Airon Wireless products

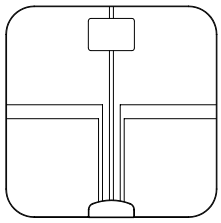
Airon Wireless system is a series of products which provide you with a good overview of some of your most important health-related data in one application.
You can also try:

Airon Wireless Activity Tracker

Steps | Calories | Distance | Sleep | Watch

Airon Wireless Body Analysis Scale

Weight | Fat | Muscle | Water | Bone | BMI



CE 0123

GUANGDONG TRANSTEK MEDICAL ELECTRONICS CO., LTD
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CE 0123

Version:1.0

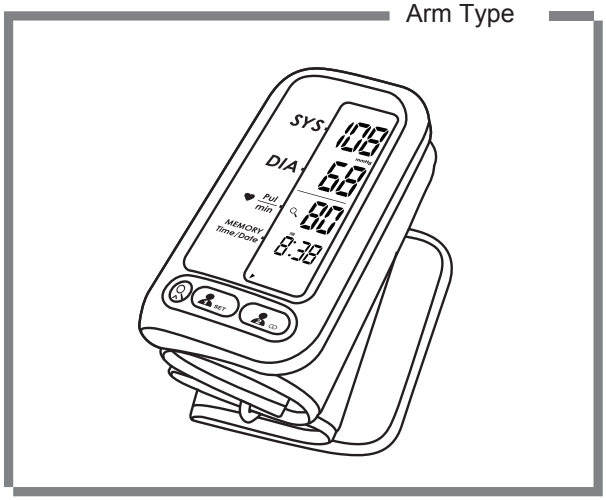
AIRON

English User Manual

Airon Wireless Blood Pressure Manual

APP: Airon
Model: LS808-B

Arm Type



- Thank you very much for selecting Airon Blood Pressure Monitor LS808-B.
- Please do read the user manual carefully and thoroughly so as to ensure the safe usage of this product, and keep the manual well for your further reference in case you have problems.

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Table of Contents

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♥ General Description

* Thank you for selecting Airon Blood pressure Monitor (LS808-B).
The monitor features blood pressure measurement, pulse rate measurement and the result storage. The design provides you with two years of lifetime.
* This manual contains important safety information and caution, and provides step by step instructions for using the product.
* Please do read this user manual carefully and thoroughly before use.

FEATURES:

- 86.5mm×24mm Blue LCD Display with White Backlight
- Measure-during-inflating Technology
- Up to 60 pieces of record stored

♥ Indications for Use

The Airon Blood Pressure Monitor is digital monitors intended for use in measuring blood pressure and heartbeat rate with arm circumference ranging from 22 cm to 32 cm (about 9-13 inches).
It is intended for adult indoor use only.

♥ Measurement Principle

This product uses the Oscillometric Measuring Method to detect blood pressure. Before every measurement, the unit establishes a “zero point” equivalent to the atmospheric pressure. Then it starts inflating the cuff. Meanwhile, the unit detects pressure oscillation generated by beat-to-beat pulsatile, which is used to determine the systolic pressure and diastolic pressure as well as pulse rate.
The device also compares the longest and the shortest intervals of detected pulse wave to with the average value, and then calculates the standard deviation. The monitor will light up a warning symbol when the calculated standard deviation is larger than or equal to 15.

♥ Safety Information

The below signs might be in the user manual, labeling or other components. 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 - Wast electrical 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”
Bluetooth SMART	The Bluetooth Combination Mark	EC REP	Symbol for “Authorised Representative in the European Community
	Symbol for “MANUFACTURE DATE”	F1	T1A/250V Φ3.6*10CCC
	Symbol for “ Class II Equipment”		Symbol for indoor use only

