WEGO威高

Upper Arm Type Electronic Blood Pressure Monitor

User's Manual and Technical Instructions

WG-BP13 Series

Contents

1. Preface

1.1 Purpose of Use

- Medical purpose: This product is a medical instrument designed for measuring and displaying blood pressure and pulse for adults and children with an arm circumference of 12 to 40 cm.
- Target users: Medical staff and family members.
- Measurement subject: Adults/children (over 3 years old).
- Environment: Home, hospital, clinic, and other facilities.

1.2 Measurement Items

Non-invasive measurement of blood pressure and pulse rate.

1.3 Precautions

Please refer to [3. Warnings and Precautions] for details.

⚠ Caution: It is necessary to ask a professional physician to explain the measured blood pressure values!

❗ Accurate measurements can only be obtained with the correct measurement method!

⚠ Caution: Pay attention to the following points when measuring blood pressure, otherwise, it may cause inaccurate measurements!

❗ Every blood pressure measurement is affected by the subject's posture and physical condition. Before the measurement, please ask the subject to sit still for 5 minutes and adopt the proper posture (to maintain his/her emotions calm and stable)!

⃠ Do not take the measurements when the subject's body part is under pressure.

⃠ Do not take the measurements after smoking, or drinking alcohol, coffee, or black tea.

⃠ Do not take the measurements immediately after the subject has exercised or taken a shower.

⃠ Do not allow subjects to speak, move, or shake their bodies during the measurement.

⃠ Do not take the measurements in extremely cold or hot environments or when there are drastic changes in conditions.

⃠ Do not take the measurements within an hour after meals.

⃠ Do not take the measurements in a moving vehicle.

⃠ Do not use a mobile phone near this product.

⃠ Do not use the product during maintenance or care.

❗ Please take the measurements again if it is impossible to measure normally due to an incorrect operation!

1.4 About the Manual

- This Manual mainly introduces the installation and usage methods and precautions of this product.
- Before using this product, please make sure to read this Manual completely (including "Warnings and Precautions").
- Please carefully read the measurement items related to this product and use it properly.
- Please refer to [5. Use Method] for details of unpacking, installation, and pre-use inspection.
- Please refer to [5.5 Standard Operating Procedure] for details.
- Please refer to [6 Maintenance] for access to help services and frequency of routine maintenance, recalibration, and cleaning.
- The blood pressure values measured by this device are equivalent to the value measured with the auscultatory method, and the error meets the requirements stipulated in YY0667-2008.

1.5 Symbols and Their Meanings

	Type BF applied part
	Class II equipment
	Caution! Refer to accompanying documents
IP21	Indicating that this product can prevent solid foreign objects with a diameter of not less than 12.5 mm from entering and prevent vertical dripping
	Fragile, be careful
	Keep up
	Keep dry
	Indicating that the stacking limit for the same transport package is 10

	Atmospheric pressure for transportation and storage
	Temperature for transportation and storage
	Humidity for transportation and storage

2. Statement

- This Manual is prepared in accordance with the Provisions on the Administration of Instructions and Labels of Medical Devices. Revision date of this Manual: June 3, 2024.
- The information provided in this Manual is based on product characteristics, rather than the customer's customization requirements, and does not involve any personal information of the customer.

2.1 Copyright Statement

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2.2 Quality Assurance

Under normal circumstances, the raw materials and production & processing of the product are free from defects, because we strictly follow the ISO13485 quality system certification during the production and waive the cost of materials and manual maintenance in the warranty period. Normal use and maintenance should be carried out in accordance with the instructions and guidance in this Manual. The guarantee is no longer applicable under the following circumstances:

- ✓ Product damage during shipment
- ✓ Using accessories not approved by WEIGAO Health
- ✓ Abuse, misoperation, and rough use without following the instructions or guidance in this Manual
- ✓ Damage caused by uncontrollable factors such as environmental conditions, temperature, humidity, and force majeure (such as lightning and other natural disasters) beyond the control of WEIGAO Health
- ✓ Dismantling of devices by maintenance organizations or individuals without authorization from WEIGAO Health

3. Warnings and Precautions

- Important safety measures and information on the proper use of the device are provided in this Manual. Please read them carefully before using this upper arm type electronic blood pressure monitor.
- Before use, operators should understand the professional skills, operation, and knowledge of the product in this Manual, as well as the restrictions on any place or environment where the product can be used and related warnings and precautions.
- When the patient operates and uses the product themselves, the patient is the expected operator and needs to read this Manual before use.

3.1 Safety Requirements

Warning	Remind users that incorrect operation of the blood pressure monitor may result in incorrect or unexpected measurement results.
Caution	Remind users to pay attention to the operation of the blood pressure monitor. Incorrect operation of the blood pressure monitor may result in inaccurate measurement results or malfunction of the monitor. Please contact your doctor promptly in case of discomfort.
Note	Provide specific information through suggestions, requests, or supplementary explanations.

3.2 Warnings

- Do not use the blood pressure monitor in extremely cold, hot, dusty, or humid environments.
- Do not use the blood pressure monitor in environments with flammable anesthetic gases. Do not bring this product into places where there are highly flammable anesthetics or potentially flammable gases, as well as high-pressure oxygen chambers or oxygen tents, otherwise, it may cause explosions or fires.
- Do not use the blood pressure monitor during nuclear magnetic resonance imaging (MRI) or CT examinations. Do not use this product together with nuclear magnetic resonance imaging diagnostic devices (MRI devices). When performing an MRI examination, please remove the cuff, etc., connected to this product from the patient's body, otherwise, the patient may be burned due to local heating caused by induced electromotive force.
- Do not use the blood pressure monitor in combination with a defibrillator.
- Do not use the blood pressure monitor in combination with electrocardiographic surgical devices.
- Do not use the blood pressure monitor in environments with a strong electromagnetic field.
- In case the electrolyte in the battery accidentally splashes into the eyes, please rinse immediately with plenty of water and seek treatment at the nearest hospital, otherwise, it may cause blindness.
- If battery electrolyte accidentally contacts skin or clothing, rinse immediately with plenty of water to prevent skin damage.
- Please do not hold the cuff, power adapter, etc. to move this product, otherwise, the cable may fall off, causing the product to injure the patient.
- Do not operate or store this product outside the conditions specified in this Manual, otherwise, it may cause faults or operation failure.
- Do not use this product in environments with extreme temperature, humidity, and height. Please strictly follow the environmental conditions. Correct measurement is available only if the environmental conditions are followed during use.
- Do not impact or drop this product, otherwise, it may cause faults or operation failure.
- Do not plug or unplug the power plug with wet hands, otherwise, it may cause electric shock or burns.
- This product complies with EMC standards. Therefore, it can be used simultaneously with many medical devices. However, when using this product near instruments such as electric surgical scalpels and microwave therapy devices that generate noise, please check the operating status of this product during or after use, otherwise, it may cause faults or operation failure.
- When measurement mistakes occur or the measured values are questionable, please confirm through auscultation, otherwise the changes in the patient's condition may be impossible to observe, leading to condition aggravation.
- Please plug the power plug into the bottom of the socket, otherwise, it may cause fire and electric shock.
- Please confirm the following before use: whether the power adapter cable is damaged (core wire is exposed, broken, etc.), and whether the connection is loose, otherwise, it may cause faults, operation failures, or fires.

