

MedTalk 1330S



Wrist Measurement Blood Pressure Monitor Operation Guide



THE OPERATION GUIDE MUST BE READ

Contents

Important Information	2	Body Posture During Measurement	18
Contents And Display Indicators	3	Taking Your Blood Pressure Reading	18
Intended Use	4	Displaying Stored Results	20
Package Contents	4	Deleting Measurements From The Memory	21
Contraindication	4	Assessing High Blood Pressure For Adults	22
Product Description	5	Technical Alarm Description	23
Specifications	6	Troubleshooting (1)	24
Notice	8	Troubleshooting (2)	25
Setup And Operating Procedures	13	Maintenance	26
Battery Loading	13	Explanation Of Symbols On Unit	27
Clock And Date Adjustment	14	Warranty Information	29
Voice Setting	15	Service Center	29
Connecting The Cuff To The Monitor	16	Electromagnetic Compatibility Information	29
Applying The Cuff	17		

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 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



Systolic

Diastolic

Pulse



irregular heartbeat symbol



low battery



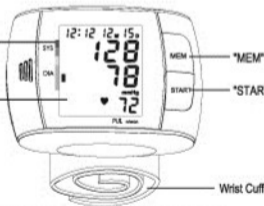
the pressure in cuff is instable, or much remnant air in cuff



find an error, please re-inflate

Blood Pressure
Level Classification
Indicator

LCD



"MEM" Button/Clock Setting

"START" Button/Clock Adjusting

Wrist Cuff

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

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 wrist. The cuff circumference is limited to 14cm-19.5cm (approx. 5 1/2"-7 11/16").

Package Contents

- 1 Blood Pressure Monitor with Wrist Cuff
- 1 Operation Guide
- 1 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 1x60 measurements can be stored in the memory with date and time stamp. The voice function will ease the operation. The Electronic Sphygmomanometers corresponds to the below standards: IEC 60601-1 Edition 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: Wrist Blood Pressure Monitor
- 2.Model: MEDTALK 1330S
- 3.Classification: Internally powered, Type BF applied part, IP22, No AP or APG, Continuous operation
- 4.Machine size: Approx. 87mm×70mm×29mm (3 7/16" x 2 3/4" x 1 5/32")
- 5.Cuff circumference: 14cm - 19.5cm(5 1/2" - 7 11/16")
- 6.Weight: Approx. 133g (4 11/16oz.) (exclude batteries)
- 7.Measuring method: Oscillometric method, automatic inflation and measurement
- 8.Memory volume: 60 times with time and date stamp
- 9.Power source: batteries: 2 ×1.5V --- SIZE AAA
- 10.Measurement range:
 - Cuff pressure: 0-300mmHg
 - Systolic: 60-260mmHg
 - Diastolic: 40-199mmHg
 - Pulse rate: 40-180 beats/minute

Specifications

11. Accuracy:

Pressure: ± 3 mmHg

Pulse rate: Less than 60: ± 3 bpm

More than 60 (incl.) : $\pm 5\%$

12. Environmental temperature for operation: $5^{\circ}\text{C} \sim 40^{\circ}\text{C}$ ($41^{\circ}\text{F} \sim 104^{\circ}\text{F}$)

13. Environmental humidity for operation: $\leq 90\%$ RH

14. Environmental temperature for storage and transport: $-20^{\circ}\text{C} \sim 55^{\circ}\text{C}$ ($-4^{\circ}\text{F} \sim 131^{\circ}\text{F}$)

15. Environmental humidity for storage and transport: $\leq 90\%$ RH

16. Environmental pressure: 80kPa-105kPa

17. Battery life: Approx 120 times.


1. 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 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 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.

Notice


8.  This electronic blood pressure monitor 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 magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.


Notice


12.If Irregular Heartbeat (IHB) is detected in the procedure of blood pressure measurement, a signal of  will be displayed. Under this condition, the electronic blood pressure monitors 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

Notice

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. Measurements are not possible in patients with a high frequency of arrhythmias.
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 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).

Notice

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. 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.
25. Attention that changes or modification not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
26. 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.
27. If you are allergic to plastic/rubber, please don't use this device.

Setup And Operating Procedures

1. Battery Loading

- a. Open battery cover at the back of the monitor.
- b. Load two “AAA” 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

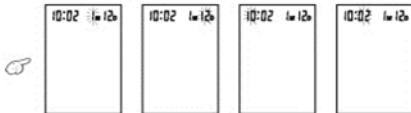


The monitor, the batteries and the cuff, must be disposed of according to local regulations at the end of their usage.

