# Operation Guide
# (V1.0)

Product/project name：Blood Pressure Monitor

Model name：KD-5811BT.

Drafted by：_____ Date：_____.

Reviewed by：_____ Date：_____.

Approved by：_____ Date：_____.

# MODEL KD-5811BT

## Wireless Blood Pressure Monitor

(ELECTRONIC SPHYGMOMANOMETER)

## OPERATION GUIDE

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# IMPORTANT INFORMATION

## NORMAL BLOOD PRESSURE FLUCTUATION

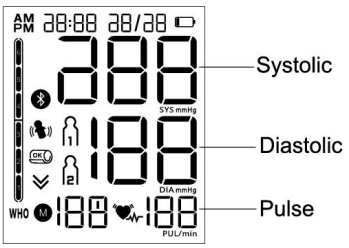
All physical activity, excitement, stress, eating, drinking, smoking, body posture and many other activities or factors (including taking a blood pressure measurement) will influence blood pressure value. Because of this, it is mostly unusual to obtain identical multiple blood pressure readings.

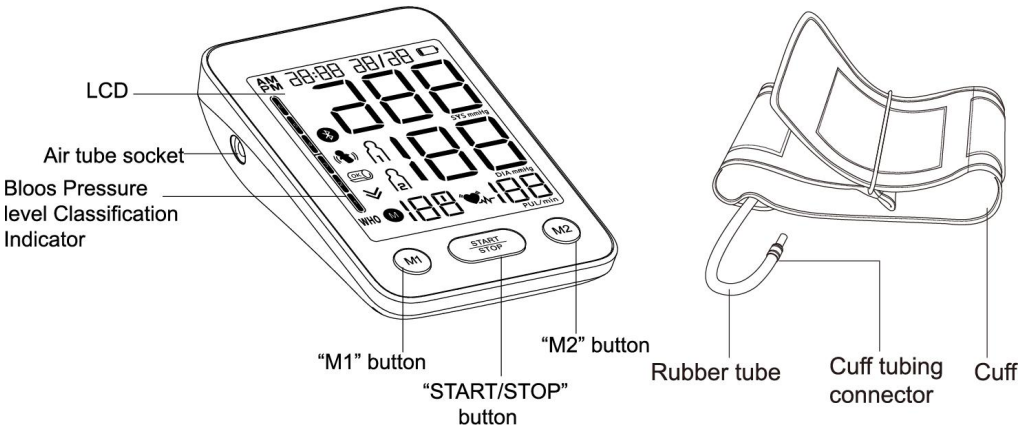
Blood pressure fluctuates continually day and night. The highest value usually appears in the daytime and lowest one usually at midnight. Typically, the value begins to increase at around 3:00AM, and reaches to highest level in the daytime while most people are awake and active.

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






*Note:The pictures in the manual are for reference only.*

## 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 17cm-42cm(approx.6 11/16″ – 16 17/32″ ).

## PACKAGE CONTENTS

- 1 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 2x120 measurements can be stored in the memory with date and time stamp. The Electronic Sphygmomanometer corresponds to the below standards: IEC 60601-1: 2005+AMD1: 2012+AMD2:2020/EN 60601-1:2006+AC:2010+A1:2013+A12:2014+AC:2016+A2:2021(Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance), IEC 60601-1-2:2014/AMD1:2020/EN 60601-1-2:2015+A1:2021(Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests), IEC80601-2-30:2018/EN IEC 80601-2-30:2019(Medical electrical equipment –Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers).EN 1060-3: 1997 + A2: 2009 (Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems);ISO81060-2 ： 2018(Non-Invasive Sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type).