- Please make sure to use standard accessories or products designated by WEIGAO Health for power adapters, consumables, and other products connected to this product, otherwise, it may cause faults, operation failures, or fires.
- Do not use this product when it emits smoke, odors, or abnormal sounds, otherwise, it may cause explosions or fires.
- Do not bring mobile phones, walkie-talkies, or other devices into the room where this product is placed, otherwise, it may cause misoperation.
- Do not connect multiple units of this product to one patient, otherwise, it may endanger the patient's safety.
- Do not connect to socket outlets controlled by wall switches, otherwise, it may cause the power supply to fail to supply this product.
- Please do not place any items on this product. If any liquid spills onto the device or foreign objects enter the interior of the device, it may cause fire, electric shock, or faults.
- Do not use this product in places with high moisture or that may have contact with water, such as bathrooms, otherwise, it may cause fire, electric shock, and faults.
- Before measurement, please confirm whether the patient has the following conditions: - Peripheral circulatory disorders, low blood pressure, or hypothermia (due to limited blood flow at the measurement site)
  - Using Extracorporeal Membrane Oxygenaton (due to lack of pulsation)
  - Wearing SpO_2 sensor and cuff on the same arm
  - Arterial aneurysm
  - Arrhythmia
  - Spasms, venous pulsations, tremors, and other body movements (during cardiac massage, weak continuous vibrations, rheumatism, etc.). Otherwise, it may not be possible to measure correctly.
- Before use, please confirm whether the appearance of the device has been deformed due to falling off or other reasons, whether there is dirt, or whether it has been soaked, otherwise, it may cause faults or operation failure.
- When this product is not used for a long time, please make sure to confirm whether the device can operate properly and safely before use, otherwise, it may cause accidents.
- Do not use this product in places where it is easy to fall off. In addition, if this product falls off, confirm whether it can still operate normally and safely, because falling may affect the accuracy and performance.
- When the airbag is in excessively inflated for a long time, there may be risks.
- Please cut off the power supply and unplug the power adapter from this product during maintenance, otherwise, it may cause electric shock.
- After maintenance, thoroughly dry the device and then plug into a medical power socket outlet, otherwise, it may cause electric shock.
- Do not spray, inject, or leak liquids into the opening of this product, accessories, connectors, buttons, or housing, otherwise, it may cause electric shock.
- To use this product safely and correctly, please conduct the pre-startup inspection and maintenance inspection, otherwise, accidents may occur.
- Do not modify this product at will. Do not disassemble or modify this product and adapter, otherwise, it may cause fire and electric shock.
- Any maintenance of the product is prohibited during its use.
- Prefer to place the product in those places where it is easy to unplug when in use, not in places where it is difficult to unplug.

- Warnings: Do not modify this device.
- When the performance of the device system changes, please stop using it, contact the manufacturer, and do not disassemble the device for maintenance.
- Do not use components other than those specified in this Manual, otherwise, it may affect the accuracy or performance or pose a danger.
- Before each use, the device should be cleaned and disinfected according to the instructions in this Manual.
- Do not expose this device and its accessories to places with high temperatures, high humidity, dust, cotton wool, insects, or direct sunlight.
- Keep this device out of the reach of pets or children, as there may be a risk of damage to the device.
- There may be measurement errors in cases of common arrhythmias such as premature atrial contraction (PAC), premature ventricular contraction (PVC), and atrial fibrillation (AF).
- If the original components are replaced with parts not provided by the manufacturer, it may cause incorrect measurements.

3.3 Precautions

- This blood pressure monitor is intended for adults and children over 3 years old.

- Do not use this product for infants and pregnant women, otherwise, it may fail to obtain accurate measurement values.
- When this blood pressure monitor is used by multiple persons, please disinfect it with 75% medical alcohol before use to prevent skin cross infection.
- In case of discomfort while using this blood pressure monitor, please stop using it immediately and consult a doctor, distributor, or manufacturer.
- If you have any questions during use, please contact the distributor. Do not disassemble this device by yourself, otherwise, you will lose any warranty promised by WEIGAO Health, and be responsible for all problems arising from this.
- The service and maintenance of the device should be carried out by WEIGAO Health or its authorized distributors and agents, and they will not be responsible for any direct, indirect, or ultimate damage or delay caused by other factors.
- This device cannot be operated during transfer. Please do not place this product in the following places:
  - Where it may come into contact with water or steam
  - Where chemicals or corrosive gases are stored
  - Where the air contains a large amount of dust, salt, sulfur, etc.
  - Where it will be exposed to direct sunlight for a long time (especially where liquid crystal may deteriorate due to ultraviolet radiation)
  - Where vibrations and impacts may occur
  - Where the temperature and humidity are not within an appropriate range (ambient temperature: -25°C—70°C, humidity: 15%RH—93%RH)
- Otherwise, it may cause a fire or result in faults or operation failures.
- Do not use this product near large equipment that requires switch control with conversion relays, otherwise, it may affect the operation of this product.
- Do not connect the positive and negative electrodes of rechargeable batteries with steel wires or other metals to prevent short circuits.

- When using disinfectant for maintenance, please follow the instructions of the product manufacturer, otherwise, it may damage the surface of this product.
- Please maintain the product regularly, otherwise, it may cause faults or operation failures.
- Do not use solvents such as diluents or volatile oils during maintenance, otherwise, they may damage the surface of this product.
- Do not sterilize the device with high-pressure sterilizers, or gases (EOG, formaldehyde, high-concentration ozone, etc.), otherwise, it may cause damage to the device.
- When removing or installing the battery from this product, please be sure to unplug the power adapter from this product before operation, otherwise, it may cause electric shock.
- Do not apply pressure to the battery to prevent deformation. Additionally, please do not throw or strike the battery, or cause it to fall, bend, or be strongly impacted, otherwise, it may expand or explode.
- Ensure the correct polarity when installing batteries to avoid overheating, leakage, or rupture, which could damage the blood pressure monitor.
- Do not mix old and new batteries or different types of batteries as it may cause fire hazards.
- Do not connect the positive and negative terminals of the battery with steel wires or other metals. In addition, do not transport or store the battery together with metal necklaces, hair clips, etc., otherwise, the battery may be short-circuited, generate excessive current, and cause liquid leakage, heating, rupture, and fire. In addition, steel wires, necklaces, hair clips, and other metals may also generate heat.

