

# Operation Guide (V1.0)

Product/project name: Blood Pressure Monitor

Model name: KD-926

Project number:

Drafted by: \_\_\_\_\_ Date

Reviewed by: \_\_\_\_\_ Date

Approved by: \_\_\_\_\_ Date

## MODEL KD-926

### Wireless Blood Pressure Monitor

(ELECTRONIC SPHYGMOMANOMETER)

## OPERATION GUIDE

### INDEX

<b>IMPORTANT INFORMATION .....</b>	<b>2</b>
<b>CONTENTS AND DISPLAY INDICATORS.....</b>	<b>2</b>
<b>INTENDED USE .....</b>	<b>3</b>
<b>CONTRAINDICATION.....</b>	<b>3</b>
<b>PRODUCT DESCRIPTION.....</b>	<b>3</b>
<b>SPECIFICATIONS.....</b>	<b>4</b>
<b>NOTICE .....</b>	<b>4</b>
<b>SETUP AND OPERATING PROCEDURES.....</b>	<b>6</b>
<b>1. DOWNLOAD THE FREE APP .....</b>	<b>6</b>
<b>2. BATTERY LOADING AND AC ADAPTER LOADING .....</b>	<b>6</b>
<b>3. CLOCK AND DATE ADJUSTMENT .....</b>	<b>7</b>
<b>4. CONNECTING THE CUFF TO THE MONITOR .....</b>	<b>8</b>
<b>5. APPLYING THE CUFF .....</b>	<b>8</b>
<b>6. BODY POSTURE DURING MEASUREMENT .....</b>	<b>9</b>
<b>7. TAKING YOUR BLOOD PRESSURE READING .....</b>	<b>9</b>
<b>8. DISPLAYING STORED RESULTS .....</b>	<b>10</b>
<b>9. SYNCHRONIZING STORED RESULTS .....</b>	<b>10</b>
<b>10. DELETING MEASUREMENTS FROM THE MEMORY.....</b>	<b>11</b>
<b>11. ASSESSING HIGH BLOOD PRESSURE FOR ADULTS .....</b>	<b>11</b>
<b>12. TECHNICAL ALARM DESCRIPTION.....</b>	<b>12</b>
<b>13. TROUBLESHOOTING (1) .....</b>	<b>12</b>
<b>14. TROUBLESHOOTING (2).....</b>	<b>13</b>
<b>MAINTENANCE .....</b>	<b>14</b>
<b>EXPLANATION OF SYMBOLS ON UNIT.....</b>	<b>14</b>
<b>WARRANTY INFORMATION.....</b>	<b>15</b>
<b>SERVICE CENTER .....</b>	<b>15</b>
<b>IMPORTANT INFORMATION REQUIRED BY THE R&amp;TTE .....</b>	<b>15</b>
<b>ELECTROMAGNETIC COMPATIBILITY INFORMATION.....</b>	<b>16</b>

## IMPORTANT INFORMATION

### NORMAL BLOOD PRESSURE FLUCTUATION

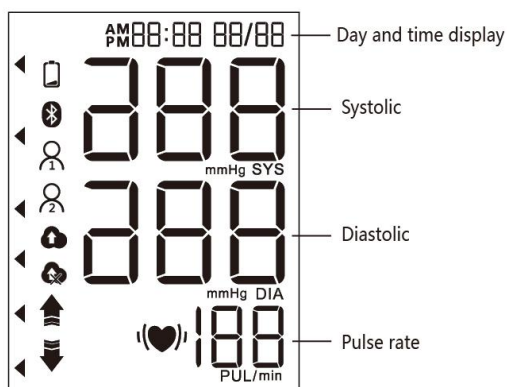
All physical activity, excitement, stress, eating, drinking, smoking, body posture and many other activities or factors (including taking a blood pressure measurement) will influence blood pressure value. Because of this, it is mostly unusual to obtain identical multiple blood pressure readings.

Blood pressure fluctuates continually day and night. The highest value usually appears in the daytime and lowest one usually at midnight. Typically, the value begins to increase at around 3:00 AM, and reaches to highest level in the daytime while most people are awake and active.