2. Clock And Date Adjustment

a. Once you install the battery or turn off the monitor, it will enter Clock Mode, and LCD will display time and date.

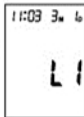
b. While the monitor is in Clock Mode, press the "START" and "MEM" button simultaneously for two seconds, the month will blink at first. Press the button "START" repeatedly, the day, hour and minute will blink in turn. While the number is blinking, press the button "MEM" to increase the number. Keep on pressing the button "MEM", the number will increase fast.



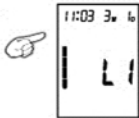
- c. You can turn off the monitor by pressing “START” button when the minute is blinking, then the time and date is confirmed.
- d. The monitor will turn off automatically after 1 minute of no operation, with the time and date unchanged.
- e. Once you change the batteries, you should readjust the time and date.

3. Voice Setting

a. Voice language setting: In clock 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. “L0” 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.

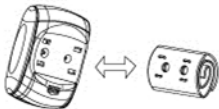


b. Voice volume setting: Once you have selected a language, keeping on pressing the button “MEM” again. A column of bar will appear on the left side of the LCD. The higher the bars, the louder the volume. Release button “MEM” at your desirable volume for confirmation.



4. Connecting The Cuff To The Monitor

The cuff is attached to the monitor when it is packaged. Should the cuff become unattached, align the two plugs and four brackets of the cuff with the plug sockets and bracket sockets of the monitor and press the cuff to the monitor until the plugs and brackets are securely attached.



5. Applying The Cuff

- a. Place the cuff around a bare wrist 1-2cm above the wrist joint on the palm side of the wrist.
- b. While seated, place the arm with the cuffed wrist in front of your body on a desk or table with the palm up. If the cuff is correctly placed, you can read the LCD display. If you want to measure with the right wrist, you should invert the monitor and you will see the inverted blood pressure value.
- c. The cuff must be neither too tight nor too loose.
- d. You can also take a measurement on your right wrist as the picture.

Note:

1. Please refer to the cuff circumference range in "SPECIFICATIONS" to make sure that the appropriate cuff is used.
2. Measuring on same wrist each time.
3. Do not move your arm, body, or the monitor during measurement.
4. Stay quiet, calm for 5 minutes before blood pressure measurement.



5. Please keep the cuff clean. Clean the cuff by wet soft cloth and mild detergent if the cuff becomes dirty. Do not remove the cuff from the monitor. Clean the cuff after the usage of every 200 times is recommended.
6. Do not place the cuff around your wrist if the wrist has any inflammation, acute diseases, infections skin wounds.

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 a desk or table.
- The middle of the cuff should be at the level of the right atrium of the heart.

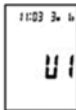


7. Taking Your Blood Pressure Reading

- After applying the cuff and your body is in a comfortable position, press the "START" button. A beep is heard and 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.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. If the voice function is switched on, the monitor will speak out measurement tips.



c.Then the monitor inflates the cuff until sufficient pressure has built up for a measurement. 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. The blood pressure classification indicator and Irregular heartbeat symbol (if any) will blink on the screen. If the voice function is on, it will announce the measurement result.



d. After measurement, the monitor will turn off automatically after 1 minute of no operation. Alternatively, you can press the “START” button to turn off the monitor manually.

e. 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.

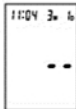
8. Displaying Stored Results

a. In Clock Mode, press “MEM” button, the last result will be displayed with date and time. Irregular heartbeat symbol (if any) and the indicator of blood pressure classification will blink at the same time. If the voice function is on, the monitor will announce each result displaying on the screen. Press “MEM” button repeatedly to review the results measured previously.

b. When displaying the stored results, the monitor will turn off automatically after 2 minutes of no operation. You can also press the button “START” to turn off the monitor manually.

9. Deleting Measurements From The Memory

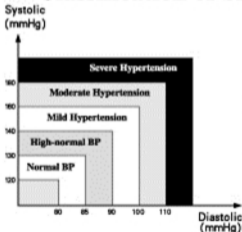
When any result is displaying, keeping on pressing button “MEM” for three seconds, all results will be deleted after three “beep”. Press the button “MEM” or “START”, the monitor will turn off.



10. 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.

11. 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.

