

# **History Revision**

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# Operation Guide (V1.0)

<u>Monitor</u>			
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Product/project name: Wireless Blood Pressure



#### **MODEL KD-552**

#### **Wireless Blood Pressure Monitor**

(ELECTRONIC SPHYGMOMANOMETER)

#### **OPERATION GUIDE**

#### **INDEX**

IMPORTANT INFORMATION	2
CONTENTS AND DISPLAY INDICATORS	2
INTENDED USE	3
PACKAGE CONTENTS	3
CONTRAINDICATION	3
PRODUCT DESCRIPTION	3
SPECIFICATIONS	4
NOTICE	4
SETUP AND OPERATING PROCEDURES	6
1. BATTERY LOADING AND AC ADAPTER LOADING	6
2. CLOCK AND DATE ADJUSTMENT	
3. VOICE SETTING	8
4. CONNECTING THE CUFF TO THE MONITOR	9
5. APPLYING THE CUFF	
6. BODY POSTURE DURING MEASUREMENT	10
7. TAKING YOUR BLOOD PRESSURE READING	10
8. DISPLAYING STORED RESULTS	
9. SYNCHRONIZING STORED RESULTS	
10. DELETING MEASUREMENTS FROM THE MEMORY	13
11. ASSESSING HIGH BLOOD PRESSURE FOR ADULTS	
12. TECHNICAL ALARM DESCRIPTION	14
13. TROUBLESHOOTING (1)	
14. TROUBLESHOOTING (2)	
MAINTENANCE	
EXPLANATION OF SYMBOLS ON UNIT	16
WARRANTY INFORMATION	
SERVICE CENTER	
ELECTROMAGNETIC COMPATIBILITY INFORMATION	18



#### NORMAL BLOOD PRESSURE FLUCTUATION

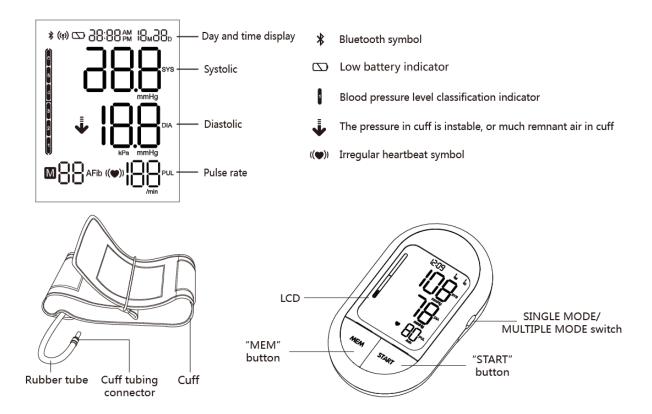
All physical activity, excitement, stress, eating, drinking, smoking, body posture and many other activities or factors (including taking a blood pressure measurement) will influence blood pressure value. Because of this, it is mostly unusual to obtain identical multiple blood pressure readings.

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**





#### **INTENDED USE**

Fully Automatic Electronic Sphygmomanometer 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-48cm(approx. 8 21/32" -18 29/32").

#### **PACKAGE CONTENTS**

- 1 Wireless Blood Pressure Monitor
- 1 Operation Guide
- 1 Arm Cuff
- 1 Soft Storage Case

#### 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 4×60 measurements can be stored in the memory with date and time stamp. The Electronic Sphygmomanometer corresponds to the below standards: IEC 60601-1Edition 3.1 2012-08/EN 60601-1:2006/A1:2013 (Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance), IEC60601-1-2:2014/EN 60601-1-2:2015 (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);ISO81060-2: 2013(Non-Invasive Sphygmomanometers - Part 2: Clinical Validation Of Automated Measurement Type).