3. 4 Warnings and Precautions

- Please dispose of the cuff used by patients with infectious diseases as medical wastes, or thoroughly disinfect it before reuse, otherwise, it may lead to infection.
- When using the cuff frequently for continuous NIBP measurement, please monitor the patient's circulatory status regularly. In addition, please wear the cuff according to the precautions in this Manual, otherwise, it may cause ischemia, suggillation, and neurological disorders.
- When wrapping a cuff around the arm on the side where the breast has been removed for blood pressure measurement, please confirm with the patient if there are any abnormalities, as the patient may feel pain.
- Do not connect the cuff or cuff connector of NIBP to the Luer taper locking adapter, otherwise, it may cause accidents.
- Especially after changing positions, please be careful not to bend or block the air hose, otherwise, there may be residual air in the cuff, which may block the blood flow in the arm and lead to peripheral circulatory disorders.
- Do not wear the cuff on the following parts:
  - Limbs subject to intravenous infusion and blood transfusion
  - Limbs wearing SpO_2 sensors or IBP catheters

- Limbs wearing shunts for hemodialysis treatment

Otherwise, it may lead to accidents.

- Please conduct blood pressure measurement on the upper arm.
  - Otherwise, it may not be possible to measure correctly.
  - Otherwise, it may affect the measurement accuracy.
- When measuring blood pressure, please ask the patient not to move their body too much and keep their body not shaking as much as possible, otherwise, it may not be possible to measure correctly.
- For patients diagnosed with bleeding tendency or hypercoagulability, please confirm if there are any abnormalities in the arm after measurement, otherwise, it may cause circulatory disorders due to dot hemorrhages or thrombus.
- Please use a cuff of the appropriate size to obtain accurate measurement values, otherwise, it may result in inaccurate measurements. If a larger cuff is used, the measured value will be lower than the actual blood pressure value.
- Before and during the measurement, please confirm whether the patient has the following conditions:
  - Measuring with a cuff of an inappropriate size
  - Different height of the cuff wrapping area from the height of the heart (if there is a height difference of 10 cm, the blood pressure value may sometimes differ by 7 mmHg to 8 mmHg)
  - Moving the body or speaking during the measurement
  - Wearing a cuff on thicker clothing
  - The rolled-up clothes compress the arm

  Otherwise, it may not be possible to measure correctly.
- For adults, the cuff's tightening force should be enough to insert two fingers between the cuff and the wrapping area, otherwise, it may not be measured correctly.
- Please take measures after confirming the patient's condition, otherwise, it may lead to condition aggravation.
- Do not use this product when the cuff is damaged or has holes, otherwise, it may be broken during the measurement.

3.5 General Advice Usage

Usage Suggestions

- Please carefully read the attached manual before using the products sold separately. This Manual does not record any precautions for products sold separately.
- Like other medical devices, please be careful not to wrap or tie cables to the patient when using them.
- Before or during use, please confirm the followings when the power is turned on:
  - There should be no smoke, odor, or abnormal sounds
  - The time should be set correctly
  - All buttons should function normally

- The icon light should be on and flash normally
- This product should be able to measure normally, and the error should be within the standard value

- Do not use this product when the screen cannot be displayed normally.
- Dispose of the main body, accessories, and products sold separately in accordance with the relevant city regulations on environmental protection.

Maintenance

- Maintenance (see "Maintenance" section)

Battery

- To prevent accidents, store batteries out of reach of children.
- If you suspect the battery is malfunctioning, immediately move it to a safe place and contact admin or call customer service for assistance.
- The device may not operate on battery power if the battery voltage is too low.

Measurement

- Please follow the doctor's advice if the part wrapped by the cuff suffers from acute inflammation, purulent disease, trauma, etc.
- NIBP requires compression of the upper arm for measurement. Some people may feel intense pain or experience instantaneous spotting due to subcutaneous bleeding. Although the spot will naturally disappear after a period of time, patients who may have spots should be informed that "spots may appear" and the measurement may need to be temporarily stopped depending on the actual situation.
- Due to lack of clinical trials, please do not use this product for infants and pregnant women.
- Let the patient relax and not speak during the blood pressure measurement to ensure accurate measurement.
- Let the patient rest for 5 minutes before starting the measurement to ensure accurate measurement.

4. Product Introduction

4.1 Product Description

The upper arm type electronic blood pressure monitor mainly consists of a power supply, cuff, pump, valve, sensor, LCD screen, MCU, etc., and it is a medical device that adopts modern electronic technology and the principle of indirect blood pressure measurement to measure blood pressure. The declared measurement methods of the product mainly include the oscillometric method and auscultation, both of which use cuff inflation to compress blood vessels and measure the lateral pressure generated by blood on the vessel wall to determine the blood pressure.

4.2 Product Structure and Composition

The main components of the upper arm type electronic blood pressure monitor include the main unit, cuff, lithium battery or dry battery, power adapter (optional), and charging cable (optional).

4.3 Intended Use

To measure blood pressure and pulse rate.

4.4 Contraindications

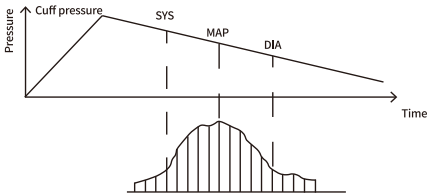
None

4.5 Software

- Software name: Upper arm type electronic blood pressure monitor
- Specification/model: See configuration table
- Software release version: V1

4.6 Product Working Principle

Reduced pressure oscillometric method: The electronic blood pressure monitor uses an air pump to inflate and pressurize the cuff, make the inflated cuff compress the arterial blood vessels and keep them completely blocked, and then open the slow deflation valve to slowly decrease the pressure inside the cuff. As the pressure inside the cuff decreases, the arterial blood vessels undergo a process of complete obstructed, gradually unblocking, and completely free of obstruction. The trend of the magnitude of the arterial pressure amplitude during blood pressure reduction is shown in the figure below:



The pressure sensor captures the changed pressure inside the cuff, converts it into a digital signal, and sends it to the MCU. The embedded software can identify the corresponding pressure points during the process of arterial blood flow obstruction, and calculate the DIA and SYS of the human body based on software algorithms.