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CAUTION

* It is intended for adult indoor use only. Sensitive people, including pregnant women pre-eclamptic patients, patients who implanted medical electronic instruments and have atrial fibrillation (AF), premature ventricular beats and peripheral arterial disease (PAD), should avoid using the unit whenever possible. If you need, please consult professional doctor.
* 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.
* Please use the device under specified environment by user manual, otherwise the accuracy of the device will be influenced.
* Do not confuse self-monitoring with self-diagnosis. This unit allows you to monitor your blood pressure. Please start or end medical treatment basing solely on physician's treatment advice.
* If you are taking medication, consult your physician to determine the most appropriate time for your measurement. Never change a prescribed medication without your physician's consent.
* This unit is not suitable for continuous monitoring during medical emergencies or operations. After the cuff inflated long time, the patient's arm and fingers will be blood supply insufficiency, anaesthesia, distending pain and ecchymosis.
* If the pressure of the cuff exceeds 40 kPa (300 mmHg), the unit will automatically deflate. If the cuff don't deflate when its pressure exceeds 40 kPa (300 mmHg), detach the cuff from the arm and press the START/STOP button to stop inflation.
* Do not use the monitor under the conditions of strong electromagnetic field (e.g. medical RF equipment) that radiates interference signal or electrial fast transient/ burst signal.
* The device is not AP/APG equipment. It is not suitable for use in the presence of a flammable anesthetic mixture with air (or oxygen, nitrous oxide).
* Please keep the unit out of reach of infants, children or pets, since inhalation or swallowing of small parts is dangerous or even fatal.
* Please use ACCESSORIES and detachable parts specified / authorised by MANUFACTURER. Otherwise, it may cause damage to the unit or danger to the user / patient.
* The patient is an intended operator. The patient can measure, transmit data and charge battery under normal circumstances and maintain the device and its accessories according to the user manual.
* The blood pressure monitor, its adaptor, and the cuff are suitable for use within the patient environment. If you are allergic to dacron or plastic, please don't use this device.
* The device is not intended for PATIENT transport outside a healthcare facility.
*This device cannot be used with HF surgical equipment at the same time.
* The adaptor is specified as a part of ME equipment.
* If Luer lock connectors are used in the construction of tubing, there is a possibility that they might be inadvertently connected to intravascular fluid systems, allowing air to be pumped into a blood vessel.
* The device is not suitable for public use.
* The adapter insulates the device from the main supply. Do not position the plug in a position where it is difficult to disconnect from the supply mains.
* Be careful to strangulation due to cables and hoses, particularly due to excessive length.

♥ LCD Display Signal

SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic Blood Pressure	High blood pressure
DIA	Diastolic Blood Pressure	Low blood pressure
Pul/min	Pulse	beat/minute
	Low Battery	Low battery and please charge the power.
KPa mmHg	Unit	Measurement unit of blood pressure
	IHB Detector	Irregular Heartbeat Detector
	Data pending to transmit	Measurement data stored in the device
	Data transmitting	Data transmission succeeds.
	Memory Query	Recalling the history records
	User ID	Start measurement for selected user, and transmit the measuring result
	Current time	Year/Month/Day(Hour:Minute)
	Shocking reminder	Shocking will result in inaccurate
♥	Heartbeat	Heartbeat Detection during the measurement

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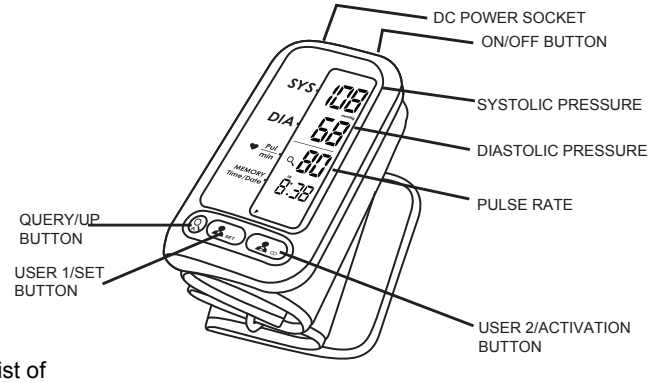
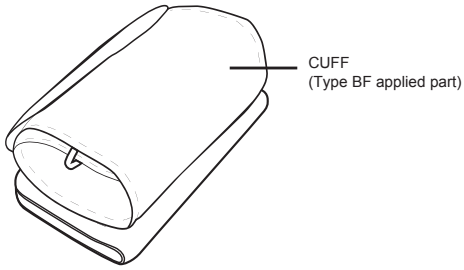
♥ Monitor Components



