blood pressure before taking the measurement by yourself.
- · If the cuff causes any discomfort, please turn off the equipment by pressing the
- · If the arm cuff doesn't deflate automatically after the equipment has pressurized to 300mmHg (40kPa), please press the SET button to stop inflation and take off
- · This product applies only for adults. Please keep the unit out of reach
- · The device complies with RF specifications when the device is used at Omm from your body.

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- . This monitor is calibrated at the time it was manufactured, if the monitor is used according to the instruction, periodic recalibration is not required. If it is inaccurate often, please contact Smart Meter Customer Service Mon-Fri. 9am - 5pm FT at 1-844-445-8267.
- . Do not disassemble, repair, or remodel the main unit or the cuff of the blood pressure monitor by yourself. If necessary, contact Smart Meter Customer Service
- The user must check that the equipment functions safely and see that it is in proper working condition before being used.
- If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the blood pressure monitor.
- . Please do not continue to use the cuff if you are allergic to it.
- Please only use the arm cuff that was supplied with your iBloodPressure Plus.
- · If non-manufacturer supplied parts are used, errors in measurement results may be caused.
- Please check whether the battery is leaking before use, if it leaks, do not use it.
- Please check whether the power adapter is in good condition before use. If it is damaged please replace with a new one
- Do not remove the power adapter during the measurement when using the power adapter to supply power
- . The operator shall not touch output of AC adapter and the patient simultaneously.
- · The Type-C power socket used for charging needs to be securely isolated from the power grid, such as the security isolation adapter or power source with IEC60950 or IEC62368 or iec60601-1, the power adapter and product constitute the medical system when charging, and the risk of leakage of current should be naid attention to
- · Changes or modifications to this product not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- 2 General precautions
- . Do not forcibly crease the arm cuff or the air tube excessively.
- · Do not press the air tube while taking a measurement.

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Do not drop the monitor or subject the device to strong shocks or vibrations.

- . Do not inflate the arm cuff when it is not wrapped around your arm.
- Do not use the device outside the specified environment. It may cause an
- Dispose of the device, components and optional accessories according to applicable local regulations. Unlawful disposal may cause environmental pollution.

Tips for operation

Reading may be inaccurate if they are taken under the following circumstances:

Less than 1 hour after eating or drinking.

Immediate measurement after tea, coffee, smoking,

Less than 20 minutes after taking a bath.

When talking or moving your fingers.

In a very cold enviroment.

When you want to discharge urine.

Care and Maintenance

1. Cleaning the monitor and cuff

Make sure the monitor is off prior to cleaning.

The monitor can be sterilized using 70% medical alcohol on a soft towel or

Clean the monitor with a soft dry cloth

Do not use any abrasive or volatile cleaners.

Use a soft moistened cloth and soap to clean the arm cuff, do not immerse

Never immerse the monitor or any of the components in water.

2. Maintaining the monitor and arm cuff

Keep the monitor and arm cuff in the storage box when not in use.

Do not forcefully bend the arm cuff or air tube. Do not fold tightly.

Do not press the USER buttons and start a measurement before the arm cuff is properly applied.

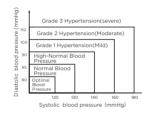
Do not disassemble or attempt to refit the device or components.

Do not subject the monitor to strong shocks, such as dropping the device on the floor.

Protect the device from contamination and dust and direct sunlight. If the device will not be used for a long time, please fully charge the device.

Standard blood pressure classification

Below illustrates the blood pressure classification mode by World Health Organization (WHO) and International Society of Hypertension (ISH) in 1999:



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Optimal Mild Moderate SVS <130 130~139 140~159 160~179 >180 <120 DIA <80 <85 85~89 90~99 100~109

CAUTION

Only a physician can tell you your normal blood pressure range and the point at which you are at risk. Consult your physician to obtain these values. If the measurements taken with these products fall outside the range, consult your physician immediately.

Common Q&A on Blood Pressure

Q1: Why does my blood pressure fluctuate throughout the day?

1. Individual blood pressure varies throughout the day, it is also affected by the way you apply your arm cuff and your measurement position, so please take the measurement under the same conditions, when possible.

- 2. Medications may affect blood pressure readings.
- 3. Wait at least 4 5 minutes between measurements.

Q2: Why is the blood pressure I get from the hospital different when I test at home? Blood pressure varies throughout the day and can be affected by many environmental factors, like stress, weather, exercise, etc.