## SPECIFICATIONS

1. Product name: Wireless Blood Pressure Monitor
2. Model: KD-5811BT
3. Classification: Internally powered, Class II, Type BF applied part, IP21, No AP or APG, Continuous operation
4. Machine size: Approx.139.4mm×93.8mm×43.4mm( 5 1/2″ x 3 11/16″ x 1 23/32″ )
5. Cuff circumference: 22cm-42cm(8 21/32″ - 16 17/32″ ), 17cm-22cm（6 11/16″ ~8 21/32″ ）(Optional), 22cm-30cm(8 21/32″ - 11 13/16″ )(Optional), 30cm-42cm(11 13/16″ -16 17/32″ )(Optional)
6. Weight: Approx. 239g (8 7/16 oz.) (exclude batteries and cuff)
7. Measuring method: Oscillometric method, automatic air inflation and measurement
8. Memory volume: 2×120 times with time and date stamp
9. Power source:

   Medical AC adapter: 5V ⎓ 1A, batteries: 4 ×1.5V ⎓ 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%

    precision of the displayed values：1mmHg
12. Environmental temperature for operation: 5℃～40℃(41℉～104℉)
13. Environmental humidity for operation: ≤85%RH
14. Environmental temperature for storage and transport: -20℃～55℃(-4℉～131℉)
15. Environmental humidity for storage and transport: ≤90%RH
16. Environmental pressure: 80kPa-105kPa
17. Battery life: Approx 270 times.
18. Wireless communication:

    Bluetooth V5.2 Class 2

    Frequency Band: 2.402-2.480GHz

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 quiet, 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 a minimum moment of 1 to 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 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 or lymph node clearance;
   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.It is suggested that the blood pressure monitor be kept at least 30 cm away from other wireless devices, such as WLAN unit, microwave oven, etc.It can't be used near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magneticresonance imaging, where the intensity of EM DISTURBANCES is high.
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. Medical AC adapter which output is DC 5.0V 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, such as input: 100-240V, 50/60Hz, 0.2A; output: DC 5V, 1A. Please note that the monitor jack size: hole Φ5.5mm, center pin Φ2.0mm.

17. 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.

18. 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.)
19. Motion, trembling, shivering during measurement may affect the measurement reading.
20. 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).
21. The device would not apply to the patients who use an artificial heart and lung (there will be no pulse).
22. 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.
23. The patient is an intended operator.
24. Attention that changes or modification not expressly approved by the party responsible for compliance could void the user’s authority to operate the equipment.
25. 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.
26. If you are allergic to plastic/rubber, please don’t use this device.
27. The blood pressure monitor is not intended to exposed to the Electromagnetic Interference (EMI)environment, please do not use the blood pressure monitor within the environment of the following device: Magnetic Resonance Imaging (MRI), computerized axial tomography (CT), diathermy, Radio Frequency Identification (RFID), and electromagnetic security systems such as metal detectors.
28. Keep the cuff tube and/or the cable away from children to prevent the risk of strangulation or asphyxiation.

# SETUP AND OPERATING PROCEDURES

## 1. BATTERY LOADING AND AC ADAPTER LOADING

1) BATTERY LOADING

a. Open battery cover at the back of the monitor.

b. Load four “AA” size 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.

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.

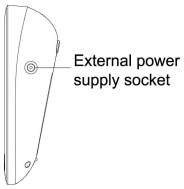
⚠Make sure the battery cover is intact and not damaged before installing the battery.

2) 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.

⚠Do not position the monitor so that it is difficult to operate the disconnection device.

*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 AND BLUETOOTH SET

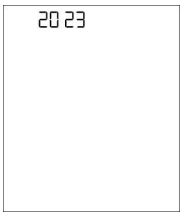
a. At first the Blood Pressure Monitor is totally off, once you insert the battery, the Blood Pressure Monitor will enter Clock and Date Adjustment Mode.

b. If the time of the device is already set and need to be changed, adjustment can be reached by pressing both the “MEM1” and “MEM2” button for 2 seconds in Standby Mode.

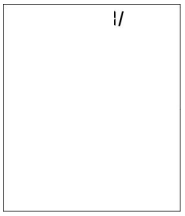
c. In Clock and Date Adjustment Mode , the time format will blink at first , see picture2-1 .The default time format is 24h and the default clock and date is 2023-1-1 1:00.

d. Press the button “START/STOP” repeatedly, the year (first usage: default is 2023, range is 2023~2099), month, day, hour and minute will blink in turn, see picture 2-2& 2-3 & 2-4 & 2-5 & 2-6. While the number is blinking, press the button "MEM1" to increase the number and press the button "MEM2" to decrease the number, keep on pressing the button "MEM1" or "MEM2" , the number will increase or decrease faster.

