Wireless Blood Pressure Monitor
MODEL KD-5819
(ELECTRONIC SPHYGMOMANOMETER)
Instruction Manual

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IMPORTANT INFORMATION

Please read this instruction manual carefully before using the product.

Thank you for purchasing the Wireless Blood Pressure Monitor. Please retain this Instruction Manual for reference.

NORMAL BLOOD PRESSURE FLUCTUATION

Blood pressure is affected by various factors, including excitement, stress, body position, and physical activities such as eating, drinking, smoking, or even taking a blood pressure measurement. As a result, it is unusual to obtain identical blood pressure readings multiple times.

Blood pressure fluctuates constantly throughout the day and night. Typically, it continues to rise during the day and peaks while most people are awake and active. It then drops in the evening, reaching its lowest between midnight and 3 a.m. while most people sleep.

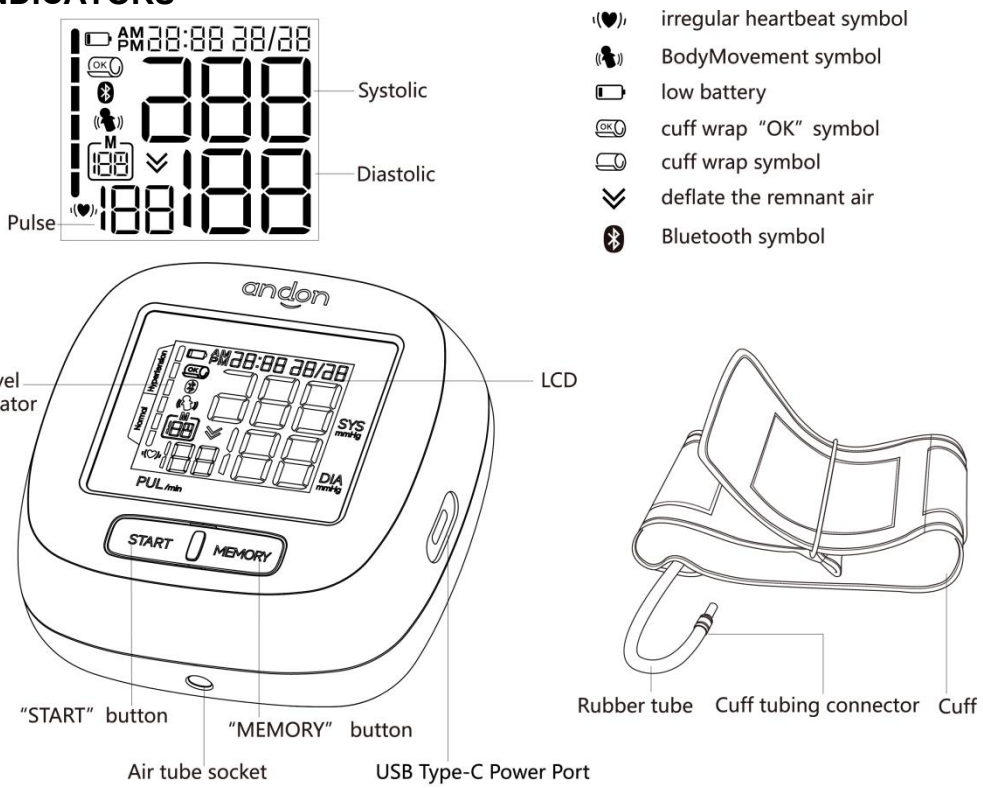
Considering the above information, measuring your blood pressure at approximately the same time every day is recommended.

Taking measurements more often than necessary may cause an injury due to blood flow interference, so please always rest at least 60 to 90 seconds between measurements to allow the blood circulation in your arm to recover.

BOX CONTENTS

- 1 × Blood Pressure Monitor
- 1 × Instruction Manual
- 1 × Cuff
- 1 × Storage Bag

DISPLAY INDICATORS



INTENDED USE

Fully Automatic Electronic Blood Pressure Monitor is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a noninvasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 15cm-48cm (approx. 5.9″- 18.9″).
Intended user:Medical professionals or lay person.

CONTRAINDICATION

⚠ This wireless blood pressure monitor (electronic sphygmomanometer) is not suitable for people with severe arrhythmia.

