



Korotkoff Sound Blood Pressure Monitor User Manual

KSY3150 | KSY3150B | KH3160 | KH3160B | KSY3200 | KSY3200B | KSY3200A

Beijing Hanvon Health Technology Co., Ltd.

- Thank you for purchasing Hanvon Korotkoff Sound Blood Pressure Monitor.
- To ensure safe usage of this product, please read this user manual carefully before use.
- After reading, please keep it carefully for future reference.
- This Blood Pressure Monitor utilizes the electronic Korotkoff sound method for measurement.
- This product is suitable for scenarios such as families, hospitals, and clinics, etc.



Intended purpose: The device is a digital monitor intended for use in measuring the systolic pressure and diastolic pressure, as well as the pulse rate of adults and adolescents via a non-invasive auscultatory method in medical facilities or at home, with an inflatable cuff wrapped around the upper arm for arm circumferences ranging from 22 to 42 cm. The measurement ranges of the device are systolic pressure 40 ~ 280 mmHg (supported by automatic mode for 40 to 210 mmHg and manual mode for 210 to 280 mmHg), diastolic pressure 20 ~ 220 mmHg, and pulse rate 40 ~ 240 beats/min.

The device can detect Irregular Heart Beat (IHB), Atrial Fibrillation, Tachycardia, and evaluate Blood Pressure Variability (BPV), Time in Target Range (TTR) according to the measured blood pressure values.

Intended Patient: Adults and adolescents (> 12 years)

Clinical Benefit: Patient's blood pressure can be measured non-invasively and simply in the home and clinical environment.

Contraindications:

DO NOT use this monitor on an injured arm or an arm under medical treatment.

DO NOT apply the arm cuff on your arm while on an intravenous drip or blood transfusion.

DO NOT use this monitor on infants, toddlers, children or persons who cannot express themselves.

Structural Composition: It is composed of the main unit, the cuff, and the AC adapter (optional).

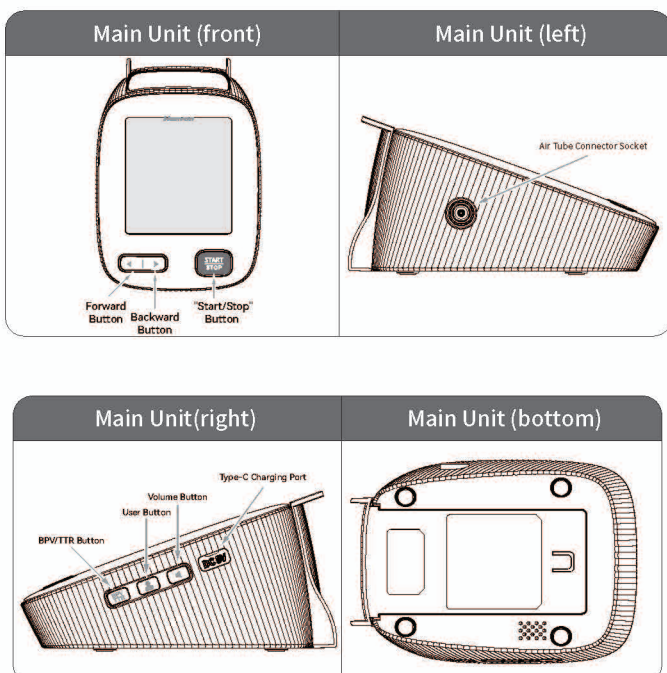
1. Product Introduction

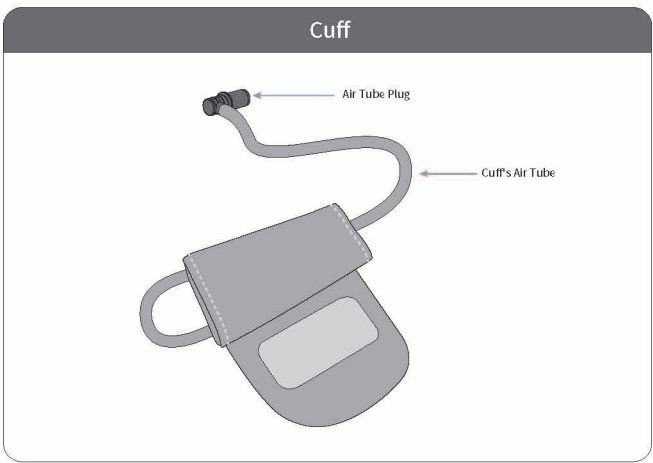
1.1 Packing List

All products are packed inside the packaging box. Open the box to check whether the products are complete. The list of items included in the box is shown in the table below. If you find any missing items, please contact the after-sales service.