4.7 Technical Parameters

Name	Upper Arm Type Electronic Blood Pressure Monitor
Measurement method	Oscillometric method
Display screen	LCD screen (with date and time)
Recording function	Capable of storing 120 groups of measurement data
Display screen	LCD
Measurement range	Blood pressure: 0 mmHg~300 mmHg Pulse rate: 40~199 beats/min
Accuracy	Blood pressure error: ±3 mmHg Pulse rate error: ±2 beats/min or ±2%
Power supply	Power adapter: Input: AC100~240V, 50Hz/60Hz,0.5A, output: DC5V,1A Dry battery: DC6V, model: AA, DC1.5V×4
Suitable arm circumference	12～40cm
Operation mode	Continuous operation
Category by protection against electric shock	Class II device, internal power supply unit, type BF applied part
Level of protection against harmful ingress of liquid and particulate matter	IP21
Suitable for use in oxygen-enriched environments	N/A
Measures for disconnecting from the power grid	Plug
List of parts	Main unit, dry battery, cuff, power adapter (optional), charging cable (optional)
Key components	Pressure sensor, cuff, inflation pump
Sterilization method	Non-sterile

Applied part	Cuff
Service life	10 years

4.8 Model Configuration Table

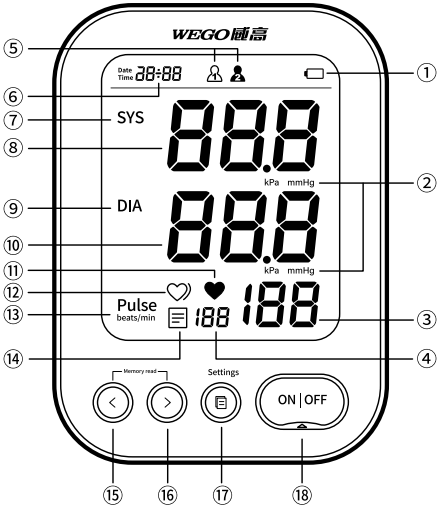
Model / Config.	WG-BP13 Series							
	BP1390	BP1380	BP1370	BP1360	BP1330	BP1320	BP1310	BP1300
Cardiac spectrum	—	—	—	—	—	—	—	—
Auscultation mode	—	—	—	—	—	—	—	—
Autocorrection	✓	✓	✓	✓	✓	✓	✓	✓
Systolic blood pressure	✓	✓	✓	✓	✓	✓	✓	✓
Diastolic blood pressure	✓	✓	✓	✓	✓	✓	✓	✓
Pulse rate range	40~199	40~199	40~199	40~199	40~199	40~199	40~199	40~199
Blood pressure range	0~300	0~300	0~300	0~300	0~300	0~300	0~300	0~300
Recording function	120	120	120	120	120	90	60	30
Number of user groups	Multi-user	—	Multi-user	—	Multi-user	—	Multi-user	—
Battery	Lithium battery	Lithium battery	Lithium battery	Lithium battery	Dry battery	Dry battery	Dry battery	Dry battery

5. Use Method

5.1 Unpacking and Pre-use Inspection

Before using the product, please unpack and confirm whether the accessories are complete and whether there is any damage to the body and accessories. Once the accessories are insufficient or found to be damaged, please contact the distributor from which you purchased the device or call the customer service hotline for consultation.

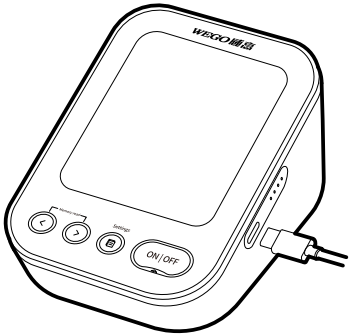
Key Function Description



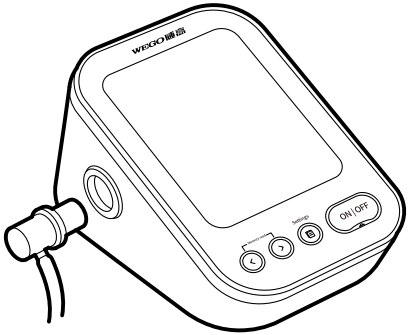
SN	Icon	Function description
①		Battery power
②	kPa mmHg	Unit, kPa, mmHg
③	188	Pulse rate display, measurement range of 40-199
④	188	Memory group count, maximum memory value of 120
⑤		User 1, User 2
⑥	Date Time 88:88	Date, time
⑦	SYS	SYS
⑧	88.8	Measured SYS

SN	Icon	Function description
⑨	DIA	DIA
⑩	888	Measured DIA
⑪	♥	Pulse rate alert
⑫	♡	Arrhythmia
⑬	Pulse beats/min	Pulse, beats/min
⑭		Memory icon
⑮		Memory read, left
⑯		Memory read, right
⑰		"Settings" button, long press to enter settings mode
⑱	ON|OFF	"ON|OFF" button, press the button to turn on and start measurement, and press the button again to cancel measurement and turn off

Machine Base Socket



The above figure shows the power on diagram



The above figure shows the cuff connection diagram

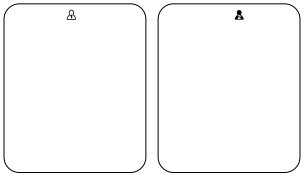
Warning: Do not use adapters that are not provided by WEIGAO Health or not applicable to this model, otherwise, there may be risks of fault, power short circuit, combustion, and explosion. Any maintenance of the adapter by the user is prohibited.

Battery Installation/Replacement Method

The blood pressure monitor uses dry batteries. If a battery symbol [▭] appears on the display, turn off the device, replace the batteries with new ones, and remove batteries during extended periods of non-use. Always reinstall batteries before each use.

User Switch

In the off state, press the "Settings" button to switch between User 1 and User 2 as shown below.

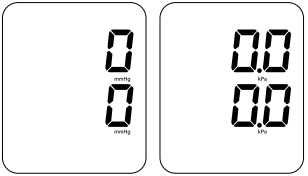


System Time Setting

a) In the power off state, press and hold the "Settings" button until the time setting screen appears and then release to enter the system time setting state.
b) Press the ⑮ memory read (left) or ⑯ memory read (right) to set the system time.
c) Use the ⑰"Settings" button to select the item to adjust (year, month, day, hour, minute), and the adjusted item will appear in a continuous flashing state.