Component list of
pressure measuring system
1 PCBA
2 Air pipe
3 Pump
4 Valve
5 Cuff



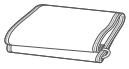
♥ List

1.Blood Pressure Monitor (LS808-B)

2.AC Adaptor

3.User Manual

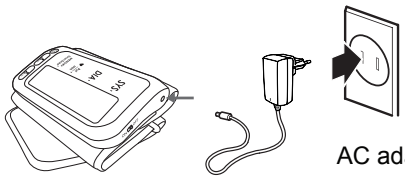
4. Cuff (22-32cm) (Type BF Applied Part)



(Please use TRANSTEK authorized cuff.)

♥ Power Supply and Charge Power

1. The battery of LS808-B is built-in rechargeable li-polymer battery, the battery current is 1000 mAh.
2. Please use the AC adaptor to charge the battery, just like the following picture:



AC adaptor

Charging the power under following circumstances:

- +Lo displays on the LCD
- The LCD display dims
- When powering on the monitor, the LCD doesn't light up.

CAUTION

1. The battery of LS808-B is built-in rechargeable li-polymer battery, please do not disassemble it by the unauthorized maintenance personel.
2. Under the normal using, it can charge power about 300 times, if the battery cannot charge the power normally or the blood pressure monitor cannot use 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 20 days.
3. Storge and use the blood pressure monitor at the cool, dry and ventilated environment. Avoid to approach to the fire and the heat source, or it will cause the battery explode.
4. Only can use the Transtek's authorized AC Adaptor to charge the power. You cannot use the blood pressure monitor during the process of charging.
5. During the process of charging, the blood pressure monitor display . When the charging is finished, please pull the plug in time.
6. When charging, shall not touch charging connector and the patient simultaneously.

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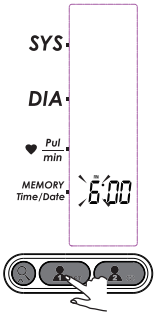
♥ Setting the Time and Unit

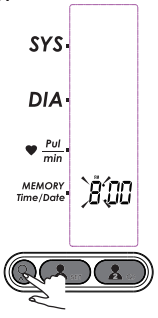
To ensure the stored measurement result has correct time record, please set time and unit before device is used.

Before use,switch the button to the “ON” side to turn on the monitor.
Note: If the button is on the “OFF” side, there is no reaction when you press any button.

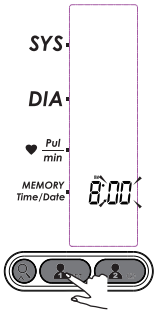
(1) When the monitor is off, press and hold User 1 button for 3s to enter Time Setting Mode.



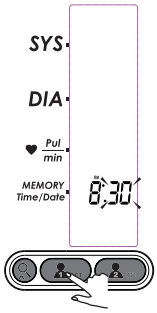
(2) As pictured in the right, the blinking numeral representing [HOUR]. Press “Query” button to change the numeral. Each press will increase the numeral by one in a cycling manner.



(3) Press “User 1” button again to confirm [HOUR]. Then the numeral representing [MINUTE] blinks.



(4) Repeat step 2 and 3 to confirm [MINUTE].