PRODUCT DESCRIPTION

Based on oscillometric methodology and a silicon-integrated pressure sensor, blood pressure and pulse rate can be measured automatically and non-invasively. Users can operate the device themselves. The liquid crystal display (LCD) shows blood pressure and pulse rate. This wireless blood pressure monitoring device can store up to 120 readings for each of two different users, along with the date and time of each measurement.

This wireless blood pressure monitor has been designed in accordance with the requirements of ISO 81060-2:2018.

SPECIFICATIONS

1. Product name: Wireless Blood Pressure Monitor
2. Model: KD-5819
3. Classification: Internally powered, Class II, Type BF applied part, IP21, No AP or APG, continuous operation
4. Monitor size: Approx. 98.5 mm × 97 mm × 46 mm (3.9” × 3.8” × 1.8”)
5. Cuff circumference: 22cm-42cm(8.7″-16.5″);
   15cm-24cm(5.9″-9.4″)(Optional);
   20cm-34cm(7.9″-13.4″)(Optional);
   30cm-44cm(11.8″-17.3″)(Optional);
   40cm-48cm(15.7″-18.9″)(Optional);
   17cm-22cm(6.7″~8.7″)(Optional);
   22cm-30cm(8.7″-11.8″)(Optional);
   22cm-32cm(8.7″-12.6″)(Optional);
   22cm-36cm(8.7″-14.2″)(Optional);
   30cm-42cm(11.8″-16.5″)(Optional);
   42cm-48cm(16.5″-18.9″)(Optional).
6. Weight: Approx. 163 g (5.7 oz) (excluding batteries and cuff).
7. Measuring method: Oscillometric method
8. Memory volume: Two users, 120 measurements each
9. Power source:
   Medical AC adapter: 5V ⎓ 1A, batteries: 4 × 1.5V ⎓ SIZE AAA
10. Measurement ranges:
    Cuff pressure: 0 to 300 mmHg
    Systolic: 60 to 260 mmHg
    Diastolic: 40 to 199 mmHg
    Pulse rate: 40 to 180 beats/minute
11. Accuracy:
    Pressure: ±3 mmHg
    Pulse rate: Less than 60: ±3 bpm
    More than 60 (incl.): ±5%
12. Environmental temperature for operation: 5 ℃ to 40 ℃ (41 ℉ to 104 ℉)
13. Environmental humidity for operation: ≤85% RH
14. Environmental temperature for storage and transport: –20 ℃ to 55 ℃ (–4 ℉ to 131 ℉)
15. Environmental humidity for storage and transport: ≤90% RH
16. Environmental pressure: 80 kPa to 105 kPa
17. Battery life: Approx. 120 measurements
18. Wireless communication:
    Modulation types: GFSK
    Frequency Band: 2.400 GHz to 2.483 GHz
    Effective radiated power: < 0 dBm
19. Product life:
    Monitor: 3 years

Cuff: 3 years (with 3 uses daily)

IMPORTANT SAFETY INFORMATION

Please read the Important Safety Information in this instruction manual before using the device.

⚠**Warning**	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

- The device should not be used for patients with artificial hearts or lungs.
- The device should not be used for neonates, infants ,children or persons who cannot express themselves. This device has not been validated for use on pregnant patients.
- The device should not be used for patients with poor peripheral circulation, noticeably low blood pressure, or low body temperature.
- Consult your physician before using the device for any of the following conditions: common arrhythmias, such as atrial or ventricular premature beats or atrial fibrillation, arterial sclerosis, poor perfusion, diabetes, pre-eclampsia, and renal diseases.
- Do not use this device in a moving vehicle.
- Do not use this device If you are allergic to plastic/rubber.
- Please do not share the cuff to prevent the risk of infection and cross-contamination.
- This device can be used in conjunction with a medical AC adapter (Input: AC 100 to 240 V, 50/60 Hz, 0.2A; output: DC 5V, 1A). Do not use a cuff or AC adapter other than the ones supplied by the manufacturer. Disregarding this safety instruction may bring about a biocompatible hazard, result in measurement error, damage the device, or hurt the user.
- Never let children or persons incapable of expressing themselves independently use the device. Keep the device safely stored and inaccessible to children to prevent them from swallowing the batteries or other small parts.
- Keep the cuff tube and the cable away from children to avoid the risk of strangulation or asphyxiation.
- As the alternative small-bore connector used for this medical device is designed differently from the connector specified in the ISO 80369 series, the user will need to taker steps to reduce the risk of incorrectly connecting.
- See the section regarding ELECTROMAGNETIC COMPATIBILITY INFORMATION for information regarding potential electromagnetic interference (EMI) or other interference between the device and other devices.  Please do not use the device within the environment of the following devices: magnetic resonance imaging, computerized axial tomography, diathermy, radio frequency (RF) identification, active high-