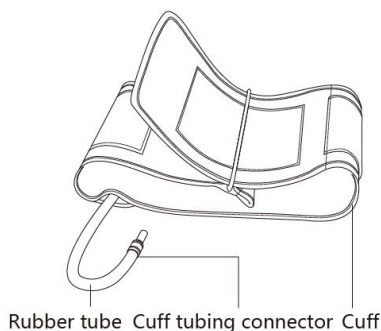
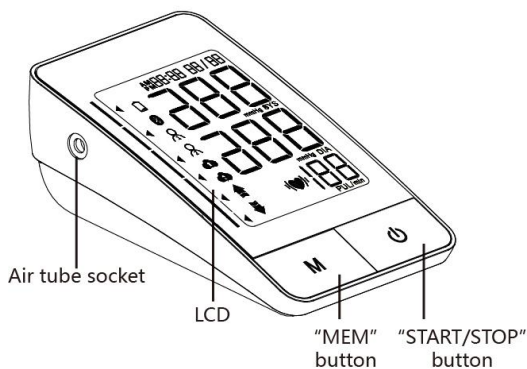
Considering the above information, it is recommended that you measure your blood pressure at approximately the same time each day.

Too frequent measurements may cause injury due to blood flow interference, please always relax a minimum moment of 1 to 1.5 minutes between measurements to allow the blood circulation in your arm to recover. It is rare that you obtain identical blood pressure readings each time.

### CONTENTS AND DISPLAY INDICATORS



- Low Battery Indicator
- Bluetooth Symbol
- Group 1 Symbol
- Group 2 Symbol
- Upload Success Symbol
- Upload Fail Symbol
- Ready to Inflate
- Blood Pressure Level Classification
- Irregular Heartbeat Symbol



## 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 non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 22cm-42cm (approx. 8 21/32" - 16 17/32" ).

## CONTRAINDICATION




It is inappropriate for people with serious arrhythmia to use this Electronic Sphygmomanometer.

## PRODUCT DESCRIPTION





Based on Oscillometric methodology and silicon integrated pressure sensor, blood pressure and pulse rate can be measured automatically and non-invasively. The LCD display will show blood pressure and pulse rate. The most recent 2 × 60 measurements can be stored in the memory with date and time stamp. The Electronic Sphygmomanometer corresponds to the below standards: IEC 60601-1:2005 +A1:2012(E)/EN 60601-1: 2006/A11: 2011 (Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance), IEC60601-1-2:2007/EN 60601-1-2:2007 /AC:2010 (Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests), IEC80601-2-30:2009+AMD1: 2013/EN 80601-2-30:2010/A1: 2015 (Medical electrical equipment –Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers) EN 1060-1: 1995 + A2: 2009 (Non-invasive sphygmomanometers - Part 1: General requirements), EN 1060-3: 1997 + A2: 2009 (Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems).

## SPECIFICATIONS

1. Product name: Wireless Blood Pressure Monitor
  2. Model: KD-926
  3. Classification: Internally powered, Type BF applied part, IP20, No AP or APG, Continuous operation
  4. Machine size: Approx. 145 mm x 90 mm x 51 mm
  5. Cuff circumference: 8-21/32" to 16-17/32" (22cm-42cm)
  6. Weight: Approx. 234g (8 1/4oz.) (exclude cuff)
  7. Measuring method: Oscillometric method, automatic inflation and measurement
  8. Memory volume: 2×60 times with time and date stamp
  9. Power source: batteries: 4x1.5V  SIZE AA, DC 6V 600mA
  10. Measurement range:
    - Cuff pressure: 0-300mmHg
    - Systolic: 60-260mmHg
    - Diastolic: 40-199mmHg
    - Pulse rate: 40-180 beats/minute
  11. Accuracy:
    - Pressure: ±3mmHg
    - Pulse rate: ±5%
  12. Environmental temperature for operation: 10°C-40°C (50°F -104°F)
  13. Environmental humidity for operation: ≤85%RH
  14. Environmental temperature for storage and transport: -20°C~50°C (-4°F ~122°F)
  15. Environmental humidity for storage and transport: ≤85%RH
  16. Environmental pressure: 80kPa-105kPa
  17. Battery life: Approx 300 times.
  18. Wireless Connection:
    - Smart Bluetooth
    - Frequency Band: 2.400~2.4835GHz
  19. All components belonging to the pressure measuring system, including: Pump, Valve, LCD, Cuff, Sensor
- Note: These specifications are subject to change without notice.