Packing List	Quantity
Main Unit	1 unit
Cuff	1 piece
User Manual	1 copy
Quick Operation Guide	1 copy

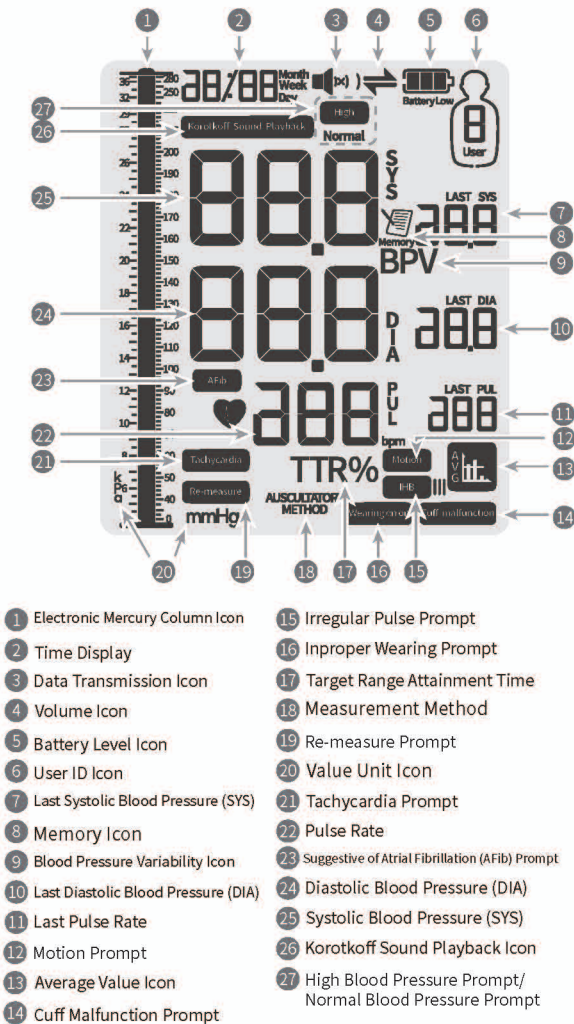
1.2 Component Description





* This product only supports the dedicated cuff of Hanvon.

1.3 Function Introduction



2. Safety Precautions

The terms "Warning" and "Caution" used in this manual pertain to the safety of using this product, with the following specific meanings:
Warning: Failure to comply may result in personal injury or death.
Caution: Failure to comply may result in personal injury or damage to property.

Explanation of Symbols

	Refer to instruction manual/ booklet		Temperature limit
	Warning		Humidity limitation
	Caution		Atmospheric pressure limitation
	CLASS II equipment		Keep away from sunlight
	Device classification: Authorized EU type BF applied part		Keep dry
	Non-ionizing electromagnetic radiation		Manufacturer
	Serial number		Authorized representative in the European Community
	Date of manufacture		Unique Device Identifier
	LOT number		Medical device
	Ingress Protection Rating		Model number

Warning

1. Do not frequently measure blood pressure unless medically necessary. Excessive frequent measurements may injure the patient due to blood flow interference, potentially leading to poor circulation or bruising.
2. If symptoms such as skin irritation occur during use, discontinue use and consult a physician; otherwise, symptoms may worsen.
3. If the Blood Pressure Monitor malfunctions or feels abnormal, discontinue use and arrange for inspection and repair.
4. Do not use simultaneously with other medical electrical equipment on the same limb. Cuff inflation may temporarily impair the function of monitoring ME equipment used concurrently on the same limb.
5. Do not apply the cuff to an arm with wounds or inflammation; otherwise, symptoms may worsen.
6. Do not use this product on an arm where other catheters are inserted, or on any limb undergoing intravascular intervention or treatment, or an arteriovenous (A-V) shunt, as this may temporarily interfere with blood flow and potentially injure the patient.
7. Do not use this device on the arm on the side of a mastectomy or lymph node dissection.
8. Do not use simultaneously with other medical electrical equip-

ment, as there is a risk of this product malfunctioning.

