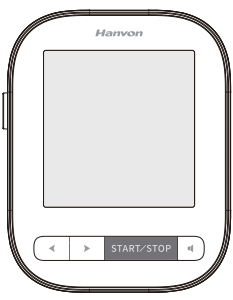
Hanvon

Korotkoff Sound Blood Pressure Monitor User Manual

KSY3110/KSY3118B/KSY3110B

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) and Tachycardia. Model KSY3118B additionally supports Atrial Fibrillation detection.
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).

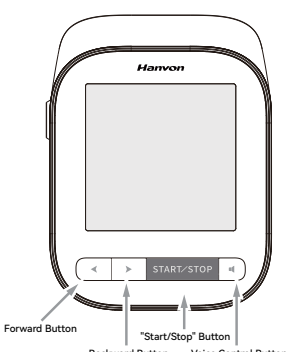
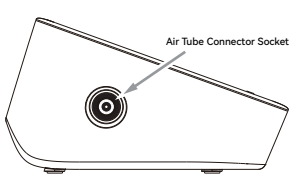
1. Product Introduction

1.1 Packing List

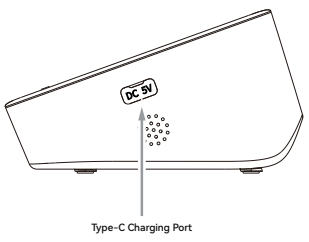
All products are packed inside the packaging box. Open the box to check whether the products are complete. The list of items included in the box is shown in the table below. If you find any missing items, please contact the after-sales service.

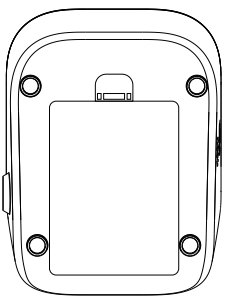
Packing List	Quantity
Main Unit	1 unit
Cuff	1 piece
AA Battery	4 pieces
User Manual	1 copy
Quick Operation Guide	1 copy

1.2 Component Description

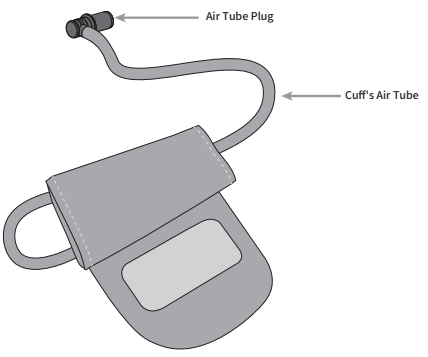
Main Unit (front)	Main Unit (left)
	

Main Unit(right)	Main Unit (bottom)