## NOTICE

1. Read all of the information in the operation guide and any other literature in the box before operating the unit.
2. Stay still, calm and rest for 5 minutes before blood pressure measurement.
3. The cuff should be placed at the same level as your heart.
4. During measurement, neither speak nor move your body and arm.
5. Measuring on same arm for each measurement.
6. Please always relax at least 1 or 1.5 minutes between measurements to allow the blood circulation in your arm to recover. Prolonged over-inflation (cuff pressure exceed 300 mmHg or maintained above 15 mmHg for longer than 3 minutes) of the bladder may cause ecchymoma of your arm.
7. Consult your physician if you have any doubt about below cases:

- 1) The application of the cuff over a wound or inflammation diseases;
  - 2) The application of the cuff on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present;
  - 3) The application of the cuff on the arm on the side of a mastectomy;
  - 4) Simultaneously used with other monitoring medical equipments on the same limb;
  - 5) Need to check the blood circulation of the user.
8.  This Electronic Sphygmomanometer is designed for adults and should never be used on infants or young children. Consult your physician or other health care professionals before use on older children.
  9. Do not use this unit in a moving vehicle, This may result in erroneous measurement.
  10. Blood pressure measurements determined by this monitor 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.
  11. Information regarding potential electromagnetic or other interference between the blood pressure monitor and other devices together with advice regarding avoidance of such interference please see part ELECTROMAGNETIC COMPATIBILITY INFORMATION.
  12. If Irregular Heartbeat (IHB) brought by common arrhythmias is detected in the procedure of blood pressure measurement, a signal of  will be displayed. Under this condition, the Electronic Sphygmomanometer can keep function, but the results may not be accurate, it's suggested that you consult with your physician for accurate assessment.  
There are 2 conditions under which the signal of IHB will be displayed:
    - 1) The coefficient of variation (CV) of pulse period >25%.
    - 2) The difference of adjacent pulse period  $\geq 0.14s$ , and the number of such pulse takes more than 53 percentage of the total number of pulse.
  13. Please do not use the cuff other than supplied by the manufacturer, otherwise it may bring biocompatible hazard and might result in measurement error.
  14.  The monitor might not meet its performance specifications or cause safety hazard if stored or used outside the specified temperature and humidity ranges in specifications.
  15.  Please do not share the cuff with other infective person to avoid cross-infection.
  16. 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.

17. Medical AC adapter which output is DC 6.0V 600mA and complied with IEC 60601-1/EN 60601-1/UL 60601-1 and IEC 60601-1-2/EN 60601-1-2/UL 60601-1-2 is suitable for this monitor. Please note that the monitor jack size: hole  $\Phi$ 5.5mm, center pin  $\Phi$ 2.0mm. Please pay attention to polarity.
18. Measurements are not possible in patients with a high frequency of arrhythmias.
19. The device is not intended for use on neonates, children or pregnant women. (Clinical testing has not been conducted on neonates, children or pregnant women.)
20. Motion, trembling, shivering may affect the measurement reading.
21. The device would not apply to the patients with poor peripheral circulation, noticeably low blood pressure, or low body temperature (there will be low blood flow to the measurement position).
22. The device would not apply to the patients who use an artificial heart and lung (there will be no pulse)
23. 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, renal diseases.

## SETUP AND OPERATING PROCEDURES

### 1. DOWNLOAD THE FREE APP

Prior to first use, download and install the Andon App from the App Store(iOS device) or Google Play(Android device). Use keyword search terms "mHealth".


### 2. BATTERY LOADING AND AC ADAPTER LOADING

- a. Open battery cover at the back of the monitor.
- b. Load four "AA" size batteries. Please pay attention to polarity.
- c. Close the battery cover.

When LCD shows battery symbol , replace all batteries with new ones.

Rechargeable batteries are not suitable for this monitor.


Remove the batteries if the monitor will not be used for a month or more to avoid relevant damage of battery leakage.