#### **SPECIFICATIONS**

- 1. Product name: Wireless Blood Pressure Monitor
- 2. Model: KD-552
- 3. Classification: Internally powered, Type BF applied part,IP20,No AP or APG, Continuous operation
- 4. Machine size: Approx. 158.5mm x 92.3mm x 76.7mm
- Cuff circumference: 22cm-30cm(8 21/32" -11 13/16"), 30cm-42cm(11 13/16" -16 17/32") (Optional), 42cm-48cm(16 17/32" -18 29/32") (Optional), 22cm-42cm(8 21/32" -16 17/32") (Optional)
- 6. Weight: Approx. 270g (9 17/32oz.) (exclude batteries and cuff)
- 7. Measuring method: Oscillometric method, automatic inflation and measurement
- 8. Memory volume:  $4\times60$  times with time and date stamp
- 9. Power source: DC: 6V === 1A, batteries: 4x1.5V === SIZE AA
- 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: Less than 60: ±3bpm

More than 60 (incl.): ±5%

- 12. Environmental temperature for operation:  $10^{\circ}\text{C} \sim 40^{\circ}\text{C} (50^{\circ}\text{F} \sim 104^{\circ}\text{F})$
- 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 270 times.
- 18. Wireless Connection:

**Smart Bluetooth** 

Frequency Band: 2.400~2.4835GHz

19. All components belonging to the pressure measuring system, including accessories: 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



Operation Guide

mmHg or maintained above15 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 wireless blood pressure monitor and other devices together with advice regarding avoidance of such interference please see part ELECTROMAGNETIC COMPATIBILITY INFORMATION. It is suggested that the wireless blood pressure monitor be kept 10 meters away from other wireless devices, such as WLAN unit, cell phone, microwave oven, etc.
- 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 ≥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



Operation Guide

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 1A 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 Φ5.5mm, center pin Φ2.0mm. 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.
- 24. The patient can be an intended operator.
- 25. 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.
- 26. Attention that changes or modification not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- 27. Swallowing batteries and/or battery fluid can be extremely dangerous. Keep the batteries and the unit out of the reach of children and disabled persons.
- 28. If you are allergic to plastic/rubber, please don't use this device.

#### SETUP AND OPERATING PROCEDURES

#### 1. 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.

The negative terminal of the battery needs to be compressed into the battery compartment properly after horizontal compression of the negative electrode. The battery is in contact with the spring.

Make sure the battery cover is intact and not damaged before installing the battery.

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. 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.

#### 2. CLOCK AND DATE ADJUSTMENT

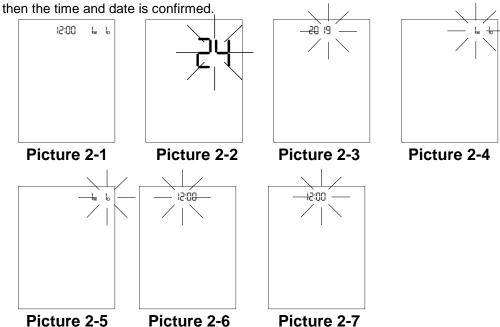
- Once you install the battery, it will enter Clock Mode, and LCD will display time and date. See picture 2-1. The monitor will enter Standby Mode after 10 seconds with no operation.
- While the monitor is in Clock Mode or Standby Mode, press the "START" and "MEM" button simultaneously for two seconds, then release the buttons, the monitor will be in Clock and Date Adjustment Mode.
- In Clock and Date Adjustment Mode, the time format will blink at first. See picture 2-2. While time format is blinking, press the button "MEM" to change the time format. The default time format is 24h.
- Press the button "START" repeatedly, the year (range is 2019~2099), month, day, hour and minute will blink in turn. See picture 2-3 & 2-4 & 2-5 & 2-6 & 2-7. While the number is blinking, press the button "MEM" to increase the number, keep on pressing the button "MEM", the number will increase faster.
- During adjusting clock and date, the monitor will turn off automatically after 1 minute



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with no operation.

f. You can turn off the monitor by pressing "START" button when the minute is blinking,



#### Note:

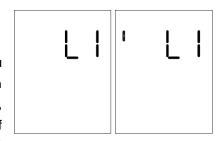
- 2.1 The clock format could be set by user.
- 2.2 Table 2-1 instructs the conversion relations between 24 hour format and 12 hour format.

Table 2-1

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

#### 3. VOICE SETTING

a. Voice language setting: In Standby Mode, you can select the voice language by keeping on press the button "MEM". Now LCD blink "L0", "L1", "L2" ... "Ln" (n means the number of language) circularly. See picture 3-1. "L0"



Picture 3-1 Picture 3-2



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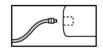
Operation Guide

represents closing voice function, "L1" represents language 1, "L2" represents language 2,...,"Ln" represents language n, and so on. You can select the wanted language by releasing button "MEM" when display the corresponding language code.