9. Ensure (e.g., by observing the relevant limb) that this product does not cause persistent damage to the patient's blood circulation. Patients with circulatory disorders or blood diseases shall use this product under medical supervision.

10. When measuring blood pressure, please note whether there is continuous cuff pressure caused by internal tubing kinking; if so, please stop the measurement.

11. Do not use in locations prone to fire or explosion, such as environments with flammable gases or high concentrations of oxygen.

12. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Blood Pressure Monitor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Caution

1. Please follow your doctor's instructions, do not self-diagnose or treat based on measurement results

2. When AFib, irregular heartbeat, or tachycardia prompts appear, it shall be confirmed after examination and diagnosis by a physician.

3. In common arrhythmias (such as atrial or ventricular premature beats and atrial fibrillation), arteriosclerosis, poor perfusion, diabetes, age, pregnancy, pre-eclampsia, kidney disease, patient movement, tremors, shivering, etc., measurements may cause errors.

4. Intended patient population: Adults aged 12 years and older; not suitable for neonates. The effectiveness of blood pressure measurement in pregnant women, including those with pre-eclampsia, has not been determined. Intended operators include patients.

5. Do not place within reach of neonates or children. There is a risk of neonates or children becoming entangled in the cuff air tube or AC adapter, and component parts may cause choking if swallowed.

6. During measurement, do not use electromagnetic interference-generating devices (e.g., mobile phones) near the device.

7. During measurement, keep the Blood Pressure Monitor and its vicinity free from significant vibration.

8. Do not use components not provided by the manufacturer; otherwise, measurement errors may occur.

9. Do not disassemble or modify the main unit or cuff of the Blood Pressure Monitor yourself.

10. Do not use beyond the product's service life.

11. Used batteries, instruments, and components must not be disposed of as general household waste; they shall be handled in accordance with local regulations.

12. Any blood pressure measurement is affected by the measuring site, posture, movement, and physiological condition of the measured individual. If you have doubts about the measurement results, rest for 5 minutes and remeasure, or consult a physician.

13. If an abnormality occurs during measurement (e.g., the cuff remains excessively inflated), please remove the cuff; otherwise, the arm may be compressed, leading to bruising or paralysis.

14. All functions of this product can be safely used by patients and can be simply maintained according to the cleaning and maintenance methods.

15. If there are contaminants such as dust or lint on the device surface, clean it according to the cleaning and disinfection methods.

16. Do not use this product in the following environments: near high-frequency surgical equipment, magnetic resonance imaging (MRI) devices, or CT scanners; or in high-oxygen environments.

17. Do not use this product in moving vehicles such as cars or airplanes.

18. Do not place the device in a location where unplugging it is difficult.

19. Do not use the device in environments containing flammable anesthetic gases mixed with air, oxygen, or nitrous oxide.

20. Do not use this device near televisions, microwave ovens, mobile phones, X-ray equipment, or other sources of strong electromagnetic fields, as these may interfere with measurements.

21. This Blood Pressure Monitor and cuff are not waterproof, so avoid rain, sweat, and water. Do not use in damp or splash-prone areas.

22. This Blood Pressure Monitor is a precision instrument; avoid excessive use in unsuitable environments such as high temperatures, low temperatures, humidity, direct sunlight, vibration, or dust.

23. When the ambient temperature is 20°C, the Electronic Blood Pressure Monitor requires a 4-hour stabilization period after being moved from the minimum or maximum storage temperature before it is ready for measurement.

24. Operating environment: Temperature: 5°C - 40°C, relative humidity: 15% - 90%, non-condensing, atmospheric pressure: 700hPa - 1060hPa.

25. Transport and storage environment: Temperature: -20°C - 55°C, relative humidity: <93%, non-condensing, atmospheric pressure: 500hPa - 1060hPa.

26. If stored or used outside the manufacturer's specified temperature, relative humidity, and atmospheric pressure ranges, the system may not achieve the claimed performance specifications.

27. This device can be charged via a Type-C interface, charging input: DC 5V 1A. Please use an AC adapter that complies with the requirements of IEC 60601-1 standard.