 Avoid the battery fluid to get in your eyes. If it should get in your eyes, immediately rinse with plenty of clean water and contact a physician.

- d. If you use the AC adapter, please make sure the monitor turn off or no batteries. Put the connector plug of the adapter into the socket as the picture, 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.

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

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

 If the AC adapter is abnormal, please change the adapter.

 Do not pull out the adapter when you are using the monitor.

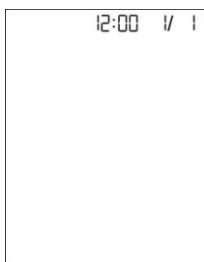
Do not use any other type of AC adapter as it may harm the monitor.



The monitor, the batteries and the cuff, must be disposed of according to local regulations at the end of their usage.

### 3. CLOCK AND DATE ADJUSTMENT

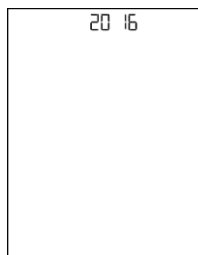
- a. Once you install the battery, the Blood Pressure Monitor will enter Clock and Date Adjustment Mode. When you turn off the monitor, it will enter Clock Mode, and LCD will display time and date.
- b. While the monitor is in Clock Mode, adjustment can be reached by pressing both the “START/STOP” and “MEM” button for 1 seconds in Clock Mode to change the time. See [picture3](#).
- c. In Clock and Date Adjustment Mode, the time format will blink at first, see [picture3-1](#). The default time format is 24h (Europe Version) and the default clock and date is 2016-1-1 12:00.
- d. Press the button “START/STOP” repeatedly, the year (first usage: default is 2016, range is 2016~2099), month, day, hour and minute will blink in turn, see [picture3-2&3-3 & 3-4 & 3-5 & 3-6](#). While the number is blinking, press the button “MEM” to increase the number, keep on pressing the button "MEM", the number will increase faster.



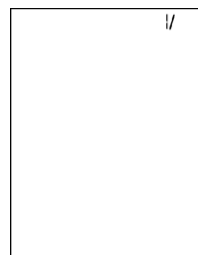
**Picture 3**



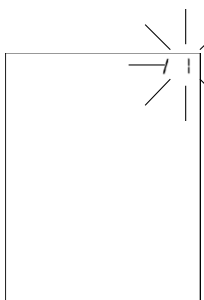
**Picture 3-1**



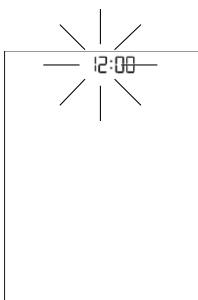
**Picture 3-2**



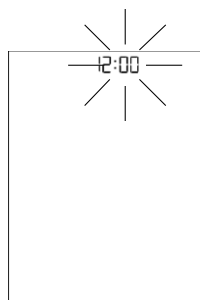
**Picture 3-3**



**Picture 3-4**



**Picture 3-5**



**Picture 3-6**

- e. During adjusting clock and date, the monitor will go back to Clock Mode automatically when no button will be pressed within 60 seconds.
- f. You can turn off the monitor by pressing “START/STOP” button when the minute is blinking, then the time and date is confirmed.

**Note:**

3.1 The clock format could be set by user.



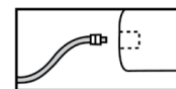
3.2 Table 1 instructs the conversion relations between 24 hour format and 12 hour format.

**Table 1**

24 hour format	12 hour format	24 hour format	12 hour format
0:00	12:00 AM	12:00	12:00 PM
1:00	1:00 AM	13:00	1:00 PM
2:00	2:00 AM	14:00	2:00 PM
3:00	3:00 AM	15:00	3:00 PM
4:00	4:00 AM	16:00	4:00 PM
5:00	5:00 AM	17:00	5:00 PM
6:00	6:00 AM	18:00	6:00 PM
7:00	7:00 AM	19:00	7:00 PM
8:00	8:00 AM	20:00	8:00 PM
9:00	9:00 AM	21:00	9:00 PM
10:00	10:00 AM	22:00	10:00 PM
11:00	11:00 AM	23:00	11:00 PM

#### 4. CONNECTING THE CUFF TO THE MONITOR

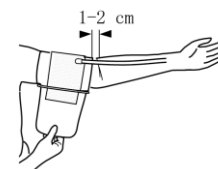
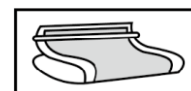
Insert the cuff tubing connector into the air port in the side of the monitor. Make sure that the connector is completely inserted to avoid air leakage during blood pressure measurements.