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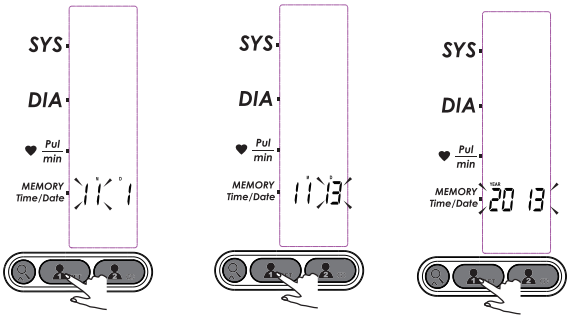
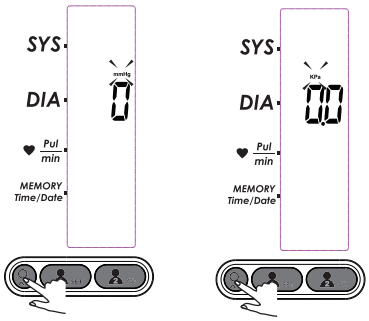
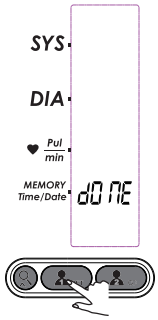
(5) Repeat step 2 and 3 to confirm[MONTH], [DAY] and [YEAR].



(6) Repeat step 2 and 3 to confirm the measurement unit.



(7) After confirming the measurement unit, the LCD will display “dOnE” and the monitor will shut off.



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♥ Pair up the Blood Pressure Monitor with Your Device

1. Download and install the **Airon app** on your device which supports Bluetooth 4.0 technology. (For iPad, download the iPhone app).
2. Start the app, sign up and register your user informations.
3. Push the "settings" symbol in the upper right hand corner.
4. Push the "+" sign to add the activity monitor.
5. Push the BT4.0 symbol in the app and hold the ACTIVATION button on the blood pressure monitor to start pair-up.

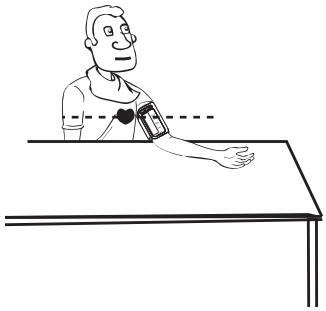
6. The symbol  and the symbol  will be shown on the LCD alternatively, indicating pair-up is proceeding.
If succeed, symbol  will be shown on the LCD.
If fail, symbol  will be shown on the LCD.
7. The monitor will shut off automatically after pair-up process is complete.

Bluetooth Module No. : nRF8001			
Frequency Range	2.402 - 2.480 GHz	Supply Voltage	3.3 V
Output Power Range	0 dBm		

♥ Tie the Cuff

1. Remove all accessories from your left arm.
   If your physician has diagnosed you with poor circulation in your left arm, use your right arm.
2. Roll or push up your sleeve to expose the skin.
3. Apply the cuff to your left arm with your palm facing up.
4. Position the edge of the cuff about 2-3 cm.
5. Fasten the arm 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. Correct Posture for Patients with Hypertension, especially for Hypertension patient
   - Bare your arm or wear tights only when starting measurement.
   - Sit comfortably with legs uncrossed, feet flat on the floor, back and arm supported.
   The central of the cuff should maintain at the same level as the right atrium of the heart.

• Resting for 5 minutes before measuring.
• Wait at least 3 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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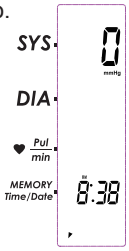
♥ Start Measurement

When the monitor is off, press User 1 button to turn on the monitor and it will finish the whole measurement, and then save the measure data for User 1.
The same to the User 2.

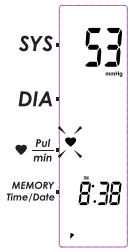
(1) When the monitor is off, press the User 1 button to turn on the monitor.

LCD display

Adjust to zero.



Inflating and measuring.



Display and save the results.
The data transmission will proceed.

(2) Press User 1 button to power off, otherwise it will turn off with one minute.

Tips:
A. When finish the whole measurement, press another user button, the blood monitor will begin measuring again.
B. Maximum 60 records are both for user 1 and user 2.

CAUTION

1.With LS808-B successfully pair-up with your iPhone, the measurement data will be automatically transmitted to your mobile via Bluetooth.
2.The symbol will disappear after successful data transmission, and you may check your personal health data stored in your iPhone.
3.If the data transmission fails, the symbol will remain. The pending measurement data will be transmitted to your iPhone when next measurement is complete.