frequency surgical equipment, electromagnetic security systems such as metal detectors, and not intended for use in an oxygen-rich environment.

⚠**Caution**	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user.

- Stay quiet and calm, and rest for five minutes before taking your blood pressure measurement. Relax for a minimum of 1 to 1.5 minutes between measurements to allow the blood circulation in your arm to recover.
- Do not speak or move your body or arm during the measurement. Motion, trembling, and shivering during measurement may affect the result.
- Prolonged overinflation (cuff pressure exceeds 300 mmHg or is above 15 mmHg for longer than 3 minutes) of the bladder may cause ecchymoma (a tumor-like swelling composed of extravasated blood) of the arm.
- The device might not meet its performance specifications or cause safety hazards if stored or used outside the specified temperature and humidity ranges listed in the specifications.
- Consult your physician before use if any of the following scenarios are applicable:
  1) The cuff will be applied over a wound or inflammation disease;
  2) The cuff will be applied on any arm where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present;
  3) The cuff will be applied to the arm on the same side as a mastectomy or lymph node clearance;
  4) The device will be used simultaneously with other monitoring medical equipment on the same arm;
- Blood pressure measurements determined by this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultation method, within the limits prescribed by the American National Standard Institute, electronic or automated sphygmomanometers.
- This equipment has been tested and found to comply with the limits for a Class B digital device under part 15 of the FCC Rules. These limits are designed to protect reasonably against harmful interference in a residential installation. This equipment generates, uses, and can radiate RF energy and, if not installed and used by the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. Suppose this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on. In that case, 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 the receiver.
  —Connect the equipment to 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.
- RF Exposure statement :The device has been evaluated to meet general RF exposure requirement.

- A signal will be displayed if the blood pressure measurement procedure detects an irregular heartbeat (IHB) brought on by common arrhythmias. Under this condition, the electronic sphygmomanometer can keep functioning, but the results may not be accurate. Please consult your physician for a precise assessment.
  There are two conditions under which the signal of IHB will be displayed:
  1) The coefficient of variation of pulse period >25 percent.
  2) The difference in adjacent pulse periods is≥ 0.14 seconds, and the number of such pulses is more than 53 percent of the total number.
- Please check the condition of the arm being used to ensure that the device is not impairing the patient's blood circulation when in use.

SETUP AND OPERATION

1. DOWNLOAD THE APP (Optional)

Before first use, download and install the iHealth MyVitals app from the App Store (iOS device) or Google Play (Android device). Use the search term “myvitals”.

2. INSTALLING BATTERY OR AC ADAPTER

1) INSTALLING BATTERY

a. Open the battery cover at the back of the device.
b. Insert four “AAA” batteries. Make sure the batteries are inserted according to the positive and negative marks ("+" and "－") printed in the battery housing.
c. Close the battery cover.

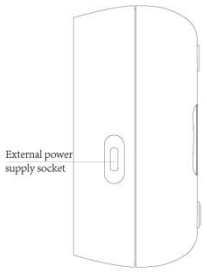
Note:

—When LCD shows a low battery symbol , replace all batteries with new ones.
—Rechargeable batteries are not suitable for this device.
⚠Avoid getting battery fluid in your eyes. If battery fluid gets in your eyes, immediately rinse with plenty of clean water and consult with your physician.
⚠ The negative (–) side of the battery should be touching the spring.
⚠ Ensure the battery cover is intact and not damaged before installing the battery.

2) INSTALLING AC ADAPTER

If you use the AC adapter, please make sure the device turn off or no batteries. Put the connector plug of the adapter into the socket , Then plug the adapter to AC outlet. When disconnect the AC Adapter:
Remove the AC Adapter from the electrical outlet;
Remove the AC Adapter plug from the monitor socket.