28. Non-transit- operable.

29. Cuff is the applied part.

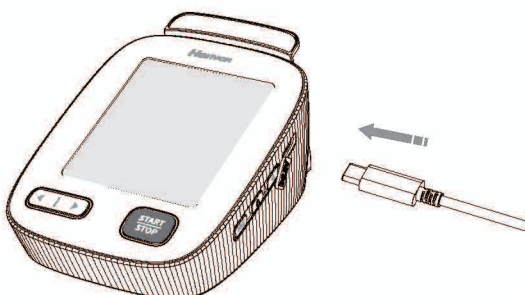
30. This Blood Pressure Monitor has undergone clinical investigation in accordance with the requirements of ISO 81060-2:2018+AMD

1:2020.

3. Product Charging and Setting

3.1 Product Charging

- This blood pressure monitor uses lithium battery power, please ensure sufficient power when in use.
- When in use, if the  icon appears, it indicates low battery power, please charge the battery as soon as possible.
- Connect the AC adapter to the Type-C interface and power supply for charging, the battery bar flashes during charging, and  is displayed after full charge.



- Please connect the AC adapter to the main unit's charging port and a safe and reliable power outlet, ensuring a reliable connection between the AC adapter and the outlet.
- After charging is complete, please disconnect the power promptly and unplug the charging adapter.

Battery Life

Under the conditions of the ambient temperature (25°C), 28cm arm circumference, and a patient simulator set to 120/80mmHg (16.0/10.6kPa) standard measurement mode, a set of fully charged lithium batteries can perform approximately 300 measurements. The actual number of measurements may vary depending on the usage environment and the blood pressure level of the user.

Under standard test conditions (temperature: 23±2°C, humidity: ≤75%RH, atmospheric pressure: 86-106kPa), the battery can undergo approximately 300 charge-discharge cycles, the actual number of cycles may vary due to different charging and discharging environments.

Precautions

- This device can be charged via a Type-C interface, charging input: DC 5V 1A. Please use an AC adapter that complies with the requirements of IEC 60601-1 standard.
- When the batteries are depleted, Setting will revert to factory defaults, but stored measurement values will not be lost.
- Do not disassemble or replace the lithium battery, otherwise, it may cause battery heating, leakage, rupture, etc., damaging the blood pressure monitor's main unit.
- If the lithium battery's performance significantly degrades or it is damaged, please contact after-sales service personnel.
- Do not place the device near a fire source.
- Do not subject the lithium battery to pressure from hard objects.
- If the device is not used for an extended period (more than 6 months), please charge the battery, otherwise, it may cause over-discharge of the battery, damaging the device.
- Dispose of used batteries according to local environmental protection regulations.
- During use, if the product has no charging icon prompt when powered via AC adapter, please contact the supplier promptly.
- Please use the original factory's legitimate AC adapter, disconnect the AC adapter from the power supply after the device is fully charged.
- When unplugging the AC adapter, hold the plug itself, and do not pull the AC adapter.
- When using the AC adapter, be careful to avoid damage. Do not modify, forcefully bend, stretch, bundle, or pinch it, and do not place heavy objects on it.
- Do not use damaged AC adapters or power plugs. Do not plug or unplug the AC adapter with wet hands.
- When not in use for an extended period, please unplug the AC adapter.

3.2 Setup Menu

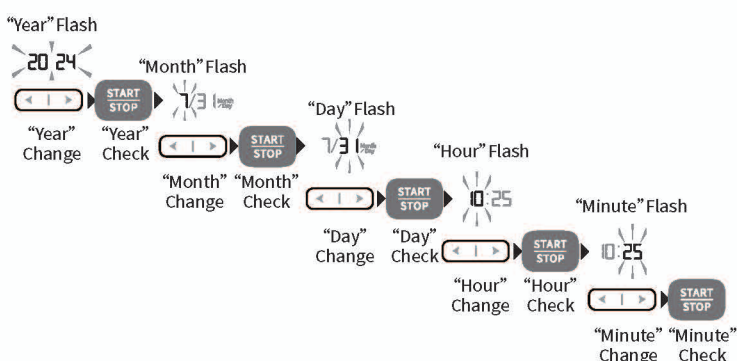
With the device powered off, simultaneously press and hold the Forward and Backward buttons  for more than three seconds to enter the Setting menu.

In the Setting menu, configurable items include: Date and Time, Pressure Unit, TTR Systolic and Diastolic Pressure Target Values, and Data Transmission Method.

Date and Time Setting:

Automatically synchronize network time and date after connecting to Bluetooth, users can also manually set the device's time and date.

Manual setting methods: Year Setting, Month Setting, Day Setting, Hour Setting, and Minute Setting.