Unit Switch

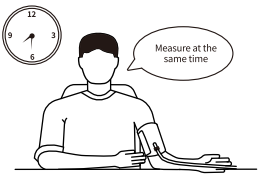
In the state of setting voice, press the "Settings" button again to enter the unit switching mode, as shown in the figure below:



Press the ⑮ memory read (left) or ⑯ memory read (right) to switch units.

5.2 Precautions for Measurement

a) Please relax your body and mind, and measure in a natural position when measuring the blood pressure.
b) Rest for at least 5 minutes before measuring.
c) It is preferable to measure blood pressure in the early morning when you wake up and do not have the feeling of urination; if this is not possible, please try to take measurements before breakfast when you have not done a lot of physical exercise.



d) During measurement, keep quiet and do not speak; pulse values and blood pressure may vary slightly due to muscle tension or changes in posture.
e) If it is impossible to deflate and the airbag continues to inflate excessively, it may cause discomfort in the patient's arm. Please immediately turn off the device or remove the tube.

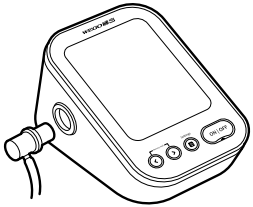
5.3 Cuff Selection

- Measure the patient's arm circumference and select a cuff that is suitable for the patient's size.
- Only by using a cuff suitable for the patient's arm circumference can accurate measurement results be obtained. Please choose a size suitable for the patient from the following cuffs or similar options.

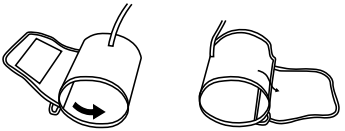
Product name	Arm circumference (cm)	Remarks
Blood pressure cuff	31～40	Optional
Blood pressure cuff	23～33	Optional
Blood pressure cuff	17～25	Optional
Blood pressure cuff	12～19	Optional
Blood pressure cuff	22～36	Optional

5.4 Usage of Cuff

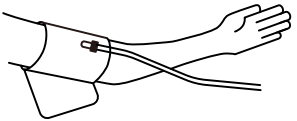
a) Insert the cuff air plug into the air plug hole of the device, with the longer end inserted into the device and the shorter end connected to the tube. After insertion, the silicone ring is flexible, and can be shaken slightly as a normal phenomenon.



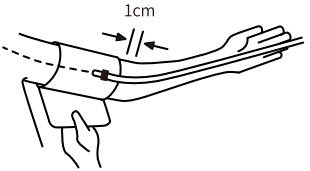
b) Open the cuff so that the loop hole of the cuff forms a cylindrical type. If a cuff with a metal ring is used and metal detachment is found, please install the cuff into the metal ring first, as shown in the figure below.



c) Thread your left hand through the ring, and ensure that the tube is in the same direction as your palm. If you are wearing thick clothes, please take them off first.



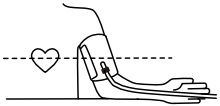
d) With the palm facing upwards, adjust the cuff to a position about half an inch (1 cm) above the elbow (based on the texture when bending the arm), and adjust the position of the tube to the center of the arm and the side of the body, so that it forms a straight line with the middle finger.



e) Grasp the extended part of the cuff ring and wrap it while pulling.
f) Lower the arm naturally and place the cuff at the same height as the heart to ensure the consistency of measurement values. Place the cuff at the same height as the heart (caution: if it is placed too high, the measurement value will decrease; if placed too low, the measurement value will increase).

Note: If you have any questions, please consult the manufacturer or authorized agent.

5.5 Standard Operating Procedure



a) If the power is not turned on, please press the "ON/OFF" button.
1) All display record numbers will appear, and the following figure shows the self-test of the measuring instrument screen.

2) After the built-in self-test of the device is completed and ready, the screen will display a "0" status. During the measurement, if the "ON|OFF" button is pressed, the device will stop inflating and quickly exhaust, and the power will be turned off.
b) When the device starts to automatically measure and sense the pulse, the heart-shaped mark [ ] will automatically flash. After the measurement is completed, the device will automatically start the exhaust and record the measurement time and results.

Note: The maximum number of recorded data is up to 120 sets. If new measurement results are added, the oldest recorded data will be automatically deleted.

c) After the measurement is completed, the screen will display the measured SYS and DIA as shown below. The "date: month-day" and "time:hour:minute" will be switched automatically.

Display SYS, DIA and Pulse

d) After the measurement is completed, press the "ON|OFF" button to turn off the power.
Caution: Even if you forget to turn off the device, it will automatically shut down after about 3 minutes.
Special instructions for safe use
Caution: As the device is still measuring during exhaust, do not swing the cuff or tube.
Caution: After the measurement is completed, the screen will display the measured SYS, DIA, and pulse rate simultaneously.
The maximum number of recorded data is up to 120 sets. If new measurement results are added, the oldest recorded data will be automatically deleted.

5.6 Records

a) There are 2 memory read buttons  on the device panel, which can be operated after turning on the power to view measurement records;
b) Press the memory read(left) or (right) buttons to browse through the measurement records;
c) The maximum number of recorded data is up to 120 sets. If new measurement results are added, the oldest recorded data will be automatically deleted.

5.7 Quick Measurement Guidance

a) Do not eat, smoke, or exercise 30 minutes before the measurement.
b) Insert your left arm into the cuff and ensure that the bottom of the cuff is about 1 cm away from your elbow.
c) Pull the bottom of the cuff to ensure that it is evenly wrapped around the arm, and tighten the cuff. Please be careful to ensure that the skin is not clamped by a metal ring when inflating. If the skin is accidentally clamped, promptly turn off the "ON|OFF" button to exhaust, and then adjust the cuff.
d) Please sit on a chair of appropriate height, place your feet flat on the ground and your left arm on the table, and keep the position of the cuff at the same height as your heart.
e) Press the "ON|OFF" button.
f) When the screen displays the pressure as "0", press the "ON|OFF" button.
g) When the blood pressure measurement is in progress, please do not swing your arms or body.
h) After the measurement is completed, the screen will display your blood pressure and pulse rate readings, and the device will automatically exhaust, and record the measurement time and results.
i) If another measurement is required, do not proceed immediately to avoid affecting the accuracy of the measurement. Please relax and rest for 5 min—10 min before taking the measurement. Depending on your physical condition, you may need a longer interval.
Caution! In case of an emergency stop, please press the "ON|OFF" button or unplug the air plug connector of the cuff.