Troubleshooting (1)

Problem	Possible Cause	Solution
LCD Display shows battery symbol	Low Battery	Change all the batteries
LCD Display shows "EE"	Arm or blood pressure monitor was moved during testing	Re-test taking care to not move your arm or the blood pressure monitor
	The cuff does not inflate properly or pressure falls quickly during testing	Make certain the plugs and brackets of the cuff are securely attached to the monitor.
	Irregular heartbeat (arrhythmia)	It is inappropriate for people with serious arrhythmia to use this blood pressure monitor.

Troubleshooting (2)

Problem	Possible Cause	Solution
LCD Display shows "EE"	The cuff was not properly applied.	Review the cuff applying and testing sections of the instructions and re-test.
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 and testing 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
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. 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.
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.

Maintenance

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.

11. 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.

12. 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.

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”

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

 Symbol for “DATE OF MANUFACTURE”

EC REP Symbol for “EUROPEAN REPRESENTATION”

SN Symbol for “SERIAL NUMBER”

 Symbol for “KEEP DRY”

IP20 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”

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

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 ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV 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, \pm 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		

Date of issue: Aug 13, 2019

MedTalk 1330S



Wrist Measurement Blood Pressure Monitor Operation Guide



THE OPERATION GUIDE MUST BE READ

Contents

Important Information	2	Body Posture During Measurement	18
Contents And Display Indicators	3	Taking Your Blood Pressure Reading	18
Intended Use	4	Displaying Stored Results	20
Package Contents	4	Deleting Measurements From The Memory	21
Contraindication	4	Assessing High Blood Pressure For Adults	22
Product Description	5	Technical Alarm Description	23
Specifications	6	Troubleshooting (1)	24
Notice	8	Troubleshooting (2)	25
Setup And Operating Procedures	13	Maintenance	26
Battery Loading	13	Explanation Of Symbols On Unit	27
Clock And Date Adjustment	14	Warranty Information	29
Voice Setting	15	Service Center	29
Connecting The Cuff To The Monitor	16	Electromagnetic Compatibility Information	29
Applying The Cuff	17		

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 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



Systolic

Diastolic

Pulse



irregular heartbeat symbol



low battery



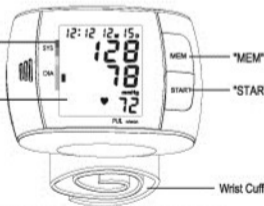
the pressure in cuff is instable, or much remnant air in cuff



find an error, please re-inflate

Blood Pressure
Level Classification
Indicator

LCD



"MEM" Button/Clock Setting

"START" Button/Clock Adjusting

Wrist Cuff

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

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 wrist. The cuff circumference is limited to 14cm-19.5cm (approx. 5 1/2"-7 11/16").

Package Contents

- 1 Blood Pressure Monitor with Wrist Cuff
- 1 Operation Guide
- 1 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 1x60 measurements can be stored in the memory with date and time stamp. The voice function will ease the operation. The Electronic Sphygmomanometers corresponds to the below standards: IEC 60601-1 Edition 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: Wrist Blood Pressure Monitor
- 2.Model: MEDTALK 1330S
- 3.Classification: Internally powered, Type BF applied part, IP22, No AP or APG, Continuous operation
- 4.Machine size: Approx. 87mm×70mm×29mm (3 7/16" x 2 3/4" x 1 5/32")
- 5.Cuff circumference: 14cm - 19.5cm(5 1/2" - 7 11/16")
- 6.Weight: Approx. 133g (4 11/16oz.) (exclude batteries)
- 7.Measuring method: Oscillometric method, automatic inflation and measurement
- 8.Memory volume: 60 times with time and date stamp
- 9.Power source: batteries: 2 ×1.5V --- SIZE AAA
- 10.Measurement range:
 - Cuff pressure: 0-300mmHg
 - Systolic: 60-260mmHg
 - Diastolic: 40-199mmHg
 - Pulse rate: 40-180 beats/minute

Specifications

11. Accuracy:

Pressure: ± 3 mmHg

Pulse rate: Less than 60: ± 3 bpm

More than 60 (incl.) : $\pm 5\%$

12. Environmental temperature for operation: $5^{\circ}\text{C} \sim 40^{\circ}\text{C}$ ($41^{\circ}\text{F} \sim 104^{\circ}\text{F}$)

13. Environmental humidity for operation: $\leq 90\%$ RH

14. Environmental temperature for storage and transport: $-20^{\circ}\text{C} \sim 55^{\circ}\text{C}$ ($-4^{\circ}\text{F} \sim 131^{\circ}\text{F}$)

15. Environmental humidity for storage and transport: $\leq 90\%$ RH

16. Environmental pressure: 80kPa-105kPa

17. Battery life: Approx 120 times.


1. 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 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 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.