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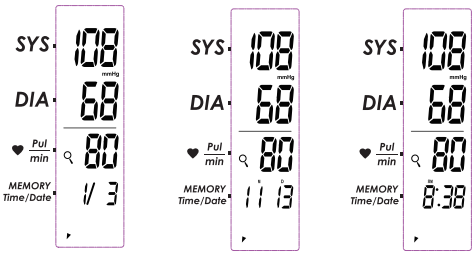
♥ Recall the Records

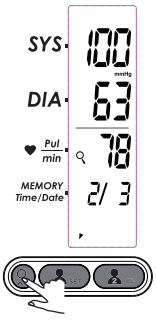
(1) When the monitor is off, press “Query” button to access the memory.

(2) The LCD will display the latest measuring result of the user ID which completes the last measurement.

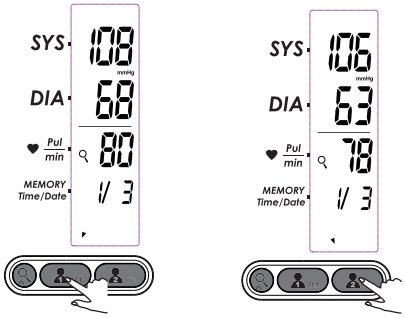
The record number, measuring date and measuring time will be displayed alternatively.



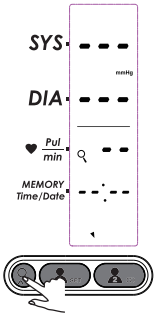
(3) Press “Query” button to rotate the history records.



(4) When in the memory mode, press the User 1 button to recall the measurement history of User 1, or press the User 2 button to recall the measurement history.



(5) When no history stored for the specific user in the monitor, press “Query” button and the LCD will display as pictured to the right.



CAUTION

The most recent record (1) is shown first. Each new measurement is assigned to the first (1) record. All other records are pushed back one digit (e.g., 2 becomes 3, and so on), and the last record (60) is dropped from the list.

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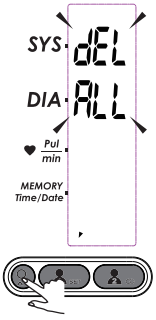
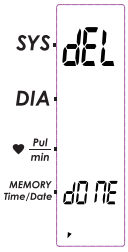
♥ Delete the Records

(1) When under the query mode, press and hold "Query" button for 3 seconds to clear the memory.

(2) When the LCD display "dEL ALL", press "Query" button to confirm.



(3) The LCD will display "dEL dOnE" and then shut off.



(4) If you wish to stop clearing the memory, you may press the other button, rather than "Query" button to turn off the monitor, or wait until the monitor shuts off.

CAUTION

1. 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: too frequent and consecutive multiple measurements;
the application of the CUFF and itspressurization on any arm where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present;
Inflating the cuff on the arm on the side of a mastectomy.
2. Do not apply the cuff over a wound, otherwise it can cause further injury.
3. 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.
4. Using it in case to result in prolonged impairment of the circulation of the blood of the PATIENT.
5. Don't link the connection tube, otherwise, the cuff pressure may continuously increase which can prevent blood flow and result in harmful injury to the PATIENT.

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♥ Tips for Measurement

It can cause inaccuracy if the measurement is 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 enviroment

When you want to discharge urine

♥ Maintenance

To obtain the best performance, please follow below instructions.

Put in a dry place and
avoid the sunshine

Avoid immersing it in the water.
Clean it with a dry cloth in case.

Avoid shaking and collision.

Avoid dusty environment and
unstable temperature surrounding

Use the slightly damp cloth
to remove the dirt.