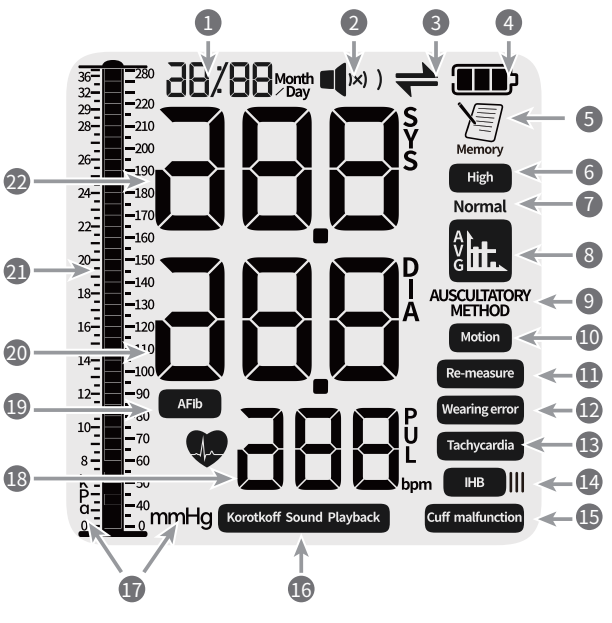


Cuff



*** This product only supports the dedicated cuff of Hanvon.**

1.3 Function Introduction



1. Time Display
2. Volume Icon
3. Data Transmission Icon
4. Battery Level Icon
5. Memory Icon
6. High Blood Pressure Prompt
7. Normal Blood Pressure Prompt
8. Average Value Icon
9. Measurement Method
10. Motion Prompt
11. Re-measure Prompt
12. Inproper Wearing Prompt
13. Tachycardia Prompt
14. Irregular Pulse Prompt
15. Cuff Malfunction Prompt
16. Korotkoff Sound Playback Icon
17. Value Unit Icon
18. Pulse Rate
19. Suggestive of Atrial Fibrillation (AFib) Prompt
20. Diastolic Blood Pressure (DIA)
21. Electronic Mercury Column Icon
22. Systolic Blood Pressure (SYS)

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
SN	Serial number	EU REP	Authorized representative in the European Community
	Date of manufacture	UDI	Unique Device Identifier
LOT	LOT number	MD	Medical device
IP20	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 equipment, 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. Measurements may be inaccurate in cases of common arrhythmias (e.g., atrial or ventricular premature beats and atrial fibrillation), arteriosclerosis, poor perfusion, diabetes, old age, pregnancy, pre-eclampsia, kidney disease, patient movement, tremors, or shivering.
4. 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 connected to an AC adapter via a Type-C interface for measurement. 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 Power Supply and Setting

3.1 Power Supply Method

(1) Lithium Batteries:

Inserting Batteries: press the clasp of the battery cover, pull outwards and remove the battery cover, insert batteries according to the positive and negative terminals inside the battery cover, and close the battery cover.

Battery Replacement:

During use, if the icon appears, it indicates the batteries are depleted; please replace them immediately.

Please replace all 4 batteries simultaneously with new ones of the same type. Turn off the Blood Pressure Monitor before replacing batteries.

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.

⚠ **Precautions**

Dispose of used batteries according to local environmental protection regulations.

● When the batteries are depleted, Setting will revert to factory defaults, but stored measurement values will not be lost.

● If the device is not used for a long period (more than 3 months), please remove the lithium batteries to prevent potential damage from battery leakage.

(2) Connect to Power with an AC adapter

This device can be connected to an AC adapter via a Type-C interface for measurement. Insert the AC adapter plug into the AC adapter port (Type-C interface) on the side of the Blood Pressure Monitor, and plug the AC adapter's power plug into an independent power outlet. Please use an AC adapter that complies with the requirements of IEC 60601-1 standard.

⚠ **Precautions**

● Do not place the device near a fire source.

● 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

3.2 Setup Menu

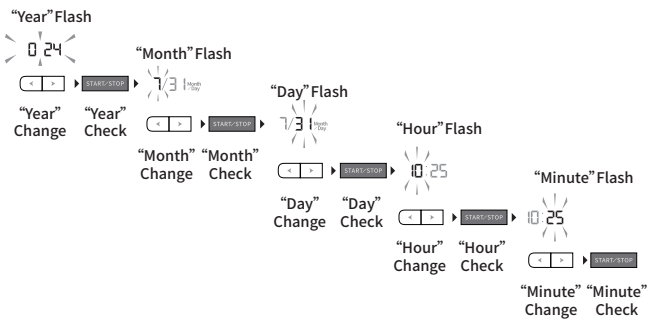
With the device powered off, press and hold both Forward and Backward buttons simultaneously for more than 3 seconds to enter the Setting menu.

In the Setting menu, configurable items include: Date and Time, Pressure Unit, 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 button to switch the pressure unit between mmHg and kPa, and press the START/STOP button to confirm the pressure unit setting.

Data Transmissi on Setting:

KSY3110: No data transmission function.

KSY3118B, KSY3110B: Bluetooth is enabled by default. 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 START/STOP 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.