6.Maintenance

6.1 Maintenance of the Main Unit

- To protect the device from damage and ensure measurement accuracy, please follow the followings:
  - After use or when not in use, please place and store this device and its accessories properly to prevent them from being subjected to strong impact or vibration.
  - Do not expose this device and its accessories to high temperatures, high humidity, dust, or direct sunlight, and do not disassemble or repair this device without authorization.
  - Do not replace internal parts without authorization.
  - If the device is dirty, please clean and disinfect it with a soft dry cloth dipped in about 75% medical alcohol, and do not wipe the socket with a damp cloth.
- Caution:
  Be careful to prevent liquids from entering the device. Clean and disinfect the device before each use.
- Cautions:
  1) Do not use high-pressure sterilizers, or sterilize with gases (formaldehyde, ozone, etc.) equipment, otherwise, it may cause damage to the device.
  2) Do not use diluent, volatile oil, or other solutions to wipe this device, otherwise, it may damage the outer surface of the device.
  3) When using disinfectant for maintenance, please follow the manufacturer's instructions to prevent the liquid from entering the device, otherwise, it may cause damage to the device.
  4) The adapter, lithium battery, and internal components are not within the scope of routine maintenance. Do not replace or maintain them by yourself, otherwise it may cause electric shock. The product needs to be returned to the factory for calibration and maintenance every year.

6.2 Routine Maintenance

- Remove batteries if the blood pressure monitor will not be used for an extended period (3 months or more). In addition, after the battery is used up, please replace it with a new one; otherwise, it may cause battery leakage, etc., which may damage the blood pressure monitor.
- Maintenance: Wipe with a soft dry cloth or a damp cloth dipped in neutral detergent (rather than gasoline, diluents, or other corrosive chemicals).
- Cleaning and disinfection frequency and procedures: The blood pressure monitor needs to be cleaned and disinfected before each use. The surface of the blood pressure monitor main unit can be dried naturally, disinfected with 75 % alcohol, or cleaned with a clean and dry cloth.
- Keep the operating environment clean, quiet, non-corrosive, and free of flammable substances. Do not use the device in environments with high or low temperatures and humidity.

- If the blood pressure monitor is splashed or has water condensation, please stop operating.
- When the blood pressure monitor is moved from a cold environment to a warm and humid place, do not use it immediately.
- Keep the device away from sharp objects.
- Do not immerse the blood pressure monitor in liquid or wipe its surface with organic solution, and do not spill liquid on it.
- The main unit of the blood pressure monitor has a service life of 10 years, and the cuff has a service life of 1 year. To ensure the normal use of the device within its expiration period, please pay attention to maintenance. Repeated cleaning/disinfection will not result in the loss of basic safety of the blood pressure monitor.
- Manufacturers may provide circuit diagrams, lists of components, drawing annotations, calibration rules, or other information that can assist maintenance personnel in repairing device components that can be repaired by the manufacturer's designated maintenance personnel as required. If necessary, please contact the manufacturer.
- If necessary, inexperienced operators or responsible parties should directly contact the manufacturer to obtain information about the installation, use, or maintenance of the device, as well as report abnormal operations or events.

Note: The above terms can ensure the safe operation of patients.

6.3 Prompt for Abnormalities

If you are using this device, please first check the following points:

Abnormal status	Possible Cause	Solution
E1	Blood pressure measurement failed: The cuff position is incorrect, or the tightness is inappropriate	Please readjust the position and tightness of the cuff. If there is no improvement, please contact the after-sales service for inspection
E2	Unable to apply pressure normally : 1.The connector is not connected ; 2.Check the cuff for air leaks	1.Reconnect the connector ; 2.Check the pipeline or replace the cuff with a new one; If there is no improvement, please contact the after-sales service for inspection
E3	Excessive inflation pressure. The tube is blocked due to bending	Check the tube. If there is no improvement, please contact the after-sales service for inspection
E4	Movement of the arm during measurement	Keep arm still during the measurement
E5 or E6	Low battery level	Replace the battery or plug it in. If there is no improvement, please contact the after-sales service for inspection
E7	Too slow air release speed	Contact customer service for support

E8	Too fast air release speed	Contact customer service for support
	Low battery power	Replace with new batteries or connect to a power adapter
LCD No display	1. Batteries not installed or adapter not connected; 2. Dry battery depleted	1. Install batteries or connect to a power adapter 2. Replace with new batteries

Users are not allowed to replace components on their own, and WEIGAO Health will not be responsible for any direct, indirect, or ultimate damage or delay incurred. If the user needs circuit diagrams, lists of components, drawing annotations, and calibration rules, WEIGAO Health can provide relevant information.

6.4 Environmental Conditions

Operating conditions	Temperature	5°C～40°C
	Humidity	15%RH～80%RH(non-condensing)
	Atmospheric pressure	700hPa～1060hPa
Transportation and storage conditions	Temperature	-20°C～60°C
	Humidity	10%RH～95 %RH(non-condensing)
	Atmospheric pressure	500hPa～1060hPa
This product complies with the GB/T14710 standard for low-temperature storage (-40°C). To ensure the stability of the product performance, it is recommended that the transportation and storage temperature does not fall below -20°C. When the ambient temperature is 20°C, it takes 15 minutes for the device to be ready and achieve its intended use from the lowest or highest storage temperature after use.		

- Transportation: During transportation, the blood pressure monitor should be correctly stacked according to the markings on the packaging box, and should be protected from heavy pressure, impact, severe vibration, and direct exposure to rain and snow. Other transportation requirements should be met in accordance with the provisions of the order contract.
- Storage: The packaged blood pressure monitor should be stored indoors at a temperature of -20°C to 60°C, with relative humidity not exceeding 10%RH to 95%RH, free from corrosive gases and strong mechanical vibrations, and in a clean, hygienic, and well-ventilated environment. Do not place this device in direct sunlight, or store it in environments with high temperature, high humidity, massive dust, and corrosive gases. Please be sure to remove the battery inside this machine to avoid electrolyte leakage and corrosion of the machine.
- Caution: If the device is stored or used not within the temperature and humidity range specified by the manufacturer, the system may not achieve the claimed performance!

6.5 Environmental Protection

- If the blood pressure monitor and its accessories are damaged during use or the service life of the blood pressure monitor expires, please contact the manufacturer or the institution designated by the manufacturer in a timely manner for disposal. Do not dispose of them casually to avoid environmental pollution.
- Inexperienced responsible parties must contact the corresponding local regulatory authorities to determine the appropriate method for disposing of components and accessories that may pose biological hazards.