**⚠** Avoid compression or restriction of the connection tubing during measurement, which may cause inflation error, or harmful injury due to continuous cuff pressure.

#### 5. APPLYING THE CUFF

- a. Pulling the cuff end through the medal loop (the cuff is packaged like this already), turn it outward (away from your body) and tighten it and close the Velcro fastener.
- b. Place the cuff around a bare left arm 1-2cm above the elbow joint.
- c. While seated, place palm upside in front of you on a flat surface such as a desk or table. Position the air tube in the middle of your arm in line with your middle finger.
- d. The cuff should fit comfortably, yet snugly around your arm. You should be able to insert one finger between your arm and the cuff.



**Note:**

- Please refer to the cuff circumference range in “SPECIFICATIONS” to make sure that the appropriate cuff is used.
- Measure on the left arm each time.

- **Do not move your arm, body, or the monitor and do not move the rubber tube during measurement.**
- **Stay quiet, calm for 5 minutes before blood pressure measurement.**
- **Please keep the cuff clean. If the cuff becomes dirty, remove it from the monitor and clear it by hand in a mild detergent, then rinse it thoroughly in cold water. Never dry the cuff in clothes dryer or iron it. Clean the cuff after the usage of every 200 times is recommended.**

## 6. BODY POSTURE DURING MEASUREMENT

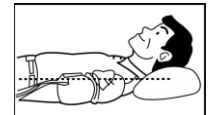
### Sitting Comfortably Measurement

- Be seated with your feet flat on the floor, and don't cross your legs.
- Place palm upside in front of you on a flat surface such as desk or table.
- The middle of the cuff should be at the level of the right atrium of the heart.



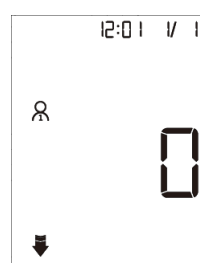
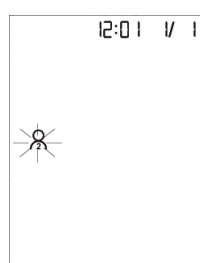
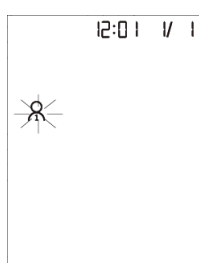
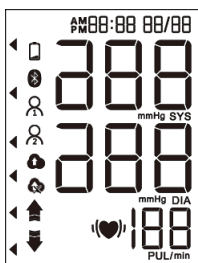
### Lying Down Measurement

- Lie on your back.
- Place your left arm straight along your side with your palm upside.
- The cuff should be placed at the same level as your heart.



## 7. TAKING YOUR BLOOD PRESSURE READING

- After applying the cuff and your body is in a comfortable position, press the "START/STOP" button. All display characters are shown for self-test. You can check the LCD display according to the right picture. Please contact the service center if segment is missing. See picture 7-1.
- Then the current memory bank (R or R) is blink. See picture 7-2. Press "MEM" button to change over to other bank. See picture 7-3. Confirm your selection by pressing "START" button. The current bank can also be confirmed automatically after 5 seconds with no operation.



Picture 7-1

Picture 7-2

Picture 7-3

Picture 7-4

Picture 7-5

- After selecting the memory bank, the monitor starts to seek zero pressure. See picture 7-4.
- Then the cuff will be slowly inflated. The blood pressure and pulse will be measured during inflation. Inflation will stop as soon as the blood pressure and pulse rate have been calculated and displayed on the LCD. The irregular

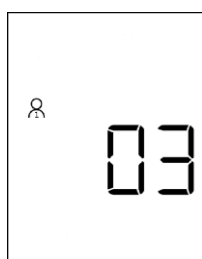
heartbeat symbol (if any) and blood pressure classification indicator will blink on the LCD. See picture 7-5. The result will automatically be stored in the Memory bank of the monitor.