⚠ **Caution:**

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

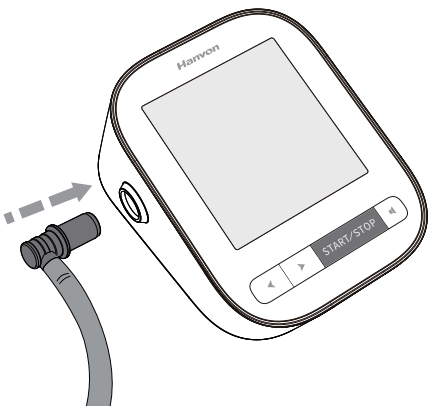
Do not use this product in locations where wireless devices are restricted, such as airplanes or hospitals, and turn off the Bluetooth communication function.

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 cuff interface on the main unit.

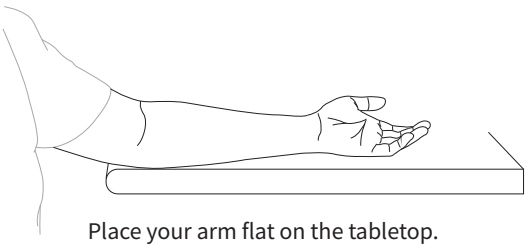


Note: If the cuff air tube is not pr operly connected, it may affect measurements and cause a device to report an error. Please refer to Section 4.13 "Common Issues" for adjustments.

4.2 Wearing the Cuff

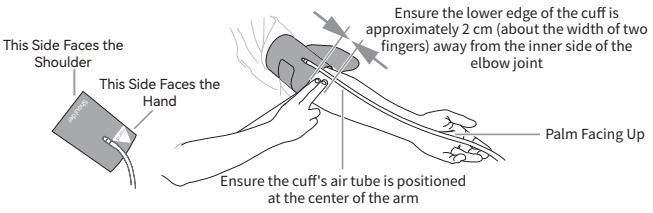
1.Select the appropriate cuff.

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.



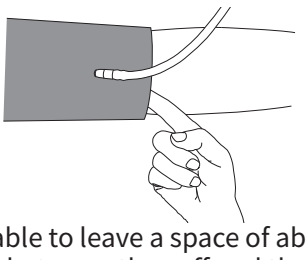
Place your arm flat on the tabletop.

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.

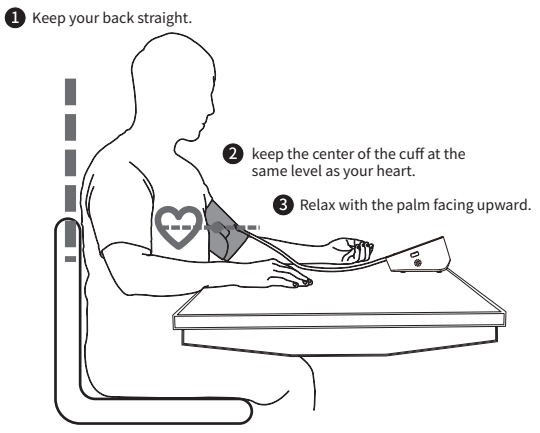
(2) The cuff is a consumable component. Based on an estimated usage frequency of 6 times per day, it is recommended to replace the cuff every two years.

(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.



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;

Please measure the blood pressure indoors at an appropriate temperature;

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;

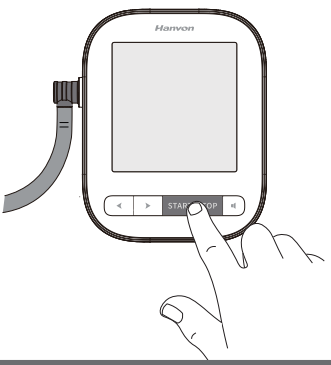
Ensure that the cuff connection tube is not compressed or restricted;

Rated range of cuff pressure: 0 - 299 mmHg (0 - 39.9 kPa).

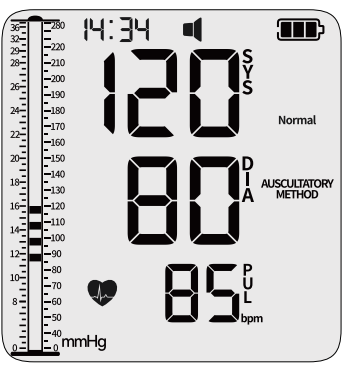
4.4 Accurately Measuring Blood Pressure with One Click

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



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:**

The blood pressure values obtained from measurements shall be interpreted by a medical professional.