⚠When connecting the adapter, connect to the device



first and then the AC outlet. When disconnecting the adapter, disconnect the AC outlet first and then the device.

⚠ Do not plug or unplug the power cord into the electrical outlet with wet hands.

⚠ Make sure the device is turned off, and there are no batteries.

⚠Do not overload power outlets. Plug the device into the appropriate voltage outlet.

⚠If the AC adapter is abnormal, please stop using it.

⚠ Do not pull out the adapter while you are using the device.

⚠Do not position the device so it is difficult to operate or disconnect.

The device, batteries and cuff must be disposed of according to local regulations after use.

3. TIME AND DATE SETUP

The time and date setup will be initiated immediately after the batteries are inserted. You can choose to set the time automatically or manually.

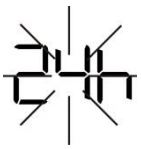
Automatic time setting:

When the Bluetooth symbol flashes, connect the device to the app to set the time automatically.

If you set the time successfully with the app, the time and date will flash. Once the flashing stops, the device will turn off automatically. No manual time setting is needed afterward.

***Note**: When the Bluetooth symbol flashes, press "**START**" button to manually set the time, and press "**MEMORY**" button to disable Bluetooth function.*

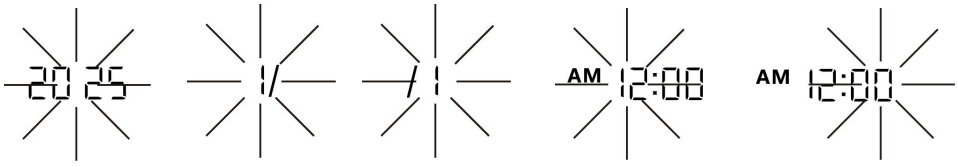
Manual time setting:



a. The default time format is set to 24 hours. Press the "**MEMORY**" button to switch to the 12-hour format. Press the "**START**" button to confirm your selection.

b. After selecting your desired time format, the year value will begin flashing. Use the "**MEMORY**" button to adjust the value. Holding down the "**MEMORY**" button enables rapid selection.

c. Press the "**START**" button to confirm your choice and proceed to the next setting screen. The setting order is "Year/Month/Day/Hour/Minute," as shown in the following figure.



To modify the time set, press and hold the "**MEMORY**" and "**START**" buttons for five seconds while the monitor is powered off.

***Note**: The default time is January 1st, 2025, at 00:00 (24-hour format). The year can be adjusted from 2025 to 2099.*
After replacing the batteries, you should readjust the time and date.

4. VOICE SETTING

Voice language setting: While the device is powered off, you can select the voice language by pressing and holding the "**MEMORY**" button. The LCD displays "Ln". ("n" equals 0 represents no language, and "n" being non-zero represents the language). See Figure 4-1. When you hear the language which you wish to set being played, please release the "**MEMORY**" button,the language setting is successful.

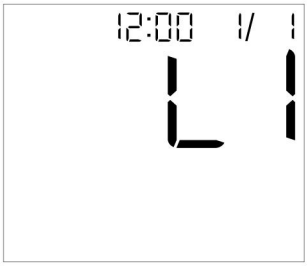


Figure 4-1

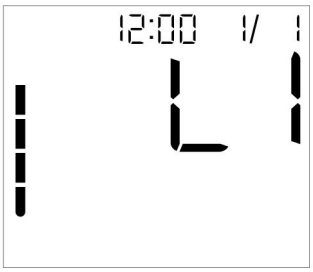


Figure 4-2

If the device only supports one language, LCD will twinkle "ON" and "--" circularly. Here "ON" represents opening the voice function and "--" represents closing the voice function. See Figure 4-3 and 4-4.

Figure 4-3

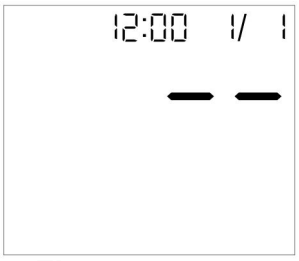


Figure 4-4

Voice volume setting: Once you have selected a language, you will enter the volume mode setup as shown in Figure 4-2. Press and hold the "**MEMORY**" button again. The bar chart on the left side of the LCD screen will change. The higher the bars, the louder the volume. Release "**MEMORY**" button at your desirable volume for confirmation.