7. After-sales Service

WEIGAO Health promises that any consumer who uses our products and encounters any product quality issues during use can call WEIGAO Health or visit its website. Our after-sales service personnel will answer your questions and provide after-sales service for you from 9:00 am to 5:00 pm on weekdays.

7.1 Scope of Services

Scope of Free Service

Devices within the scope of WEIGAO Health's warranty service can enjoy free services.

Scope of Paid Service

① WEIGAO Health will provide paid services for devices not falling within the scope of WEIGAO Health's warranty service.
② Even within the warranty period, if the product needs to be maintained due to the following reasons: damages due to human or force majeure.

WEIGAO Health is not responsible for any direct, indirect, or ultimate damages and delays due to the following reasons (including but not limited to):
① The components are disassembled, stretched, and re-commissioned.
② The parts are replaced without WEIGAO Health's permission, or disassembled or maintained by unauthorized maintenance personnel.

1. Return
If you need to return the product to WEIGAO Health, please follow the following steps:
In principle, the product sold by WEIGAO Health will not be returned except for

product quality issues. If normal returns are required, the right to return must be obtained first.

✓ It is necessary to contact WEIGAO Health's Customer Service Department and inform it of the reason for the return, the return quantity, and the product serial number. If the serial number is not clear and identifiable, the return will not be accepted.

✓ Please indicate the product model, product serial number, and return quantity in a written return note, briefly describe the reason for the return, and sign and stamp with WEIGAO Health's seal to enter the return process via email or fax.

2. Costs Incurred from Returns

Products that are recognized and approved for return by WEIGAO Health can be sent to WEIGAO Health by mail, express delivery, or consignment for shipment, and the

7.2 Warranty

- The upper arm type electronic blood pressure monitor comes with a three-year warranty from the date of sale, except for consumables such as the cuff (including tube and air connector) and battery; if the blood pressure monitor cannot be used due to missing components or design, WEIGAO Health will provide free repair or replacement with a new one.
- Warning: WEIGAO Health does not provide a free warranty for device damage caused by improper personal use, human damage, accidental damage (such as falling, disassembly), etc.

7.3 Periodic Calibration

- To meet the performance requirements of the product, it is recommended that the entire machine be returned to the factory for calibration every other year, which should be carried out by the national metrology and testing department, the manufacturer, or the maintenance center authorized by the manufacturer.
- Suggestion for verification method: Please refer to the Non-invasive Automated Sphygmomanometer (JJG692-2010) for verification.

7.4 Manufacturer Information

Medical device manufacturing license No.: LYJXSCX No. 20240028
Registration certificate No./product technical requirement No.: LXZZ 20242070338
Metering device type approval No.: PA XXXXXXXX
Registrant name: Weihai WEIGAO Health Technology Co., Ltd.
Registrant address: Plot 3, Jinnuo Road East and Binhai Avenue North, Gushan Town, Weihai Economic and Technological Development Zone, Shandong Province (within the campus of Shandong WEIGAO Hongrui Medical Technology Co., Ltd.)

Manufacturer name: Weihai WEIGAO Health Technology Co., Ltd.
Manufacturer address: Plot 3, Jinnuo Road East and Binhai Avenue North, Gushan Town, Weihai Economic and Technological Development Zone, Shandong Province (within the campus of Shandong WEIGAO Hongrui Medical Technology Co., Ltd.)
After-sales hotline: 400 0616 988
After-sales service provider: Weihai WEIGAO Health Technology Co., Ltd.

8. Electromagnetic Compatibility

The upper arm type electronic blood pressure monitor should comply with the national standard Medical Electrical Equipment — Part 1-2: General Requirements for Basic Safety and Essential Performance — Collateral Standard: Electromagnetic Compatibility — Requirements and Tests (YY9706.102-2021), and the following matters should be followed:

1) For the upper arm type electronic blood pressure monitor, special precautions regarding electromagnetic compatibility (EMC) must be taken, and the device must be used in accordance with the EMC information specified in this Manual.
2) Portable and mobile RF communication devices may affect the use of the upper arm type electronic blood pressure monitor.
3) Except for cables (transducers) sold as spare parts of internal components, the use of accessories and cables (transducers) that are not specified may result in an increase in emission or a decrease in immunity of the upper arm type electronic blood pressure monitor.
4) The upper arm type electronic blood pressure monitor should not be placed close to or stacked with other devices. If it' s necessary to do so, it should be observed and verified whether it can operate normally with proper configuration.
5) Requirements for cables and other accessories.
   The upper arm type electronic blood pressure monitor contains data cables, and their use should comply with the requirements of YY9706.102-2021. The manufacturer and model requirements for data cables are as follows:

SN	Name	Cable length	Shielded or not	Remarks
1	Charging cable	1.5m	Yes	/

6) Electromagnetic compatibility declaration

Table 1 Guidelines and manufacturer's statement - Electromagnetic emissions - for all ME equipment and ME systems

<table>
<tr><td colspan="3">Guidelines and manufacturer's statement– Electromagnetic emissions</td></tr>
<tr><td colspan="3">The upper arm type electronic blood pressure monitor is intended for use in the electromagnetic environment as specified below. The customer or the user of the device should ensure that it is used in such an electromagnetic environment.</td></tr>
<tr><td>Emission test</td><td>Compliance</td><td>Electromagnetic environment - Guidelines</td></tr>
<tr><td>RF emission GB4824</td><td>Group 1</td><td>The upper arm type electronic blood pressure monitor only uses RF energy for its internal functions. Therefore, its RF emissions are very low, and the chances of causing interference to nearby electronic devices are minimal.</td></tr>
<tr><td>RF emission GB4824</td><td>Class B</td><td rowspan="3">The upper arm type electronic blood pressure monitor is suitable for use in all facilities, including homes and those directly connected to the public low-voltage power supply network that supplies buildings for household purposes.</td></tr>
<tr><td>Harmonic emission GB17625.1</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/-flicker emission GB17625.2</td><td>Complied</td></tr>
</table>

Table 2 Guidelines and manufacturer's statement - Electromagnetic immunity - for all ME equipment and ME systems