When the predicted systolic pressure exceeds 210mmHg (28.0kPa), 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 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.

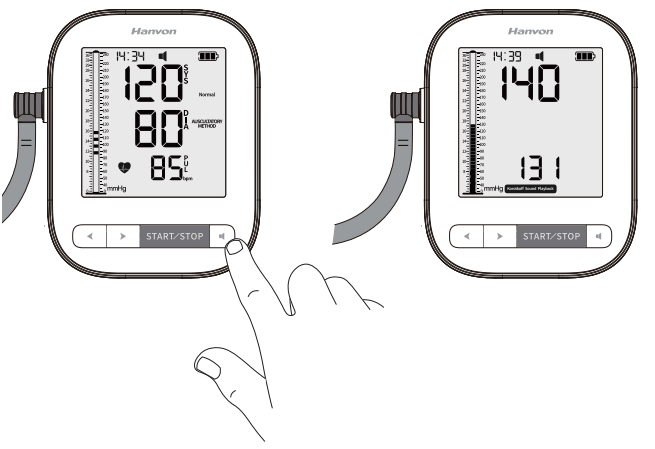
Note: Currently, there is no clear definition for hypotension. It is generally considered that hypotension is categorized as a systolic blood pressure < 90 mmHg or a diastolic blood pressure < 60 mmHg.

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. (Only KSY3118B supported)

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.



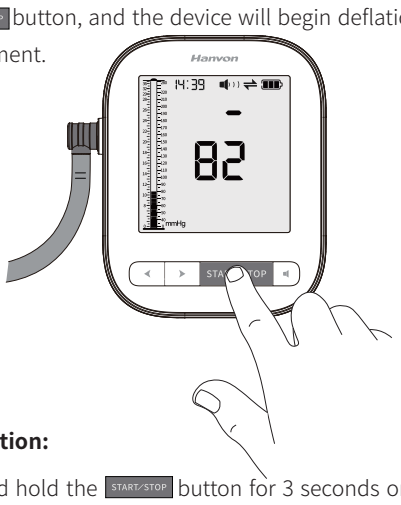
4.10 Manual Inflation

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.



Caution:

Press and hold the START/STOP button for 3 seconds or longer, and the device will enter manual inflation mode; otherwise, the device will power off.

If cuff pressure exceeds 299 mmHg/39.9 kPa, the device automatically deflates and displays 'Er03'.

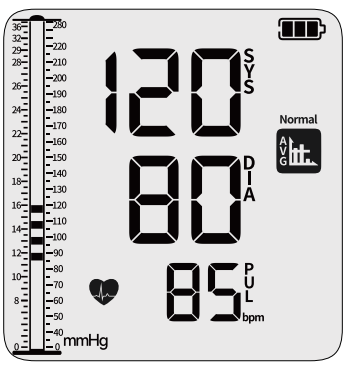
WARNING: Do not keep the arm under systolic pressure for extended periods, otherwise, it may cause acute internal bleeding. Once manual inflation is enabled, continuously monitor the condition of the arm being measured. (Measurement ranges: automatic mode effective up to 210 mmHg systolic; manual mode up to 280 mmHg systolic.)

4.11 Viewing Measurement Records and Average Value

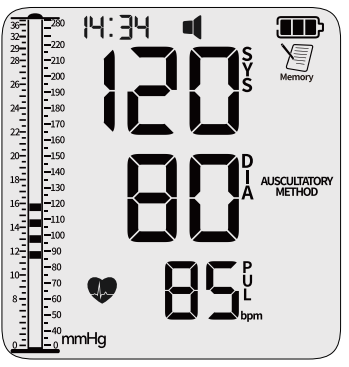
This blood pressure monitor automatically saves the date, time, blood pressure value, and pulse rate during measurement. If the date and time are not set, it will not be able to accurately memorize the measurement date and time.