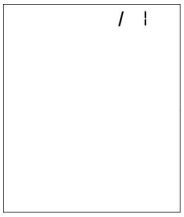
**Picture 2-1**



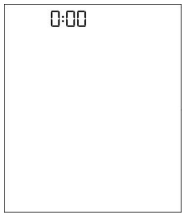

**Picture 2-2**



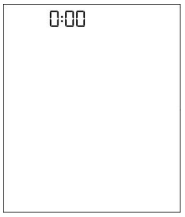
**Picture 2-3**



**Picture 2-4**

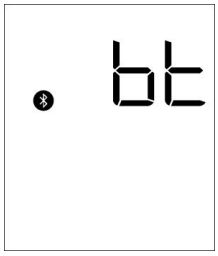



**Picture 2-5**




**Picture 2-6**

e. You can set the bluetooth by pressing “START/STOP” button when the minute is blinking, then the time and date is confirmed. press the button “MEM1” or “MEM2” to change the state of bluetooth. If bluetooth is on, bluetooth symbol twinkles. See picture 2- 7. If bluetooth is off, bluetooth symbol don’t show.




**Picture 2-7**

f. During adjusting clock and date, the monitor will go back to Standby Mode automatically and date unchanged when no button will be pressed within 1 minute .

g. You can turn off the monitor by pressing “START/STOP” button when the minute is blinking, then the time and date is confirmed.

h. Once you change the batteries, you should readjust the time and date.

**Note:**

2.1 *The clock format could be set by user.*

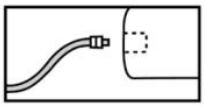
*2.2 Table 1 instructs the conversion relations between 24 hour format and 12 hour format.*

**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 |

## 3. CONNECTING THE CUFF TO THE MONITOR

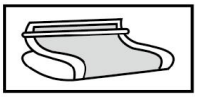
Insert the cuff tubing connector into the socket in the left side of the monitor. Make certain that the connector is completely inserted to avoid air leakage during blood pressure measurements.



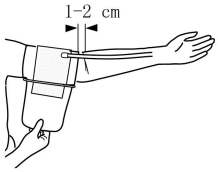
⚠ Avoid compression or restriction of the connection tubing during measurement，which may cause inflation error, or harmful injury due to continuous cuff pressure.

## 4. APPLYING THE CUFF

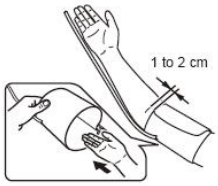
a. Pulling the cuff end through the medal loop (the cuff is packaged like this already), turn it outward (away from your body) and tighten it and close the Velcro fastener.See picture 4-1.
b. Place the cuff around a bare left arm 1-2cm above the elbow joint.
c. If you place the cuff around left arm,position the air tube in the middle of your arm in line with your middle finger.See picture4-2.
   If you place the cuff around right arm, apply the cuff so that the air tube is at the side of your elbow.See picture4-3.
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 4-1




Picture 4-2




Picture 4-3

***Note:***

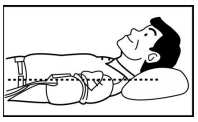
- ***Please refer to the cuff circumference range in "SPECIFICATIONS" to make sure that the appropriate cuff is used.***
- ***Measure on the same arm each time.***
- ***Do not move your arm, body, or the monitor and do not move the rubber tube during measurement.***
- ***Stay quiet, calm for 5 minutes 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.***

## 5. 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 desk or table.
c. The middle of the cuff should be at the level of the right atrium of the heart.