When you measure your blood pressure at home, ensure:

- 1, that the arm cuff is applied properly.
- 2. that the cuff is not too tight or too lose.
- 3. that you are not feeling anxious.

Q3: Will my results be different if I measure my blood pressure on my right arm? It is recommended that you use your left arm for measurements but it is okay to use your right arm if you need to. Measuring on your right arm may cause your readings to vary. We suggest measuring on the same arm every time.

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Trouble Shooting

PROBLEM	SYMPTOM	CHECK THIS	REMEDY	
No power	Display is dim or will not light up.	Battery is exhausted.	Recharge the battery.	
Low battery			Recharge the battery.	
	"Err 1"	Arm cuff deflates too fast or the pulse signal is too weak.	Apply the cuff correctly and repeat measurement.	
	"Err 2"	Disrupted by portable and mobile RF communications equipment.	Repeat the measurement and make sure there is no any portable and mobile RF communications equipment around.	
	"Err 3"	Incorrect measurement result.	Repeat measurement.	
Error message	"Err P"	Arm cuff fails to inflate.	Apply the cuff correctly and repeat measurement.	
	"Err H"	Inflating pressure is too high.	Repeat measurement in proper way.	

Electromagnetic Compatibility

The ME EQUIPMENT or ME SYSTEM is suitable for home or hospital environment. Warning: Don't near active HE surgical equipment and the RE shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances

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

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If any: a list of all cables and maximum lengths of cables (if applicable), transducers and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION and that are likely to affect compliance of the MF EQUIPMENT or ME SYSTEM with the requirements of Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY), ACCESSORIES may be specified either generically (e.g. shielded cable, load impedance) or specifically (e.g. by MANUFACTURER and EQUIPMENT OR TYPE REFERENCE). If any: the performance of the ME EQUIPMENT or ME SYSTEM that was

determined to be ESSENTIAL PERFORMANCE and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES (the defined term "ESSENTIAL PERFORMANCE" need not be used). Warning: When the device is affected by EM DISTURBANCES, the data measured

may fluctuate and may not be accurate, please measure in another environment to ensure its accuracy.

Warning: The device should not enter the MRI scanner room.

Patients with MR Unsafe devices should not be scanned. 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 emission			
Emissions test	Compliance		
RF emissions CISPR 11	Group 1		
RF emissions CISPR11	Class B		
Harmonic emissions IEC 61000-3-2	Class A		
Voltage fluctuations /flicker emissions IEC 61000-3-3	Applied		
	·		

Table 2

Immunity Test	IEC 60601-1-2 Test level	Compliance level	
Electrostatic discharge (ESD) IEC 61000-4-2	38 kV contact 32 kV, 34 kV, 38 kV, 315 kV air	38 kV contact 32 kV, 34 kV, 38 kV, 315 kV air	
Electrical fast transient/burst IEC 61000-4-4	Power supply lines: 32 kV input/output lines: 31 kV	N/A	
Surge IEC 61000-4-5	line(s) to line(s): 31 kV. line(s) to earth: 32 kV. 100 kHz repetition frequency	N/A	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle	N/A	
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz	
Conduced RF IEC61000-4-6	150KHz to 80MHz: 3Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz	N/A	
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	

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Guidance and manufacturer's declaration

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity

	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Modulation (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
	385	380 - 390	TETRA 400	Pulse modulation 18 Hz	1,8	0.3	27
	450	380 - 390	GMRS 460, FRS 460	FM 35kHz deviation 1kHz sine	2	0.3	28
	710	704- 787	LTE Band 13.	Pulse modulation	0,2	0.3	9
	745						
	780		17	217 Hz			
	810	800- 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
Radiated RF IEC61000-4-3	870						
(Test specifications for FNCLOSURE	930						
PORT IMMUNITY to RF wireless	1720	1700- 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3,4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
communications equipment)	1845						
	1970						
	2450	2400- 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
	5240	5100-	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0.3	9
	5500						
	5785						

Disposal



Do not dispose of electrical appliances as unsorted municipal waste, use separate collection facilities. Contact you local government for information regarding the collection systems available. If electrical appliances are disposed of in landfills or dumps, hazardous substances can leak into the groundwater and get into the food chain, damaging your health and well-being.

Manufactured exclusively for: Smart Meter, LLC Address: W. Waters Ave Suite 401 Tampa, FL, 33634 Website: www.SmartMeterRPM.com Tel: 1-844-445-8267 Email: support@iglucose.com



Manufacturer information

Manufacturer: Alich Medical Shenzhen Inc.

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