KSY3110, KSY3118B, and KSY3110B can save 100 sets of blood pressure measurements.

(1)Viewing Average Value: From the power-off state/measurement results interface, short-press the Backward button to display the average value of the last 2 measurement data, and simultaneously the average value icon illuminates.



(2)Viewing Measurement Records: From the power-off state/measurement results/average value interface, short-press the Forward button to view the most recent measurement. Short-press the Forward or Backward button to browse measurement records or back to the average value interface.



(3) In the record interface, long-press the button for more than 3 seconds to delete all currently memorized measurement data. This function can only delete all current data, rather than specific data.

(4) From the power-off state, long-press the Backward button for more than 20 seconds to display the software version number.

4.12 Abnormal Situation Prompts

When any of the following abnormal prompts appear on the measurement result interface: ["AFib" (KSY3118B), "Cuff malfunction", "Motion/Re-measure", "Tachycardia", "IHB", "High", "Wearing error"], the corresponding prompt text will flash on the measurement result interface.

When the "Tachycardia" prompt appears, the pulse value on the measurement result screen will also flash synchronously.

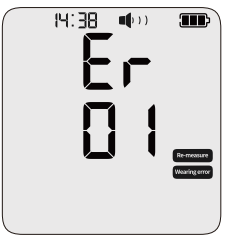
When systolic pressure (SYS) ⩾130mmHg and/or diastolic pressure (DIA) ⩾80mmHg, in addition to the "High" prompt flashing on the measurement result screen, the corresponding elevated blood pressure values will also flash synchronously on the measurement result screen.

4.13 Common Issues

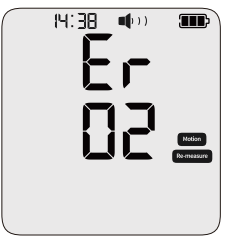
When a system error occurs or affects measurement results, an error report or prompt message will be given. Please check the error and adjust promptly.

Error Message	Cause of Error	Solution
Er01	Cuff is worn too loosely; Cuff connector is loose; Cuff is leaking air;	Please wrap the cuff correctly; Please check if the cuff connector is securely plugged in; If the above methods are ineffective, please contact after-sales service;
Er02	During measurement, arm or body movement causes improper inflation or prevents measurement	During measurement, please remain quiet and ensure that the arm and body are still. If there is no accidental movement, and the same error recurs, please use manual inflation for another measurement.
Er03	Pressure exceeds 299mmHg (39.9kPa) during measurement.	When using the manual inflation function, the maximum cuff pressure shall not be too close to 299mmHg (39.9kPa).
Er04	Unable to detect pulse due to movement of the arm or body during measurement.	Please remain still with your arm and body before measuring again.
	Before applying the cuff, overly thick clothing was not removed, or rolled-up sleeves compressed the arm.	Please remove overly thick clothing, do not roll up your sleeves, and re-apply the cuff for measurement.
Er05	Measurement results exceed the nominal measurement range.	Rated range for diastolic pressure: 20mmHg - 220mmHg (2.7kPa - 29.4kPa); Rated range for systolic pressure: 40mmHg - 280mmHg (5.3kPa - 37.4kPa).
Other errors	Errors not listed in this table occurred	Please contact customer service