Guidelines and manufacturer's statement– Electromagnetic immunity			
The upper arm type electronic blood pressure monitor is intended for use in the electromagnetic environment as specified below. The customer or the user of the device should ensure that it is used in such an electromagnetic environment.			
Immunity test	IEC60601 test level	Compliant level	Electromagnetic environment - Guidelines
Electrostatic discharge GB/T 17626.2	±6 kV contact discharge ±8 kV air discharge	±6kV contact discharge ±8kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/ burst GB/T 17626.4	±2 kV to power cord ±1 kV to input/output line	±2 kV to power cord Not applicable	The grid power should have the quality typical of commercial or hospital environments.
Surge GB/T 17626.5	±1 kV line-to-line ±2 kV line-to-ground	±1 kV line-to-line ±2 kV line-to-ground	The grid power should have the quality typical of commercial or hospital environments.
Voltage dips, short interruptions and voltage variations on the power input cable GB/T 17626.11	<5% U_T, for 0.5 cycle (>95% dip on U_T) 40% U_T, for 5 cycles (60% dip on U_T) 70% U_T, for 25 cycles (30% dip on U_T) <5% U_T, for 5s (>95% dip on U_T)	<5% U_T, for 0.5 cycle (>95% dip on U_T) 40% U_T, for 5 cycles (60% dip on U_T) 70% U_T, for 25 cycles (30% dip on U_T) <5% U_T, for 5s (>95% dip on U_T)	The grid power should have the quality typical of commercial or hospital environments. If the user of the upper arm type electronic blood pressure monitor needs to operate continuously during a power outage, it is recommended to use an uninterruptible power supply or battery power supply for it.
Power frequency magnetic field (50/60Hz) GB/T 17626.8	3A/m	3A/m	The power frequency magnetic field should be at the level characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T refers to the AC grid voltage before the test voltage is applied.			

Table 3 Guidelines and manufacturer's statement - Electromagnetic immunity - for non-life support ME equipment and ME systems

Guidelines and manufacturer's statement– Electromagnetic immunity			
The upper arm type electronic blood pressure monitor is intended for use in the electromagnetic environment as specified below. The customer or the user of the device should ensure that it is used in such an electromagnetic environment.			
Immunity test	IEC60601 test level	Compliant level	Electromagnetic environment - Guidelines
RF conduction GB/T 17626.6 RF radiation GB/T 17626.3	3V (RMS) 150kHz~80MHz 3V/m 80MHz～2.5GHz	3V (RMS) 3V/m	Portable and mobile RF communication devices should be used no closer to any part of the upper arm type electronic blood pressure monitor, including cables, than the recommended isolation distance calculated from the equation applicable to the frequency of the transmitter. $d=1.2\sqrt{P}$ 150kHz-80MHz $d=1.2\sqrt{P}$ 80MHz～800MHz $d=1.2\sqrt{P}$ 800MHz～2.5GHz Where: P–maximum rated output power of the transmitter provided by the transmitter manufacturer, in watts (W); d–recommended isolation distance, in meters (m).The field strength of a fixed RF transmitter is determined by surveying the electromagnetic fielda, and in each frequency rangeb, it should be lower than the corresponding level. Interference may occur in the vicinity of devices marked with the following symbol.
Note 1: For the frequency points at 80 MHz and 800 MHz, the formula for the higher frequency range should be used. Note 2: These guidelines might not be applicable in all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects, and human.			
a) For fixed transmitters, such as radio (cellular/cordless) phones, base stations for ground mobile radios, amateur radios, AM and FM radio broadcasting, and television broadcasting, their field strengths cannot be predicted with precision theoretically. To assess the electromagnetic environment of fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location where the upper arm type electronic blood pressure monitor is used exceeds the applicable RF compliant level, the upper arm electronic blood pressure monitor should be observed to verify its normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the upper arm type electronic blood pressure monitor. b) Within the entire frequency range from 150 kHz to 80 MHz, the field strength should be less than 3 V/m.			

Table 4 Recommended isolation distances between portable and mobile RF communication devices and the ME equipment or ME systems – for non-life support ME equipment and ME systems

The upper arm type electronic blood pressure monitor is intended for use in an electromagnetic environment where RF radiation disturbances are controlled. Based on the maximum rated output power of the communication device, purchasers or users can maintain the following recommended minimum distances between portable and mobile radio frequency communication devices (transmitters) and the upper arm type electronic blood pressure monitor to prevent electromagnetic interference.

Rated maximum output power of transmitter (W)	Isolation distance according to frequency of transmitter (m)		
	150kHz～80MHz $d=1.2\sqrt{P}$	80MHz～800MHz $d=1.2\sqrt{P}$	800MHz～2.5GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended isolation distance d, in meters (m), can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum rated output power of the transmitter provided by the transmitter manufacturer, in watts (W).
Note 1: For the frequency points at 80 MHz and 800 MHz, the formula for the higher frequency range should be used.
Note 2: These guidelines may not be applicable in all scenarios as electromagnetic propagation is influenced by the absorption and reflection properties of buildings, objects, and the human body.

9. Product Warranty

- Within one week from the date of sale, if there are any quality issues caused by non-human factors with this product, WEIGAO Health is responsible for returns, exchanges, and warranties; under normal use and storage conditions, if there is a quality issue with this product within three years, the user can receive free maintenance with the purchase invoice and warranty card, except for consumables such as cuffs (including tube and air connectors) and batteries. The maintenance required after three years will incur reasonable charges.
- No free maintenance service will be provided for the following faults or damages caused by personal reasons of users:
  1) Unauthorized disassembly, repair, or modification of the product.
  2) Failures due to incorrect operation.
  3) Damages due to accidental drops.
  4) Failures due to improper maintenance.
  5) Corrosion damage due to battery leakage.
  6) Failures due to improper maintenance by those not authorized by WEIGAO Health.
- During warranty service, if there' s a need for circuit diagrams or necessary materials, or you have difficulties in the maintenance of electrical circuits, please contact the manufacturer.

<table>
<tr><th colspan="4">Warranty Card</th></tr>
<tr><td>Machine model</td><td></td><td>Machine No.</td><td></td></tr>
<tr><td>Purchase date</td><td></td><td>Invoice No.</td><td></td></tr>
<tr><td>Address</td><td colspan="3"></td></tr>
<tr><td>Sales store stamp</td><td colspan="3"></td></tr>
<tr><td rowspan="5">Maintenance records</td><td colspan="2">Item</td><td>Maintained by</td></tr>
<tr><td colspan="2"></td><td></td></tr>
<tr><td colspan="2"></td><td></td></tr>
<tr><td colspan="2"></td><td></td></tr>
<tr><td colspan="2"></td><td></td></tr>
<tr><td>Remarks</td><td colspan="3">Please present this card when claiming warranty services.</td></tr>
</table>