Pressure Unit Setting:

The device's default pressure unit is mmHg, press the Forward or Backward navigation button  to switch the pressure unit between mmHg and kPa, press the  button to confirm the pressure unit setting.

TTR Target Value Setting:

The default target value is 135/85mmHg, press the Forward or Backward navigation button  to set the target value, and press the  button to confirm the TTR target value setting.

Data Transmission Setting:

KSY3150, KH3160, KSY3200: No data transmission function.

KSY3150B, KH3160B, KSY3200B, KSY3200A: Bluetooth is enabled by default, broadcast starts upon power on. Press the Forward or Backward button  to switch the network switch status. If the data transmission indicator  is displayed, the data transmission function is active; if not displayed, it is off. Press the  button to confirm the "Data Transmission" setting.

When data transmission is turned off, blood pressure records will not be uploaded.

When the device is powered on and communication is not connected, the screen icon  is not displayed; when communication is connected, the  icon is continuously lit; when communication is connected and data is being sent, the  icon flashes.

This product is a wireless device for low-power data communication systems.

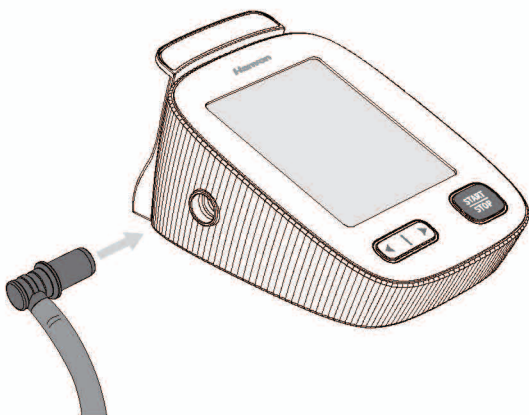
Do not use this product in locations where wireless devices are restricted, such as airplanes or hospitals, and turn off the Bluetooth communication function.

As wireless signals are used, they may be intentionally or unintentionally received by third parties. Do not use for important matters requiring confidentiality or for life-critical purposes.

4. Measuring Blood Pressure

4.1 Connecting the Cuff

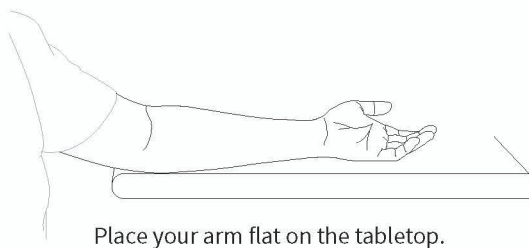
Insert the cuff air tube into the main unit's cuff interface, aligning the step of the air tube plug with the connection hole.



Note: If the cuff air tube is not properly connected, it may affect measurements and cause a device to report an error. Please refer to Section 4.15 "Common Issues" for adjustments.

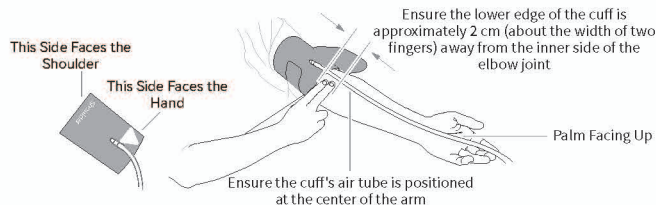
4.2 Wearing the Cuff

1. Select the appropriate cuff.
2. The cuff is made of polyester and does not contain natural latex. Place your arm flat on the tabletop with your palm facing up, sit upright, and ensure that the center of the cuff is at the same height as your heart.



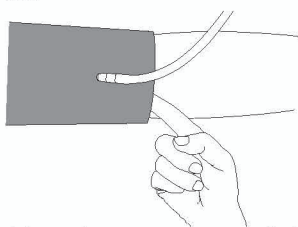
Place your arm flat on the tabletop.

Following the wearing instructions on the cuff, place the cuff on the upper arm to be measured, ensuring that the air tube is on the inside of the upper arm and the tubing is aligned with your middle finger. Make sure that the lower edge of the cuff is approximately 2 cm (0.79 inch) (about two fingers' width) above the elbow joint. Tighten the free end of the cuff and secure the adhesive strip.



⚠ Caution

(1) The cuff of this product contains sound wave sensors to collect Korotkoff Sound signals. To ensure that the product can obtain better Korotkoff Sound signals, it is advisable to leave a gap of one finger's width between the lower edge of the cuff and the skin after attachment. Excessive looseness or tightness may affect the accuracy of the measurement.