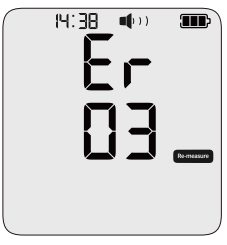
Error Message Examples



Er01

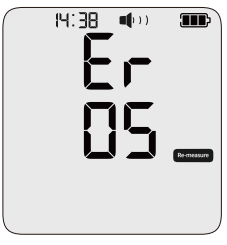


Er02



Er03

Er04



Er05

5. Operating Principle

The Blood Pressure Monitor utilizes an intelligent inflation algorithm and inflate the cuff using an air pump, then applies pressure to the arterial blood vessel with the inflated cuff. As the cuff pressure rises, the arterial vessel undergoes a process of fully open, semi-occluded, and fully occluded states. After determining the complete occlusion of the arterial vessel through pulse pressure fluctuations, cuff inflation stops, and the cuff pressure slowly decreases. When the cuff pressure drops to the systolic pressure, Korotkoff sounds are generated. When the cuff pressure drops to the diastolic pressure, Korotkoff sounds disappear. The Blood Pressure Monitor collects Korotkoff sound signals via an acoustic sensor in the cuff and measures air pressure values via a pressure sensor, applying a fixed algorithm based on neural network, to intelligently determine the user's blood pressure value. This blood pressure measurement method is called the electronic Korotkoff method, also known as the electronic auscultatory method. This new generation of Blood Pressure Monitors, employing revolutionary measurement technology, can accurately measure human blood pressure, elevating the precision of blood pressure measurement to a new height and setting a new benchmark for accurate blood pressure measurement. This electronic Korotkoff blood pressure measurement method can substitute the traditional measurement method of mercury sphygmomanometer.

6. EMC Technical Data

Electromagnetic Compatibility (This product complies with EMC standards)

It will not emit electromagnetic interference noise beyond the permissible limits to other nearby electronic devices, and the device can function normally in an electromagnetic environment where other electronic devices emit noise or similar interference.

1. This section provides specific guidance on electromagnetic compatibility. The Electronic Blood Pressure Monitor shall be installed and used in accordance with the electromagnetic compatibility information in this section.
2. Portable and mobile RF communication equipment may affect the use of the Electronic Blood Pressure Monitor. During normal use of the Monitor, it is recommended to keep it away from portable and mobile RF communication equipment or ensure they are turned off.
3. Warning: Using accessories from other manufacturers, other than those provided by our company, may lead to increased emissions from the Electronic Blood Pressure Monitor or reduced immunity to interference.
4. The Electronic Blood Pressure Monitor shall not be used in close proximity to or stacked with other equipment that operates at the same or similar frequencies. If proximity or stacking is necessary, observation and verification shall ensure that it operates normally in the configured setup.
5. The basic performance is as follows: Laboratory repeatability of blood pressure measurement for the Blood Pressure Monitor is ≤ 3mmHg (0.4kPa); within the temperature range of 5°C - 40°C and relative humidity range of 15% - 90% (non-condensing), the maximum error of cuff pressure measurement at any point within the nominal measurement range shall be ≤±2mmHg

Guidance and manufacturer’s declaration – electromagnetic emissions		
The Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of Blood Pressure Monitor should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Blood Pressure Monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Blood Pressure Monitor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/-Voltage Fluctuations and Flicker emissions IEC 61000-3-3	Pass	The Blood Pressure Monitor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

(±0.27kPa) or ±2% of the reading, whichever is greater.

6. When the Korotkoff Sound Blood Pressure Monitor is in normal use, it may generate electromagnetic interference to other diagnostic or therapeutic equipment. When in use, please maintain an appropriate distance from other equipment and carefully observe the correctness of data during the use of that equipment.

7. To ensure the normal use of Korotkoff Sound Blood Pressure Monitor functions normally and that its emissions are not increased, and its immunity is not decreased, please use the cuff and related accessories provided by our company.

Table 1: Electromagnetic Mission

Guidance and manufacturer' s declaration – electromagnetic emissions		
The Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of Blood Pressure Monitor should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Blood Pressure Monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Blood Pressure Monitor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/-Voltage Fluctuations and Flicker emissions IEC 61000-3-3	Pass	