- e. After measurement, the monitor will turn off automatically after 1 minute of no operation.
- f. During measurement, you can press the “START/STOP” button to turn off the monitor manually.

*Note: Please consult a health care professional for interpretation of pressure measurements.*

## 8. DISPLAYING STORED RESULTS

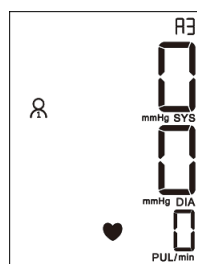
- a. In Clock Mode, press “MEM” button, the monitor will display sign of current group. The amount of results in current user memory zone will be displayed. See picture 8. Press “START/STOP” button to switch group, press “MEM” to confirm current group.
- b. Then LCD will display the average value of the last three results in this bank. See picture 8-1. If no result stored, LCD will show picture 8-2.
- c. Press “MEM” button, the LCD will display the average value of all results in the current user memory zone. See picture 8-3. If no result stored in the current user memory zone, LCD will display “0” for blood pressure and pulse rate. See picture 8-4.
- d. Press “MEM” button again, the most recent result will be displayed with date and time stamp. See picture 8-5. Irregular heartbeat symbol (if any) and blood pressure classification indicator will blink at the same time. If the monitor has no result stored in the current user memory zone, the LCD will display “0” for blood pressure and pulse rate. See picture 8-6.
- e. Press “MEM” button again to review the next result. In this way, repeatedly pressing the “MEM” button displays the respective results measured previously.



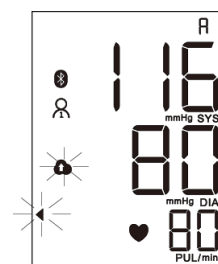
Picture8



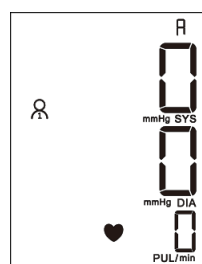
Picture 8-1



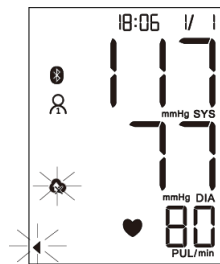
Picture 8-2



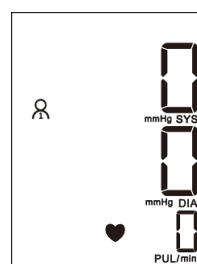
Picture 8-3



Picture 8-4



Picture 8-5



Picture 8-6

*Note: When the monitor displaying the measurement, the classification color indicator*

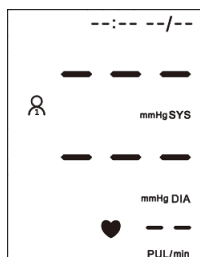
can be shown different color according to the systolic pressure and diastolic pressure. Refer to the “ASSESSING HIGH BLOOD PRESSURE FOR ADULTS” section.

## 9. SYNCHRONIZING STORED RESULTS

- a. In Clock Mode, press “MEM” button, the monitor will wait Bluetooth connect and Bluetooth symbol flashing after confirming the group. See picture 8-1. Bluetooth symbol will stop flashing when Bluetooth is connected. Send symbol flashing until Synchronize finished. See picture 8-3. Send symbol flashing means it is synchronizing the memory at this time.
- b. If an accident happens, synchronous unfinished, unfinished symbol flashing. See picture 8-5.
- c. When Bluetooth is disconnected, the monitor will turn off automatically after 1 minute of no operation. You can also press the “START/STOP” button to turn off the monitor manually.

## 10. DELETING MEASUREMENTS FROM THE MEMORY

When any result is displaying (exclude average value displaying), keeping on pressing button “MEM” for three seconds, all results in the current bank will be deleted . See picture 10. Press the button “START/STOP”, the monitor will be turned off.