Avoid washing the cuff

CAUTION

1. Please make sure the unit functions safely and it is in proper working conditions before use. Don't service or maintain while the device is in use.
2. If you have any problems with this device, such as setting up, maintaining or using, please contact with SERVICE PERSONNEL of Airon. Don't open or repair the device by yourself.
3. Please report to Airon if any unexpected operation or events occur.
4. Cleaning: Dust environment may affect the performance of the unit. Please use the soft cloth to remove the dirt of the device and cuff before and after use.
5. Calibration: The manufacturer does not require such preventive inspections or calibration by other persons and will make available on request of circuit diagrams, component part list, etc.
6. Disposal: Degraded sensors may result in inaccurate measurement while loosened electrodes may cause the monitor's failure to power on. Please dispose of ACCESSORIES, detachable parts, and ME EQUIPMENT according to local guidelines.

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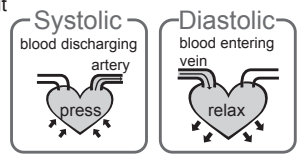
♥ What are systolic pressure and diastolic pressure?

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.

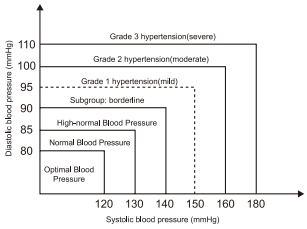


♥ What is the standard blood pressure classification?

The blood pressure classification published by World Health Organization (WHO) and International Society of Hypertension (ISH) in 1999 is as follows:

CAUTION

Only a physician can tell your normal BP range. Please contact a physician if your measuring result falls out of the range. Kindly note that only a physician could tell whether your blood pressure value has reached a dangerous point.



Blood Pressure (mm Hg) \ Level	Optimal	Normal	High-normal	Mild	Moderate	Severe
SYS	<120	120-129	130-139	140-159	160-179	≥180
DIA	<80	80-84	85-89	90-99	100-109	≥110

♥ Irregular Heartbeat Detector

This Blood Pressure Monitor is equipped with an intelligent function of Irregular Heartbeat (IHB) Detector. During each measurement, this equipment records the heartbeat intervals and works out the standard deviation. If the calculated value is larger than or equal to 15, this equipment will light up the IHB symbol on the screen when displaying the measuring result.

CAUTION

The appearance of the IHB icon indicates that a pulse irregularity consistent with an irregular heartbeat was detected during measurement. Usually this is NOT a cause for concern. However, if the symbol appears often, we recommend you seek medical advice. Please note that the device does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

♥ Why does my blood pressure fluctuate throughout the day?

1. Individual blood pressure varies every in one day, it is also affected by the way you tie your cuff and the your measurement position, so please take the measurement at the same condition.

2. The varies of the pressure is greater if the person take medicine.

3. Waiting at least 3 minutes for another measurement.

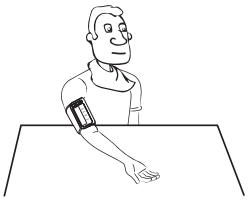
♥ Why the blood pressure I get from the hospital is different from home?

The blood pressure is different even during 24 hour because of the weather, emotion, exercise etc, specially the “white coat” in hospital which makes the results are higher than the ones at home.

The attention need to pay when you measure your blood pressure at home:
If the cuff is tie properly.
If the cuff is too tight or too loose.
If the cuff is tied on the upper arm.
If you feel anxious pressured.
You had better take deep breath 2-3 times before beginning.
Advice: adjust yourself for 4-5 minutes until you calm down.

♥ If the result is the same if measuring on the right arm?

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



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This section includes a list of error messages and frequently asked questions for problems you may encounter with your blood pressure monitor. If the products not operating as you think it should, check here before arranging for servicing.

PROBLEM	SYMPTOM	CHECK THIS	REMEDY
No power	Display will not light up.	Power is exhausted.	Charge the power
Low batteries	Display is dim or shows +Lo	Power is low.	Charge the power
Error massage	E1 shows	Communication error	Check if the App is on or not,try data transmission again.
	E 3 shows	The cuff is not secure.	Refasten the cuff and relax for a moment and then measure again.
	E 10 or E 11 shows	The monitor detected motion,talking or the pulse is too poor while measuring.	Relax for a moment and then measure again.
	E 20 shows	The measurement process does not detect the pulse signal.	Loosen the clothing on the arm and then measure again.
	E 21 shows	The treatment of the measurement failed.	Relax for a moment and then measure again.
	EExx,shows on the display.	A calibration error occurred.	Retake the measurement. If the problem persists, contact the retailer or our customer service department for further assistance.Refer to the warranty for contact information and return instructions.