Table 2: Electro magnetic Immunity 1

Guidance and manufacturer´s declaration – electromagnetic immunity			
The Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Blood Pressure Monitor should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment –guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ±8 kV Air: ±2 kV,±4 kV, ±8 kV,±15 kV	Contact: ±8 kV Air: ±2 kV,±4 kV, ±8 kV,±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. If ESD interfere with the operation of equipment, counter measurements such as wrist strap, grounding shall be considered.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	Differential mode: ±0.5 kV, ±1 kV Common mode: ±0.5 kV, ±1 kV, ±2 kV	Differential mode: ±0.5 kV, ±1 kV Common mode: ±0.5 kV, ±1 kV, ±2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT (100 % dip in UT) for 0,5 cycle 0 % UT (100 % dip in UT) for 1 cycles 70 % UT (30 % dip in UT) for 25/30cycles 0 % UT (100 % dip in UT) for 250/300 cycles	0 % UT (100 % dip in UT) for 0,5 cycle 0 % UT (100 % dip in UT) for 1 cycles 70 % UT (30 % dip in UT) for 25/30cycles 0 % UT (100 % dip in UT) for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Blood Pressure Monitor requires continued operation during power mains interruptions, it is recommended that the Blood Pressure Monitor be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power Frequency Magnetic Field Immunity should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 3: Electromagnetic Immunity 2

Guidance and manufacturer’s declaration – electromagnetic immunity			
The Blood Pressure Monitor is intended for use in the environment specified below. The customer or the user of the Blood Pressure Monitor should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment –guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz (6V in ISM bands between 0.15MHz and 80 MHz)	3 Vrms 150 kHz to 80 MHz (6V in ISM bands between 0.15MHz and 80 MHz)	Portable and mobile RF communications equipment should be used no closer to any part of the Blood Pressure Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{p}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,7 GHz	3V/m 80 MHz to 2,7 GHz	$d = 1.2\sqrt{p}$ 80 MHz to 800 MHz $d = 2.3\sqrt{p}$ 800 MHz to 2,7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
Proximity fields from RF wireless communications equipment IEC 61000-4-3	Table 9 of IEC 60601-1-2:2020	Table 9 of IEC 60601-1-2:2020	
Proximity magnetic fields IEC 61000-4-39	Table 11 of IEC 60601-1-2:2020	Table 11 of IEC 60601-1-2:2020	

FCC Caution

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

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.
This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
-Reorient or relocate the receiving antenna.
-Increase the separation between the equipment and receiver.
-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
-Consult the dealer or an experienced radio/TV technician for help.
The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

7. Specifications and Warranty

7.1 Specifications

Name	Korotkoff Sound Blood Pressure Monitor
Model	KSY3110/KSY3118B/KSY3110B
Power Supply Mode	4 “AA” batteries (DC 6V)
Display Mode	LCD screen display
Blood Pressure Measurement	Measurement and display range: SYS: 40 mmHg (5.3 kPa) ~ 280 mmHg (37.4 kPa) DIA: 2 0 mmHg (2.7 kPa) ~ 220 mmHg (29.4 kPa)
	Resolution: 1 mmHg (0.1 kPa)
	Accuracy limit under environmental conditions: ±2 mmHg(±0.27 kPa)or ±2% of the reading, whichever is greater
Pulse Measurement	Measurement range: 40 ~ 240 beats/min
	Resolution: 1 beat/min
	Measurement accuracy: ±5%
Cuff pressure display range	0 - 299 mmHg
Memory	Stores up to 50/100/200 readings, see section 7.2 for specific parameters.
Data Transmission	Bluetooth/ No Transmission, see section 7.2 for specific parameters.
Operating Mode	Continuous operation
Power Source	Use an external adapter (DC 5V 1A) or 4 “AA” batteries for power supply
Battery life	Approx. 300 measurements (using 4 “AA” batteries)
Service Life	Main Unit: 5 years from the date of manufacture (based on 6 uses per day). Cuff: 10,000 uses (recommended replacement every 2 years as a consumable).Optional AC adapter: 5 years
Operating Environment	Temperature: 5°C - 40°C; Relative humidity: 15% - 90%, non-condensing; Atmospheric pressure: 700 hPa - 1060 hPa
Transport and Storage Conditions	Temperature: -20°C - 55°C; Relative humidity: ≤93%, non-condensing; Atmospheric pressure: 500 hPa - 1060 hPa
Main Unit Weight	Approximately 300g (without batteries)
Main Unit Dimensions	Approximately Length: 128mm * Width: 97mm * Height: 75mm
Cuff Size Compatibility	Suitable for arm circumference: 22cm - 42cm, 22-36cm (optional)
Electric Shock Protection	Class II device (internal power source when not using an adapter); BF type applied part
Electromagnetic Compatibility	Group 1, Class B Equipment
IP Classification	IP20
Embedded Software Release Version	1