It is advisable to leave a space of about one finger between the cuff and the arm.

(2) The cuff is a consumable component. Based on an estimated usage frequency of 6 times per day, it is recommended to replace the cuff every two years.

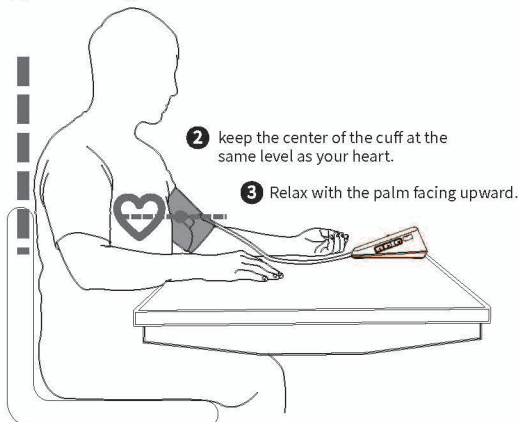
(3) If the cuff is damaged, develops air leaks, or exhibits other malfunctions, contact the after-sales service to purchase a replacement.

(4) The cuff is designed to measure arm circumferences ranging from 22 to 42 cm (8.66 - 16.54 inch) (measured at the midpoint of the upper arm). If the arm circumference falls outside this applicable range, measurement accuracy cannot be guaranteed.

4.3 Correct Measurement Posture

Incorrect measurement posture will result in inaccurate measurement results. Please adhere to the following guidelines for measurement posture and environment.

- 1 Keep your back straight.



Correct measurement postures:

Sit in a comfortable position;

Please measure your blood pressure in a room with a comfortable temperature, keeping your body relaxed and your sitting posture natural;

Place both feet flat on the ground without crossing your legs;

Keep your back and arms supported;

Ensure that the middle of the cuff is at the level of the right atrium of the heart;

⚠ Caution

Do not take measurements immediately after eating, drinking alcohol, smoking, exercising, or showering; wait at least 30 minutes before starting the measurement;

Please empty your bladder before taking the measurement;

Before the first measurement, sit quietly for 5 minutes and try to relax as much as possible;

Do not move or speak during the measurement; keep your body relaxed and your sitting posture natural. For consecutive measurements, allow an interval of at least 2 minutes;

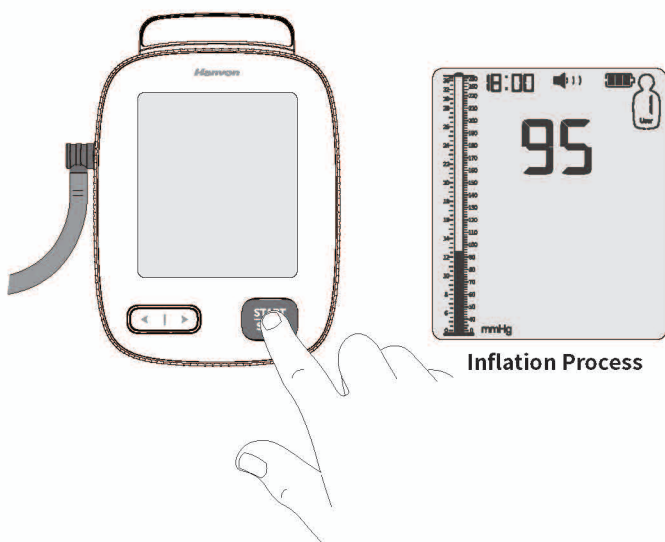
During normal use, the operator may be the patient themselves or another individual. If the operator is the patient, they must follow the above posture requirements; no special requirements apply to other operators;

Ensure that the cuff connection tube is not compressed or restricted; Rated range of cuff pressure: 0 - 299 mmHg (0 - 39.9 kPa).

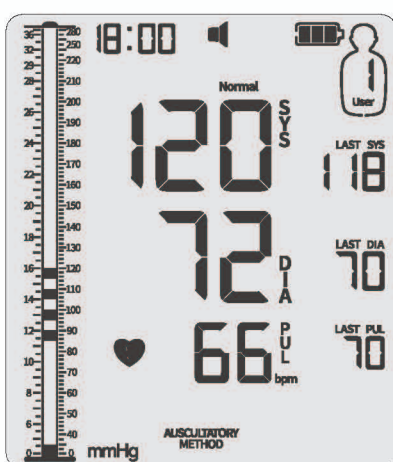
4.4 Accurately Measuring Blood Pressure with One Click

Once the cuff is properly fastened, simply press the **START STOP** button to start the blood pressure measurement. For effective blood pressure management, it is recommended to take measurements at the same time and in the same environment each day.