- If the number of language is only one, LCD will twinkle "ON" and "--" circularly. Here "ON" represents opening the voice function and "--" represents closing the voice function.
- Voice volume setting: Once you have selected a language, keeping on pressing the button "MEM" again. A column of bar will appear on the left side of the LCD. See picture 3-2. The higher the bars, the louder the volume. Release button "MEM" at your desirable volume for confirmation.

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

Insert the cuff tubing connector into the air port in the left 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,

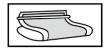
which may cause inflation error, or harmful injury due to continuous cuff pressure.

#### 5. APPLYING THE CUFF

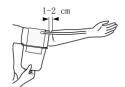
- Pulling the cuff end through the medal loop (the cuff is packaged like this already), turn it outward (away from your body) and tighten it and close the Velcro fastener. See picture 5-1.
- b. Place the cuff around a bare left arm 1-2cm above the elbow joint.
- c. If you place the cuff around left arm, position the air tube in the middle of your arm in line with your middle finger. See picture 5-2. If you place the cuff around right arm, apply the cuff so that the air tube is at the side of

your elbow. See picture 5-3.

- d. While seated, place palm upside in front of you on a flat surface such as a desk or table. Be careful not to rest your arm on the air tube, or otherwise restrict the flow of air to the cuff.
- e. The cuff should fit comfortably, yet snugly around your arm. You should be able to insert one finger between your arm and the cuff.



Picture 5-1



Picture 5-2



Picture 5-3

#### Note:

Please refer to the cuff circumference range in "SPECIFICATIONS" to make sure that the appropriate cuff is used.



- Measuring on same 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.
- Do not place the cuff around your arm if the arm has any inflammation, acute diseases, infections skin wounds.

#### 6. BODY POSTURE DURING MEASUREMENT

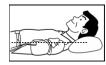
#### **Sitting Comfortably Measurement**

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

# T T

#### **Lying Down Measurement**

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



#### 7. TAKING YOUR BLOOD PRESSURE READING

#### (1) SELECT STANDARD OR MULTIPLE MODE

This device enables you to select either standard or multiple mode. The standard mode is standard single measurement, and the multiple mode



is automatic triple measurement. Since blood pressure constantly fluctuates, the blood pressure reading from multiple measurements is much more reliable than that from only one measurement.

Slide the standard / multiple switch on the right side of the monitor toward to "1" to select standard mode, and toward to "MULT" to select multiple mode before measuring blood pressure.

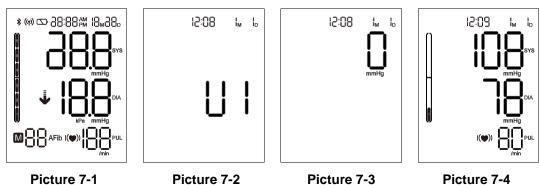
#### (2) STANDARD MODE

- a. After applying the cuff and your body is in a comfortable position, place the standard / multiple switch on the "1" side.
- b. Press the "START" button. All display characters are shown for self-test. You can check the LCD display according to the picture. Please contact the service center if segment is missing. See picture 7-1.

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- c. Then the current memory bank is blink. See picture 7-2. Press "MEM" button to change over to other bank. Confirm your selection by pressing "START" button. The current bank can also be confirmed automatically after 5 seconds with no operation.
- d. Then the monitor starts to seek zero pressure. See picture 7-3.
- e. 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 7-4. The result will automatically be stored in the Memory bank of the monitor.
- f. After measurement, the monitor will turn off automatically after 1 minute with no operation. Alternatively, you can press the "START" button to turn off the monitor manually.
- g. During measurement, you can press the "START" button to turn off the monitor manually.

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



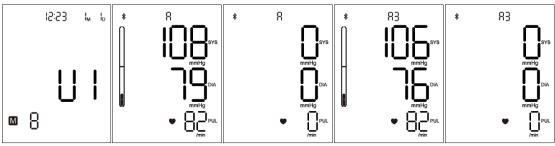
#### (3) MULTIPLE MODE

- a. After applying the cuff and your body is in a comfortable position, place the standard / multiple switch on the "MULT" side.
- b. Press the "START" button, the initial information and settings are the same as section 7(2)b~d.
- c. Then multiple measurements are automatically taken and the result is automatically analysed and displayed. The result will also be stored in the Memory bank of the monitor automatically.
- d. After measurements, the monitor will turn off automatically after 1 minute with no operation. Alternatively, you can press the "START" button to turn off the monitor manually.
- e. The measurement result will be shown after multiple measurements. The individual results will not be displayed.
- f. Please keep quiet and calm during the entire process and do not remove the cuff between measurements.
- g. During the entire measurement process, you can press the "START" button to turn off the monitor manually.