7.2 The differences among all models in this manual are as follows

Model	Communication Mode	AFib Detection
KSY3110	None	None
KSY3118B	Bluetooth	Yes
KSY3110B	Bluetooth	None

8. Cleaning, Maintenance and Warranty

8.1 Cleaning and Maintenance

The Blood Pressure Monitor is a non-sterile medical device and must be routinely cleaned by the operator before use.

Please keep the Blood Pressure Monitor clean. If the outer surface of the main unit or cuff is contaminated, use a clean, soft cloth dampened with approximately 75% medical-grade ethanol, wring it out thoroughly, then gently wipe the surface twice. Allow it to air-dry for 3 minutes. It is recommended to clean the device once a month.

Caution: Do not allow any liquid to penetrate the main unit or cuff, as this may cause damage.

If the device is used by multiple patients, ensure that it is cleaned and disinfected before each subsequent use.

⚠ **Caution:**

- When a user is using, the device cannot be maintained or serviced;

● Do not use high-pressure sterilization equipment or gas sterilization equipment; otherwise, the device may be damaged;
● Do not expose the device and accessories to high temperatures, high humidity, excessive dust, or direct sunlight;
● This device is not waterproof. Do not let liquid penetrate the main unit or cuff;
● Do not wipe with volatile oils, thinners, gasoline, etc.;
● Do not disassemble or repair this unit without authorization;
● Do not replace internal parts without authorization;
● When not in use for an extended period (more than 3 months), please remove the dry cell batteries, otherwise, the device may be damaged due to battery leakage.

8.2 Warranty

1. From the date of purchase, the main unit enjoys a three-year warranty with a proof of purchase, excluding consumables.
2. From the date of purchase, the cuff enjoys a three-month free warranty with a proof of purchase.
3. For malfunctions and damage caused by non-product quality issues or user's personal reasons, free warranty service will not be provided.
For example:
Damage caused by unauthorized disassembly, assembly, or modification of the product;
Malfunctions caused by accidental drops during use or handling;
Malfunctions caused by lack of reasonable maintenance;
Damage to the device caused by not operating it correctly according to the instruction manual;
Malfunctions caused by repairs performed by unauthorized repair shops, etc.
4.Repair services outside the warranty scope will be subject to charges in accordance with relevant regulations.
5. Before requesting repair service, please call the customer service hotline for consultation.
6. When performing warranty service, if necessary, product circuit diagrams and information on repairable components can be provided to qualified technicians recognized by us.
7. The operator may replace the cuff and battery. Maintenance personnel may replace all components. All components must use those specified by hanvon; otherwise, measurement errors may occur.

Warranty Card	
Product Model:	**Name:**
Purchase Date:	**Address:**
Dealer Name:	**Postal Code:**
Address:	**Contact Number:**
Dealer's Stamp	

8.3 Calibration

● The Blood Pressure Monitor has been carefully tested at the factory;
● It is generally recommended to having the unit inspected once a year by the manufacturer, or manufacturer-authorized repair centers;
● This unit has a pressure detection mode. Please consult our customer service.

Beijing Hanvon Health Technology Co., Ltd.
Room 162, 1st Floor and Room 256, 2nd Floor, Hanwang Building, Building 5, No.8 Dongbeiwangxi Road, Haidian District, Beijing 100193, China
TEL: +86400-810-8816
FAX: /
Website: https://www.hwbpm.com
E-mail: hwbh@hanwang.com.cn

YF-KSY311-EN-FDA-02-14
A/0
2024-8-26