**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.

## 6. TAKING YOUR BLOOD PRESSURE READING

a. 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.

b. Then the current memory bank ( , ) is displayed. If the monitor has stored results, the LCD will momentarily display the most recent one. If no result has been stored, zero will appear on LCD. Press “MEM1” or “MEM2”button to change over to other bank. Confirm your selection by pressing “START” button. The current bank can also be confirmed automatically after 3 seconds with no operation.

c. Then the monitor inflates the cuff until sufficient pressure has built up for a measurement. The cuff wrap symbol( ) flashes at the early stage of inflation, and if the monitor detects that the cuff is tight enough during inflation, the cuff wrap “ok” symbol( ) is displayed on the LCD. Otherwise, the cuff wrap symbol( ) is displayed on the LCD. Then the monitor slowly releases air from the cuff and carries out the measurement. Finally the blood pressure and pulse rate will be calculated and displayed on the LCD screen. If the monitor detects body movement during measurement, the LCD displays the Body Movement symbol. The blood pressure classification indicator and Irregular heartbeat symbol (if any) will blink on the screen. The result will be automatically stored in the monitor.

d. After measurement, If bluetooth is on,you can press the “START” button and upload current measurement result by Bluetooth.Then the monitor will turn off automatically after upload.

e. 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.*

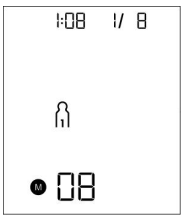
*Note: Cuff wrap indicator applies to 22cm-42cm, 22cm-30cm, 30cm-42cm cuffs, the cuff wrap symbol( and ) has no reference meaning when using other cuffs.*

## 7. DISPLAYING STORED RESULTS

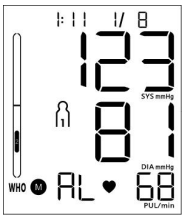
a. In StandBy Mode, press “MEM1” or “MEM2” button, the monitor will display sign of or . The amount of results in current user memory zone will be displayed. See picture 7-1. Confirm your selection by pressing MEM button that corresponds to the current bank. The current bank can also be confirmed automatically after 5 seconds with no operation. .

b. Press “MEM1” or “MEM2” to confirm current group.Then LCD will display the average value of all results in the current user memory zone. See picture 7-2. If bluetooth is on, the Bluetooth symbol flashing and the monitor will upload all memory by Bluetooth. See picture 7-8. If no result stored in the current user memory zone, LCD will display “0” for blood pressure and pulse rate. See picture 7-3.

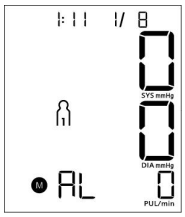
c. Press current bank MEM button, the LCD will display the average values of last 3 results in this bank. See picture 7-4. If no result stored, LCD will show zeros. See picture 7-5.




Picture 7-1

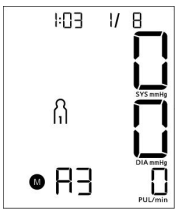



Picture 7-2



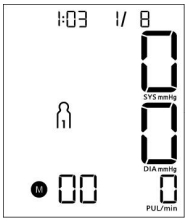

Picture 7-3

Picture 7-4




Picture 7-5

Picture 7-6




Picture 7-7

Picture 7-8

d. Press current bank MEM button again, the most recent result will be displayed with date and time stamp. See picture 7-6. 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 7-7.

e. Press current bank MEM button again to review the next result. In this way, repeatedly pressing the current bank MEM button displays the respective results measured previously.

f. Press other bank MEM button in steps “a” to “e” can switch to other bank.

g. When reviewing the results, 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.

*Note: When the monitor displaying the measurement, the classification digital indicator can be shown different numbers according to the systolic pressure and diastolic pressure. Refer to the “ASSESSING HIGH BLOOD PRESSURE FOR ADULTS” section*