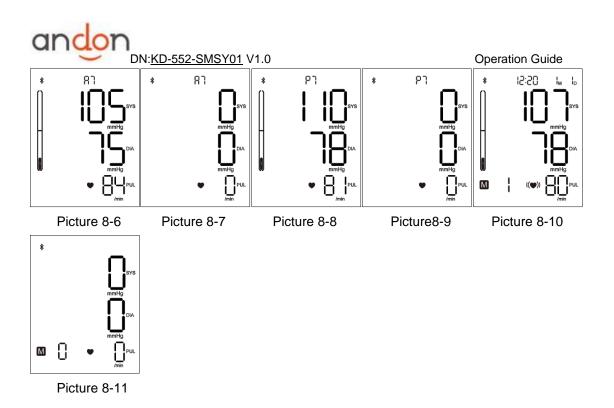


#### 8. DISPLAYING STORED RESULTS

- a. In Standby 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 8-1. Press "START" button to switch group, press "MEM" to confirm current group. The current bank can also be confirmed automatically after 5 seconds with no operation.
- b. Then LCD will display the average value of all results in the current bank. See picture 8-2. If no result stored in the current user memory zone, LCD will display "0" for blood pressure and pulse rate. See picture 8-3.
- c. Press "MEM" button, the LCD will display the average value of the last three results in the current user memory zone. See picture 8-4. If no result stored in the current user memory zone, LCD will display "0" for blood pressure and pulse rate. See picture 8-5.
- d. Press "MEM" button again, the LCD will display the average value of all results which is measured from 5 o'clock to 9 o'clock in last 7 days in the current user memory zone. See picture 8-6. If the monitor has no result which is measured from 5 o'clock to 9 o'clock in last 7 days stored in the current user memory zone, the LCD will display "0". See picture 8-7.
- e. Press "MEM" button again, the LCD will display the average value of all results which is measured from 18 o'clock to 20 o'clock in last 7 days in the current user memory zone. See picture 8-8. If the monitor has no result which is measured from 18 o'clock to 20 o'clock in last 7 days stored in the current user memory zone, the LCD will display "0". See picture 8-9.
- f. Press "MEM" button again, the most recent result will be displayed with date and time stamp. See picture 8-10. Irregular heartbeat symbol (if any) and blood pressure classification indicator will blink at the same time. Press "MEM" button repeatedly to review the results measured previously. 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 8-11.
- g. When displaying the stored results, the monitor will turn off automatically after 1 minute with no operation. You can also press the button "START" to turn off the monitor manually.



Picture 8-1 Picture 8-2 Picture 8-3 Picture 8-4 Picture 8-5



#### 9. SYNCHRONIZING STORED RESULTS

- a. In Standby Mode, press "MEM" button, the monitor will wait Bluetooth connect and Bluetooth symbol flashing after confirming the group. Bluetooth symbol will stop flashing when Bluetooth is connected. When the Electronic Sphygmomanometer has finished memory synchronization, Bluetooth symbol will disappear. If an accident happens, synchronous unfinished, Bluetooth symbol will also disappear.
- b. When Bluetooth is disconnected, the monitor will turn off automatically after 1 minute with no operation. You can also press the "START" 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 the "MEM" button for three seconds, all results in the current bank will be deleted. See picture 10. Press the "START" button, the monitor will be turned off.



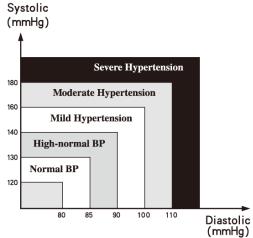
Picture 10

#### 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	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: It is not intended to provide a basis of any type of rush toward emergency conditions/diagnosis based on the number of LCD indicator and that the number of LCD indicator 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 SPECIFICACIONS. 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
	The cuff position was not correct or it was not properly tightened	Apply the cuff correctly and try again.
LCD Display shows abnormal result	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	Re-test when calm and without speaking or moving during the

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	testing	test.	
		It is inappropriate for people with	
	Irregular heartbeat (arrhythmia)	serious arrhythmia to use this	

Electronic Sphygmomanometer.