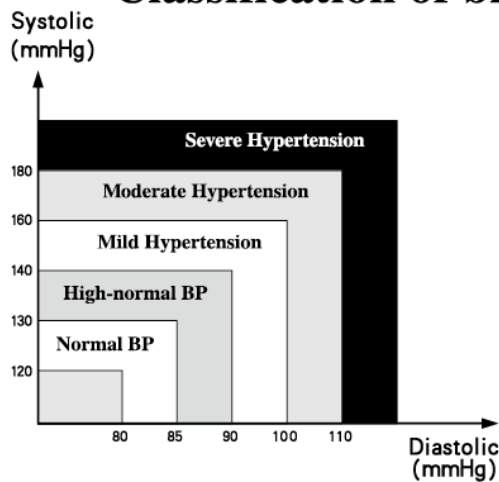


Picture 10

## 11. ASSESSING HIGH BLOOD PRESSURE FOR ADULTS

The following guideline for assessing high blood pressure (without regard to age or gender) has been established by the World Health Organization (WHO). Please note that other factors (e.g. diabetes, obesity, smoking, etc.) need to be taken into consideration. Consult with your physician for accurate assessment, and never change your treatment by yourself.

## Classification of blood pressure for adults



BLOOD PRESSURE CLASSIFICATION	SBP mmHg	DBP mmHg	COLOR INDICATOR
Optimal	<120	<80	GREEN
Normal	120-129	80-84	GREEN
High-Normal	130-139	85-89	GREEN
Grade 1 Hypertension	140-159	90-99	YELLOW
Grade 2 Hypertension	160-179	100-109	ORANGE
Grade 3 Hypertension	≥ 180	≥ 110	RED

WHO/ISH Definitions and Classification of Blood Pressure Levels

*Note: It is not intended to provide a basis of any type of rush toward emergency conditions/diagnosis based on the color scheme and that the color scheme is meant only to discriminate between the different levels of blood pressure.*

### 12. TECHNICAL ALARM DESCRIPTION

The monitor will show 'HI' or 'Lo' as technical alarm on LCD with no delay if the determined blood pressure (systolic or diastolic) is outside the rated range specified in part SPECIFICACIONES. In this case, you should consult a physician or check if your operation violated the instructions.


The technical alarm condition (outside the rated range) is preset in the factory and cannot be adjusted or inactivated. This alarm condition is assigned as low priority according to IEC 60601-1-8.

The technical alarm is non-latching and need no reset. The signal displayed on LCD will disappear automatically after about 8 seconds.




### 13. TROUBLESHOOTING (1)

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" sections of the instructions and re-test.
	Speaking, arm or body movement, angry, excited or nervous during testing	Re-test when calm and without speaking or moving during the test.
	Irregular heartbeat (arrhythmia)	It is inappropriate for people with serious arrhythmia to use this Electronic Sphygmomanometer.

## 14. TROUBLESHOOTING (2)

PROBLEM	POSSIBLE CAUSE	SOLUTION
LCD shows low battery symbol 	Low Battery	Change the batteries
LCD shows "Er 0"	Pressure system is unstable before measurement	Don't move and try again.
LCD shows "Er 1"	Fail to detect systolic pressure	
LCD shows "Er 2"	Fail 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
LCD shows "Er 4"	Pneumatic system leakage or cuff is too loose during inflation	
LCD shows "Er 5"	Cuff pressure above 300mmHg	Measure again after five minutes. If the monitor is still abnormal, please contact the local distributor or the factory.
LCD shows "Er 6"	More than 3 minutes with cuff pressure above 15 mmHg	
LCD shows "Er 7"	EEPROM accessing error	
LCD shows "Er 8"	Device parameter checking error	
LCD shows "Er A"	Pressure sensor parameter error	
No response when you press button or load battery.	Incorrect operation or strong electromagnetic interference.	Take out batteries for five minutes, and then reinstall all batteries.
Bluetooth connection unstable	Bluetooth connection unsuccessful, monitor is abnormal, or strong electromagnetic interference is present	Reset iOS/Android device. Reset monitor. Make sure the monitor and iOS/Android device are away from other electrical equipment. Please see GENERAL SAFETY AND PRECAUTIONS