5. CONNECTING THE CUFF TO THE DEVICE

Insert the end of the cuff tube firmly into the device's air tube socket.

6. APPLYING THE CUFF

a. Pull the cuff through the metal loop (See Figure 6-1). Slide your bare arm through the cuff and tighten it securely. Close the velcro to fasten the cuff in place.
b. Ensure the bottom of the cuff is positioned1 to 2 cm (½") above your elbow joint and fits comfortably, yet snugly, around your arm. You should be able to

insert one finger between your arm and the cuff.
If applying the cuff on your **left arm**, Position the cuff so that the cuff tube is in the middle of your arm and line with your middle finger (See Figure 6-2).
If applying the cuff on your **right arm**, Position the cuff so that the cuff tube is at the side of your elbow and in line with your little finger (See Figure 6-3).

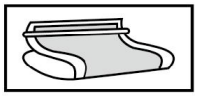


Figure 6-1

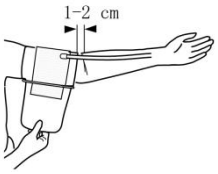


Figure 6-2

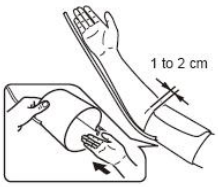


Figure 6-3

Note:

- *Please refer to the cuff circumference range in "SPECIFICATIONS" to ensure appropriate usage.*
- *Always measure on the same arm for consistency.*
- *Do not apply the cuff if the arm has inflammation, acute diseases, or skin wounds.*
- ⚠*To prevent measurement failure or injury, please avoid squeezing or bending the connection tube during the measurement process.*

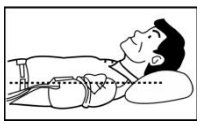
7. BODY POSTURE DURING MEASUREMENT

Sitting during measurement:

a. Sit with your feet flat on the floor and avoid crossing your legs.
b. Extend your arm with your palm facing up, resting comfortably on a flat surface.
c. Position the cuff to be at the same level as your heart.

Lying down during measurement:

a. Lie on your back.
b. Place your left arm straight along your side with your palm facing up.
c. Ensure the cuff is positioned at the same level as your heart.



8. TAKING YOUR BLOOD PRESSURE READING

a. After securing the cuff and getting comfortable, press the "**START**" button to take a measurement. Verify the LCD display matches what is shown in Figure 8-1.

Note: *Contact customer service if any display symbol is missing.*

b. The device will briefly display the current user group for three seconds. Within these three seconds, use the "**MEMORY**" button to select your desired user group (U1 or U2).

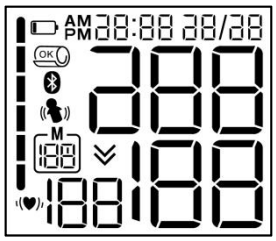


Figure 8-1

Note: *If no user group is selected, the measurement will be stored in the most recently selected user group.*

c. Then, the device will begin inflating the cuff. The blood pressure and pulse will be measured during inflation.During this process, either of the following cuff symbols will appear:
: The cuff is loose or not wrapped properly.
: The cuff is wrapped properly.

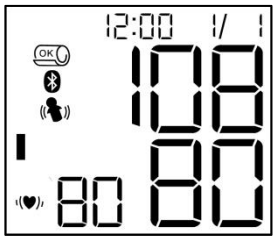


Figure 8-2

d. Inflation will stop as soon as the blood pressure and pulse rate have been calculated and displayed on the LCD (See Figure 8-2).

Notes:

1) *The blood pressure classification indicator and IHB symbol (if applicable) will blink on the screen.*
2) *If any of the symbols below are displayed, the measurement result may not be accurate. Please take another measurement.*

: The cuff is loose or not wrapped properly.
: Body movement detected during measurement.

3) *Please consult a healthcare professional for the interpretation of the measurements.*
4) *Cuff wrap indicator applies to 22cm-42cm cuff, the cuff wrap symbol(and) has no reference meaning when using other cuffs.*

e. If Bluetooth function is enable, the Bluetooth symbol flashes, you can connect app upload measurement result by Bluetooth.Then the Bluetooth symbol will disappear after upload.

f. The device will automatically turn off after one minute of inactivity. Alternatively, press the "**START**" button to turn off the device at any time.