Power supply	3.7V 1000mAH Built-in rechargeable li-polymer battery, 6V / 1A AC Adaptor
Display mode	Blue LCD with White Backlight V.A.= 86.5mm(L) x24mm(W)
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0kpa-40kpa (0mmHg-300mmHg) Measurement pressure: 4kPa-34kPa (40mmHg-230mmHg) pulse value:(40-199)beat/minute
Accuracy	Pressure: 5℃-40℃within±0.4kpa(3mmHg) pulse value:±5%
Normal working condition	Temperature:5℃ to 40℃ Relative humidity ≤85% Atmospheric pressure: 86kPa to 106kPa
Storage & transportation condition	Temperature:-20℃ to 60℃ RH: 10% to 93% Atmospheric pressure: 50kPa to 106kPa
Measurement perimeter of the upper arm	About 22cm-32cm
Net Weight	Approx.265 g
External dimensions	Approx.130×72.2×29.4mm
Attachment	AC Adaptor,user manual
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Protection against ingress of water	IP22, It means the device could protected against solid foreign objects of 12.5 mm and greater, and against vertically falling water drops when ENCLOSURE tilted up to 15°
Software version	V01
Device classification	Battery Powered Mode: Internally Powered ME Equipment AC Adaptor charged Mode: Class II ME Equipment

WARNING: No modification of this equipment is allowed.

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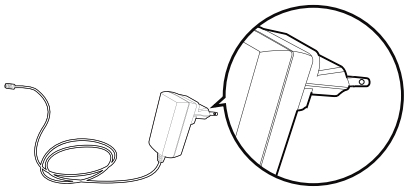
♥ Athorized Component

1. Please use the Airon authorized adaptor



Adaptor
Input: 100-240V, 50-60Hz,400mA
Output: 6V ⎓ 1A

♥ Contact Information

AIRON AGENTURER AS
Øvre Slottsgate 18 - 20
0157 Oslo
NORWAY
Tel: +47 22 41 08 00
www.airon.no

Authorized European Representative:
Company: MDSS - Medical Device Safety Service GmbH
Address: Schiffgraben 41, 30175 Hannover, Germany

♥ Complied European Standards List

Risk management	ISO/EN 14971:2012 Medical devices — Application of risk management to medical devices
Labeling	ISO/EN 15223-1:2012 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements
User manual	EN 1041: 2008 Medical equipment manufacturers to provide information
General Requirements for Safety	EN 60601-1: 2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC/EN 60601-1-11: 2010 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/EN 80601-2-30:2009 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers
Electromagnetic compatibility	IEC/EN 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard:Electromagnetic compatibility - Requirements and tests
Performance requirements	EN 1060-1:1995+A2:2009 Non-invasive blood pressure Part 1: General requirements EN 1060-3:1997+A2:2009 Non-invasive blood pressure Part 3: Supplementary requirements for electromechanical blood pressure measuring system
Clinical investigation	EN 1060-4: 2004 Automatic Blood Pressure Monitor overall system Interventional accuracy of the testing process
Usability	IEC/EN 60601-1-6: 2010 Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability IEC/EN 62366: 2007 Medical devices - Application of usability engineering to medical devices
Software life-cycle processes	IEC/EN 62304:2006+AC: 2008 Medical device software - Software life cycle processes

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EMC Guidance

1. The Blood Pressure Monitor needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS

2. 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 = 3,3 m away from the equipment.

(Note. As indicated in Table 6 of IEC 60601-1-2:2007 for ME EQUIPMENT, a typical cell phone with a maximum output power of 2 W yields d = 3,3 m at an IMMUNITY LEVEL of 3 V/m)

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