## 8. DELETING MEASUREMENTS FROM THE MEMORY

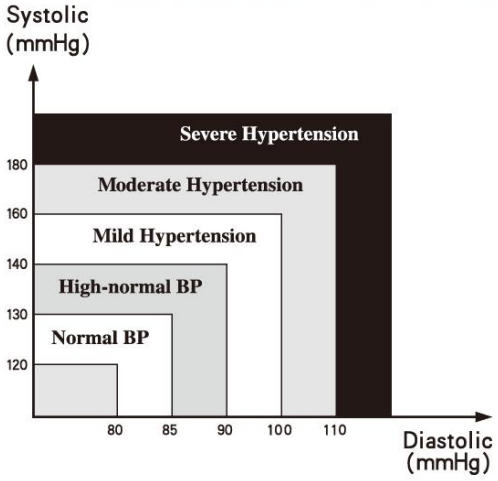
When any result is displaying, keeping on pressing button “MEM1” and “MEM2” for three seconds, all result of current group will be deleted , and the monitor will turn off after 1s.

## 9. 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 scheme and that the number scheme is meant only to discriminate between the different levels of blood pressure.***

## 10. 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.

## 11. 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. |

## 12. 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.If the monitor 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 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” | 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, 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. |
| 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. |

## 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. It is recommended the performance should be checked every 2 years or after repair. Please contact the service center.
6. Clean the monitor with a dry, soft cloth or a soft cloth squeezed well after moistened with water, diluted disinfectant alcohol, or diluted detergent.
7. 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 .
8. 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.
9. 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.
10. 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.
11. The monitor requires 6 hours to cool from the maximum storage temperature between uses until the monitor is ready for its INTENDED USE when the ambient temperature is 20 ° C.
12. No 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”

CE 0197 Symbol for “COMPILES WITH MDD93/42/EEC REQUIREMENTS”

Symbol for “DATE OF MANUFACTURE”

Symol for “Polarity if d.c. power connector”

EC REP Symbol for “EUROPEAN REPRESENTATION”

SN Symbol for “SERIAL NUMBER”

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

MR MR Unsafe

Recyclable identification

CLASS II equipment

## WARRANTY INFORMATION

Only charge the cost of components and transport.

ANDON HEALTH CO., LTD.
No. 3 Jinping Street, YaAn Road, Nankai District, Tianjin 300190, China.
Tel: 86-22-87611660

EC REP iHealthLabs Europe SAS
36 rue de Ponthieu, 75008, Paris, France

## IMPORTANT INFORMATION REQUIRED BY THE R&TTE

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

Hereby, ANDON HEALTH CO., LTD. declares that the radio equipment type KD-5811BT is in compliance with Directive 2014/53/EU.

The full text of the EU declaration of conformity is available at the following internet address:https://cdn.ihealthlabs.com/policy/EU_DECLARATION_OF_CONFORMITY.pdf

**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**

- The essential performance: 1. Limits of the error of the cuff pressure indication;2.Reproducibility of the blood pressure DETERMINATION; 3.Alarm.When electromagnetic interference 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 are operating normally.
- 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 KD-5811BT, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.”

## 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 | IEC 61000-4-2 | ±8 kV contact |

| | | |
|---|---|---|
| Discharge | | ±2kV, ±4kV, ±8kV, ±15kV air |
| Radiated RF EM field | IEC 61000-4-3 | 10V/m<br>80MHz-2.7GHz<br>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<br>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 – Input a.c. power Port

| Phenomenon | Basic EMC standard | Immunity test levels |
|---|---|---|
| | | Home Healthcare Environment |
| Electrical fast transients/burst | IEC 61000-4-4 | ±2 kV<br>100kHz repetition frequency |
| Surges<br>Line-to-line | IEC 61000-4-5 | ±0.5 kV, ±1 kV |
| Conducted disturbances induced by RF | IEC 61000-4-6 | 3V, 0.15MHz-80MHz<br>6V in ISM and amateur radio bands between 0.15MHz and 80MHz |

| | | |
|---|---|---|
| fields | | 80%AM at 1kHz |
| Voltage dips | IEC 61000-4-11 | 0% $U_T$; 0.5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° |
| | | 0% $U_T$; 1 cycle<br>and<br>70% $U_T$; 25/30 cycles<br>Single phase: at 0° |
| Voltage interruptions | IEC 61000-4-11 | 0% $U_T$; 250/300 cycles |

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