9. VIEWING STORED READINGS

You can press the "**MEMORY**" buttons while the monitor is powered off to view the stored readings for the desired user.

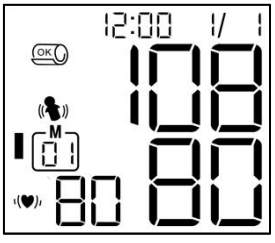


Figure 9-1

a. After pressing the "**MEMORY**" button, the LCD screen will show the most recently selected user group and the number of stored readings for three seconds. Within these three seconds, use the "**START**" button to select your desired user group. Press the "**MEMORY"** button to advance to the next screen.

b. When "A" flashes at the bottom of the LCD, the displayed numbers represent the average of all the readings for the selected user.

c. Press the "**MEMORY**" button again to display "A3," showing the average

of the selected user's three most recent readings.

d. Press the "**MEMORY**" button again to display "AM" showing the average of the selected user's readings which is measured from 5 o'clock to 9 o'clock in last 7 days.

e. Press the "**MEMORY**" button again to display "PM" showing the average of the selected user's readings which is measured from 18 o'clock to 20 o'clock in last 7 days.

f. Press the "**MEMORY**" button once more to show "01," showing the most recent reading for that user.

g. Press the "**MEMORY**" button again to navigate to the next result. Repeat to browse through all readings.

h. The device will automatically turn off after one minute of inactivity. Alternatively, you can press the "**START**" button to turn off the device anytime.

Note: *The classification indicator shows different numbers based on systolic and diastolic pressure. For details, refer to the "ASSESSING HIGH BLOOD PRESSURE FOR ADULTS" section.*

10. TRANSFERRING STORED READINGS TO THE APP

You may transfer your blood pressure readings to the app anytime you see the Bluetooth symbol flash. The Bluetooth symbol will flash whenever you view your stored readings or after a measurement.

a. When the Bluetooth symbol flashes, open the iHealth MyVitals app on your smartphone near the device (ensure Bluetooth is enabled in your settings).
b. Follow the steps in the app to connect the monitor.
c. The Bluetooth symbol will remain solid when the monitor connects to the iHealth MyVitals app. Then, the stored readings will be automatically transmitted to the app.
d. Once the results have been successfully transferred, the local storage will no longer retain the historical readings sent (only for iHealth MyVitals app).

Note: The blood pressure monitor cannot connect to the iHealth MyVitals app if the battery is low or the device is taking measurements.

11. DELETING STORED READINGS

To delete all the stored readings of the current user, press and hold the "**MEMORY**" buttons for three seconds while any result is displayed. Once complete, the device will turn off after one second.

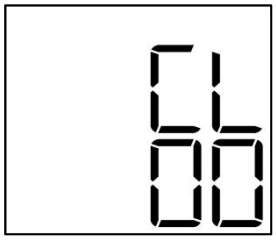
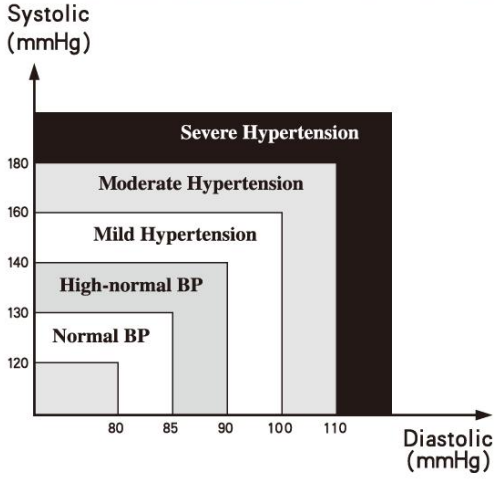


Figure 11-1

12. ASSESSING HIGH BLOOD PRESSURE FOR ADULTS

The World Health Organization has established the following guidelines for assessing high blood pressure (regardless of age or gender). Please note that other factors (e.g., diabetes, obesity, smoking, etc.) must be considered. Consult with your physician for an accurate assessment. Only change any existing course of treatment by yourself after first seeking the advice of a medical professional.