Press the **START STOP** button to start automatic accurate measurement, and the display shows the real-time cuff inflation pressure value.



4.5 High-Definition Large Screen Display of Measurement Results



After the measurement is complete, the User ID to which this measurement result belongs needs to be confirmed. When the screen displays measurement results, the device's current User ID will flash as a prompt; if you need to modify the User ID, please toggle the user button  to switch. After confirming the User ID,

the corresponding measurement result is recorded under that user. User ID switching can be performed before the device powers off, measurement results will be recorded under the last set user.

On the measurement results interface, the electronic mercury column indicator can display pulse pressure, with one grid representing 10mmHg. When the pulse pressure's single digit is greater than or equal to 5mmHg and less than or equal to 9mmHg, an additional single grid will be displayed at the bottom of the mercury column; when the pulse pressure is greater than 60mmHg, the mercury column will flash.

Remove the cuff and press the **START STOP** button to power off the device. If **START STOP** is not pressed, the device will automatically shut down after approximately 120 seconds.

Caution:

use the manual inflation function. Please refer to 4.10 Manual Inflation.

Rated range for systolic pressure: 40mmHg (5.3kPa) - 280mmHg (37.4kPa)

Rated range for diastolic pressure: 20mmHg (2.7kPa) - 220mmHg (29.4kPa)

4.6 Voice Broadcast

Voice broadcast is available for measurement preparation, measurement results, and blood pressure classification. In the power-off state or during measurement, press the Voice Control button  to turn off voice broadcast or adjust the voice broadcast volume.

4.7 Blood Pressure Classification and Hypertension

BP Category	Systolic BP	Diastolic BP
Normal	<120 mmHg and <80 mmHg	
Elevated	120-129 mmHg and <80 mmHg	
Hypertension Stage 1 Stage 2	130-139 mmHg or 80-89 mmHg ≥ 140 mmHg or ≥ 90 mmHg	

***Individuals with Systolic BP and Diastolic BP in 2 categories should be designated to the higher BP category.**

BP indicates blood pressure (based on an average of ≥ 2 careful readings obtained on ≥ 2 occasions).

Source: ACC/AHA 2017 High Blood Pressure Clinical Practice Guideline.

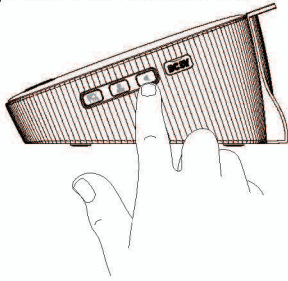
Note: Currently, there is no clear definition for hypotension. It is generally considered that hypotension is categorized as a systolic blood pressure < 90 mmHg or a diastolic blood pressure < 60 mmHg.

4.8 Atrial Fibrillation Prompt

When atrial fibrillation occurs during measurement, an "AFib" indicator will be displayed in the measurement results; when an AFib prompt appears, it needs to be confirmed after examination and diagnosis by a physician.

4.9 Korotkoff Sound Playback

On the measurement results and measurement records interface, data groups that can perform Korotkoff sound playback will display an volume icon ; short-press the Voice Control button  to play back the recorded pulsatile wave vibrations of blood flow in the brachial artery during this measurement, under the action of the cuff, to listen to Korotkoff sounds and confirm whether the blood pressure value is accurate.



4.10 Manual Inflation

This device defaults to automatic inflation mode.If your systolic pressure is more than 210 mmHg or the screen displays Er02:

After the arm cuff starts to inflate, press and hold the [START/STOP] button until the monitor inflates 20 to 30 mmHg higher than your expected systolic pressure. Do not inflate above 299 mmHg.

Manual Inflation Operation:

During device inflation, when the screen displays the pressure value, long-press the **START STOP** button, the device will automatically recognize and initiate manual inflation; continue to hold the button until the pressure value displayed is higher than the estimated maximum blood pressure (20mmHg - 30mmHg (2.6kPa - 4.0kPa)), then release the **START STOP** button, and the device will begin deflation and start the measurement.