### 14. TROUBLESHOOTING (2)

PROBLEM	POSSIBLE CAUSE	SOLUTION	
LCD shows low battery symbol \(\sigma\)	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 during inflation	Connect the cuff correctly and try again. If the monitor	
LCD shows "Er 4"	Pneumatic system leakage during inflation	is still abnormal, please contact the local distributor or the factory.	
LCD shows "Er 5"	Cuff pressure above 300mmHg		
LCD shows "Er 6"	More than 160 seconds with cuff pressure above 15 mmHg	Measure again after five minutes. If the monitor is	
LCD shows "Er 7"	Inner memory error	still abnormal, please	
LCD shows "Er 8"	Device parameter checking error	contact the local distributor	
LCD shows "Er A"	Pressure sensor parameter error	or the factory.	
No response when you	Incorrect operation or strong	Take out batteries for five	
press button or load	electromagnetic interference.	minutes, and then reinstall	
battery.		all batteries.	
		Reset iOS/Android device.	
	Bluetooth connection	Reset monitor. Make sure	
Bluetooth	unsuccessful, monitor is	the monitor and	
connection	abnormal, or strong	iOS/Android device are	
unstable	electromagnetic interference is	away from other electrical	
unstable	present	equipment. Please see	
	present	GENERAL SAFETY AND	
		PRECAUTIONS	



#### **MAINTENANCE**

- 1.
- Do not drop this monitor or subject it to strong impact.
- Avoid high temperature and solarization. Do not immerse the monitor in water as this will result in damage to the monitor.
- If this monitor is stored near freezing, allow it to acclimate to room temperature before
- 4. The monitor requires 6 hours to warm from the minimum storage temperature between uses until the monitor is ready for its INTENDED USE when the ambient temperature is 20 °C.
- The monitor requires 6 hours to cool from the maximum storage temperature between uses until the the monitor is ready for its INTENDED USE when the ambient temperature is 20 °C.
- Do not attempt to disassemble this monitor. 6.
- If you do not use the monitor for a long time, please remove the batteries.
- It is recommended the performance should be checked every 2 years or after repair. Please contact the service center.
- Clean the monitor with a dry, soft cloth or a soft cloth squeezed well after moistened with water, diluted disinfectant alcohol, or diluted detergent.
- 10. 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.
- 11. 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.
- 12. 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
- 13. Not servicing/maintenance while the monitor is in use.

#### **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"

C € 0197 Symbol for "COMPILES WITH MDD93/42/EEC REQUIREMENTS"



Symbol for "DATE OF MANUFACTURE"



Symbol for "EUROPEAN REPRESENTATION"



Symbol for "SERIAL NUMBER"



Symbol for "KEEP DRY"

#### WARRANTY INFORMATION

Only charge the cost of components and transport.

#### **SERVICE CENTER**

ANDON HEALTH CO., LTD.

No. 3 Jinping Street, YaAn Road, Nankai District, Tianjin 300190, China.

Tel: 86-22-60526081



iHealthLabs Europe SAS

36 Rue de Ponthieu, 75008, Paris, France

#### IMPORTANT INFORMATION REQUIRED BY THE R&TTE

The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, In c 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 complies with Industry Canada. IC: RSS-210 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 thedevice.



Hereby, [ANDON HEALTH CO.,LTD.] declares that the radio equipment type [KD-552] is in compliance with Directive 2014/53/EU.

The full text of the EU declaration of conformity is available at the following internet address: 
[ the internet address ]

#### **ELECTROMAGNETIC COMPATIBILITY INFORMATION**

This product is applicable to the equipment and system requirements for the purpose of receiving radio frequency energy for the purpose of the work, Bluetooth receive bandwidth 2M. This product can also be used to include RF transmitter equipment and system requirements and emission frequency of 2.4GHz ISM band, Bluetooth modulation types:GFSK, effective radiated power: < 20dBm

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	
Phenomenon		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	Band	Immunity test levels	
(MHz)	(MHz)	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			



DN:<u>KD-552-SMSY01</u> V1.0 Operation Guide

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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 - Input a.c. power Port

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

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