Classification of blood pressure for adults



BLOOD PRESSURE CLASSIFICATION	SBP mmHg	DBP mmHg	LCD INDICATOR
Optimal	<120	<80	1
Normal	120-129	80-84	2
High-Normal	130-139	85-89	3
Grade 1 Hypertension	140-159	90-99	4
Grade 2 Hypertension	160-179	100-109	5
Grade 3 Hypertension	⩾180	⩾110	6

WHO/ISH Definitions and Classification of Blood Pressure Levels

Note: The guidelines are not intended to be used as a basis for self-diagnosis or emergency conditions but only to differentiate between general classifications of blood pressure levels.

13. TECHNICAL ALARM DESCRIPTION

The device will show 'HI' or 'Lo' as a technical alarm on the LCD, with no delay, if the determined blood pressure (systolic or diastolic) is outside the range stated in the “SPECIFICATIONS” section. In this case, you should consult a physician or check to ensure you have followed the instructions.

The technical alarm is preset and cannot be adjusted or deactivated.

The technical alarm is non-latching and does not require a reset. The signal displayed on the LCD will disappear automatically after about eight seconds.

14. TROUBLESHOOTING

PROBLEM	POSSIBLE CAUSE	SOLUTION
LCD display shows abnormal result	The cuff position was not correct or it was not properly tightened.	Apply the cuff correctly and try again.
	Body posture was not correct during testing.	Review the “BODY POSTURE DURING MEASUREMENT” section of the instructions and re-test.

	Speaking, arm or body movement, angry, excited or nervous during testing.	Re-test when calm, without speaking or moving during the test.
	Irregular heartbeat (arrhythmia).	It is not suitable for people with serious arrhythmia to use this blood pressure monitor.

PROBLEM	POSSIBLE CAUSE	SOLUTION
LCD shows low battery symbol	Low battery.	Change the batteries.
LCD shows “Er 0”	Pressure system is unstable before measurement.	Do not move and try again.
LCD shows “Er 1”	Failure to detect systolic pressure.	
LCD shows “Er 2”	Failure to detect diastolic pressure.	
LCD shows “Er 3”	Pneumatic system blocked or cuff is too tight during inflation.	Apply the cuff correctly and try again. If the device is still abnormal, please contact the local distributor or the factory.
LCD shows “Er 4”	Pneumatic system leakage or cuff is too loose during inflation.	
LCD shows “Er 5”	Cuff pressure above 300 mmHg.	Measure again after five minutes. If the device is still abnormal, please contact the local distributor or the factory.
LCD shows “Er 6”	More than three minutes with cuff pressure above 15 mmHg.	
LCD shows “Er 7”	Inner memory error.	
LCD shows “Er 8”	Device parameter checking error.	
LCD shows “Er A”	Pressure sensor parameter error.	
LCD shows “Er b”	Bluetooth connection unsuccessful, device is abnormal, or strong EMI is present.	Reset iOS/Android device. Reset device. Make sure the device and iOS/Android device are away from other electrical equipment.
No response when you press button or load battery.	Incorrect operation or strong EMI.	Take out batteries for five minutes, then reinstall all batteries.

MAINTENANCE

1. ⚠Avoid dropping or subjecting the device to substantial impacts.
2. ⚠Avoid high temperatures and prolonged exposure to direct sunlight. Do not immerse the device in water, which will damage it.
3. ⚠ Changes or modifications not approved by the manufacturer will void the user's warranty.Do not disassemble or attempt to repair the device or its components.
4. ⚠Remove the batteries if the device is not used for longer than one month to avoid damage due to battery leakage.
5. ⚠It is recommended that the device's performance be checked every two years.
6. Clean the device with a dry, soft cloth or a soft cloth dampened with water, disinfectant alcohol, or diluted detergent (wring out the cloth to remove as much liquid as possible before wiping the device).
7. Please keep the cuff clean. If the cuff becomes dirty, remove it from the device and clean it by hand with mild detergent, then rinse it thoroughly with cold water. Never dry the cuff in a clothes dryer or iron it. For personal use, it is recommended that the cuff be cleaned after it has been used approximately 200 times. Disinfecting is recommended if the cuff is used in a hospital or a clinic. Wipe the cuff's inner side (the side that contacts the skin) with a soft cloth, lightly moistened with Ethyl alcohol (75 to 90 percent). Then, air-dry the cuff.
8. We can provide product circuit diagrams and repairable component information to qualified maintenance service personnel if necessary.
9. Please wait when moving the device between extreme temperatures (e.g., storage, during transport) to a normal operating environment. The device takes approximately two hours to warm up or cool down before use.
10. The device shall not be serviced or maintained while in use.