## MAINTENANCE

1.  Do not drop this monitor or subject it to strong impact.
2.  Avoid high temperature and solarization. Do not immerse the monitor in water as this will result in damage to the monitor.
3. If this monitor is stored near freezing, allow it to acclimate to room temperature before use.
4.  Do not attempt to disassemble this monitor.
5. If you do not use the monitor for a long time, please remove the batteries.
6. It is recommended the performance should be checked every 2 years or after repair. Please contact the service center.
7. Clean the monitor with a dry, soft cloth or a soft cloth squeezed well after moistened with water, diluted disinfectant alcohol, or diluted detergent.
8. No component can be maintained by user in the monitor. The circuit diagrams, component part lists, descriptions, calibration instructions, or other information which will assist the user's appropriately qualified technical personnel to repair those parts of equipment which are designated repairably can be supplied by us.
9. The monitor can maintain the safety and performance characteristics for a minimum of 10,000 measurements or three years, and the cuff integrity is maintained after 1,000 open–close cycles of the closure.
10. It is recommended the cuff should be disinfected 2 times every week if needed (For example, in hospital or in clinique). Wipe the inner side (the side contacts skin) of the cuff by a soft cloth squeezed after moistened with Ethyl alcohol (75-90%), then dry the cuff by airing.

## EXPLANATION OF SYMBOLS ON UNIT



Symbol for "THE OPERATION GUIDE MUST BE READ" (The sign background colour: blue. The sign graphical symbol: white)



Symbol for "WARNING"



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



Symbol for "ENVIRONMENT PROTECTION – Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local Authority or retailer for recycling advice".



Symbol for "MANUFACTURER"



Symbol for "COMPILES WITH MDD93/42/EEC REQUIREMENTS"



Symbol for "DATE OF MANUFACTURE"



Symbol for "EUROPEAN REPRESENTATION"

SN

Symbol for "SERIAL NUMBER"



Symbol for "KEEP DRY"

## WARRANTY INFORMATION

Only charge the cost of components and transport.

## SERVICE CENTER



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## IMPORTANT INFORMATION REQUIRED BY THE R&TTE

This product is approved in accordance to R&TTE directive transmitter interference

This product complies with Industry Canada. IC: RSS-247

### IC NOTICE

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions:

- (1) this device may not cause interference, and
- (2) this device must accept any interference, including interference that may cause undesired operation of the device.

The **Bluetooth**® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc and any use of such marks by ANDON HEALTH CO., LTD. is under license.

Other trademarks and trade names are those of their respective owners.

This product is approved in accordance to R&TTE directive transmitter.

Hereby, ANDON HEALTH CO., LTD., declares that this KD-926 is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC. See part Directive 1999/5/EC declaration of conformity



## ELECTROMAGNETIC COMPATIBILITY INFORMATION

**Table 1 - Emission**

Phenomenon	Compliance	Electromagnetic environment
RF emissions	CISPR 11 Group 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 ±2kV, ±4kV, ±8kV, ±15kV air
Radiated RF EM field	IEC 61000-4-3	10V/m 80MHz-2.7GHz 80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table 3
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz

**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 18Hz, 27V/m
450	430-470	FM, ±5kHz deviation, 1kHz sine, 28V/m
710	704-787	Pulse modulation 217Hz, 9V/m
745		
780		
810	800-960	Pulse modulation 18Hz, 28V/m
870		
930		
1720	1700-1990	Pulse modulation 217Hz, 28V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217Hz, 28V/m
5240	5100-5800	Pulse modulation 217Hz, 9V/m
5500		
5785		

**Table 4**
**For ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING**

<b>Recommended separation distances between portable and mobile RF communications equipment and the KD-926</b>			
<p>The KD-926 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the KD-926 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the KD-926 as recommended below, according to the maximum output power of the communications equipment.</p>			
<b>Rated maximum output power of transmitter W</b>	<b>Separation distance according to frequency of transmitter m</b>		
	<b>150 kHz to 80 MHz <math>d = 1.2\sqrt{P}</math></b>	<b>80 MHz to 800 MHz <math>d = 1.2\sqrt{P}</math></b>	<b>800 MHz to 2,5 GHz <math>d = 2.3\sqrt{P}</math></b>
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distance <math>d</math> in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p> <p>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

## **FCC Caution.**

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.