EXPLANATION OF SYMBOLS ON UNIT

 Symbol for "THE INSTRUCTION MANUAL MUST BE READ." (The sign's background color is blue, and the sign's graphical symbol is white.)

 Symbol for "TYPE BF APPLIED PARTS" (The cuff is type BF applied part.)

 Symbol for "ENVIRONMENT PROTECTION" Electrical products should not be disposed of as household waste. Please recycle where facilities exist. Check with your local authority or retailer for advice on recycling.

 Symbol for "MANUFACTURER"

 Symbol for "DATE OF MANUFACTURE"

Symbol for "SERIAL NUMBER"

IP21 The first characteristic numeral symbol for “Degrees of protection against access to hazardous parts and solid foreign objects.” The second characteristic numeral symbol is “Degrees of protection against water ingress.”

Symbol for “MR Unsafe”


Symbol for “CLASS II equipment”

CE 0197 Symbol for “COMPILES WITH REGULATION (EU) 2017/745”

Symbol for “Medical device”

Symbol for “EUROPEAN REPRESENTATION”

WARRANTY INFORMATION
Only charge the cost of components and transport.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Other trademarks and trade names are those of their respective owners.

Hereby, [Andon Health CO.,LTD.], declares that this [KD-5819] is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU.

ELECTROMAGNETIC COMPATIBILITY INFORMATION
- This medical device meets the following essential performance requirements:
  1. Limits of the error of the cuff pressure indication.
  2. Reproducibility of the blood pressure determination.
- When EMI affects the above performance, please stop using the device.

- Use of this equipment adjacent to, or stacked with, other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they usually operate.
- Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."
- 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 device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result."

Table 1 – Emissions

Phenomenon	Compliance	Electromagnetic Environment
RF emissions conducted emissions	CISPR 11 User 1, Class B	Home healthcare environment
Harmonic distortion	IEC 61000-3-2 Class A	Home healthcare environment
Voltage fluctuations and flicker	IEC 61000-3-3 Compliance	Home healthcare environment

Table 2 – Enclosure Port

Phenomenon	Basic EMC Standard	Immunity Test Levels
		Home Healthcare Environment
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Radiated RF EM field	IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to Table 3
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz
Proximity magnetic fields	IEC 61000-4-39	Refer to Table 5

Table 3 – Proximity Fields from RF Wireless Communications Equipment

Test frequency (MHz)	Band (MHz)	Immunity Test Levels
		Professional healthcare facility environment
385	380-390	Pulse modulation 18 Hz, 27 V/m
450	430-470	FM, ±5 kHz deviation, 1 kHz sine, 28 V/m
710	704-787	Pulse modulation 217 Hz, 9 V/m
745		
780		
810	800-960	Pulse modulation 18 Hz, 28 V/m

870		
930		
1720	1700-1990	Pulse modulation 217 Hz, 28 V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217 Hz, 28 V/m
5240	5100-5800	Pulse modulation 217 Hz, 9 V/m
5500		
5785		

Table 4 – Input AC Power Port

Phenomenon	Basic EMC Standard	Immunity Test Levels
		Home Healthcare Environment
Electrical fast transients/burst	IEC 61000-4-4	±2 kV 100 kHz repetition frequency
Surges (line-to-line)	IEC 61000-4-5	±0.5 kV, ±1 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V, 0.15 MHz to 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Voltage dips	IEC 61000-4-11	0% U_T; 0.5 cycle At 0º, 45º, 90º, 135º, 180º, 225º, 270º and 315º
		0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0º
Voltage interruptions	IEC 61000-4-11	0% U_T; 250/300 cycles

Table 5 - Test Specifications for Enclosure Port Immunity to Proximity Magnetic Fields

Test Frequency	Modulation	Immunity Test Level (A/m)
30 kHz	CW	8
134, 2 kHz	Pulse modulation 2,1 kHz	65
13, 56 MHz	Pulse modulation 50 kHz	7.5