Notice


8.  This electronic blood pressure monitor 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 magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.


Notice


12.If Irregular Heartbeat (IHB) is detected in the procedure of blood pressure measurement, a signal of  will be displayed. Under this condition, the electronic blood pressure monitors 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

Notice

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. Measurements are not possible in patients with a high frequency of arrhythmias.
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 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).

Notice

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. 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.
25. Attention that changes or modification not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
26. 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.
27. If you are allergic to plastic/rubber, please don't use this device.

Setup And Operating Procedures

1. Battery Loading

- a. Open battery cover at the back of the monitor.
- b. Load two “AAA” 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

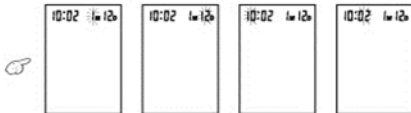


The monitor, the batteries and the cuff, must be disposed of according to local regulations at the end of their usage.

2. Clock And Date Adjustment

a. Once you install the battery or turn off the monitor, it will enter Clock Mode, and LCD will display time and date.

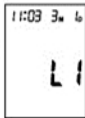
b. While the monitor is in Clock Mode, press the "START" and "MEM" button simultaneously for two seconds, the month will blink at first. Press the button "START" repeatedly, the day, hour and minute will blink in turn. While the number is blinking, press the button "MEM" to increase the number. Keep on pressing the button "MEM", the number will increase fast.



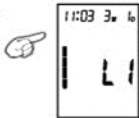
- c. You can turn off the monitor by pressing “START” button when the minute is blinking, then the time and date is confirmed.
- d. The monitor will turn off automatically after 1 minute of no operation, with the time and date unchanged.
- e. Once you change the batteries, you should readjust the time and date.

3. Voice Setting

a. Voice language setting: In clock 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. “L0” 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.

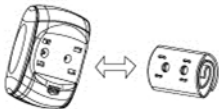


b. Voice volume setting: Once you have selected a language, keeping on pressing the button “MEM” again. A column of bar will appear on the left side of the LCD. The higher the bars, the louder the volume. Release button “MEM” at your desirable volume for confirmation.



4. Connecting The Cuff To The Monitor

The cuff is attached to the monitor when it is packaged. Should the cuff become unattached, align the two plugs and four brackets of the cuff with the plug sockets and bracket sockets of the monitor and press the cuff to the monitor until the plugs and brackets are securely attached.



5. Applying The Cuff

- Place the cuff around a bare wrist 1-2cm above the wrist joint on the palm side of the wrist.
- While seated, place the arm with the cuffed wrist in front of your body on a desk or table with the palm up. If the cuff is correctly placed, you can read the LCD display. If you want to measure with the right wrist, you should invert the monitor and you will see the inverted blood pressure value.
- The cuff must be neither too tight nor too loose.
- You can also take a measurement on your right wrist as the picture.

Note:

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



5. Please keep the cuff clean. Clean the cuff by wet soft cloth and mild detergent if the cuff becomes dirty. Do not remove the cuff from the monitor. Clean the cuff after the usage of every 200 times is recommended.
6. Do not place the cuff around your wrist if the wrist has any inflammation, acute diseases, infections skin wounds.

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 a desk or table.
- The middle of the cuff should be at the level of the right atrium of the heart.

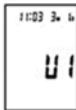


7. Taking Your Blood Pressure Reading

- After applying the cuff and your body is in a comfortable position, press the "START" button. A beep is heard and 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.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. If the voice function is switched on, the monitor will speak out measurement tips.



c.Then the monitor inflates the cuff until sufficient pressure has built up for a measurement. 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. The blood pressure classification indicator and Irregular heartbeat symbol (if any) will blink on the screen. If the voice function is on, it will announce the measurement result.



d. After measurement, the monitor will turn off automatically after 1 minute of no operation. Alternatively, you can press the “START” button to turn off the monitor manually.

e. 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.

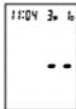
8. Displaying Stored Results

a. In Clock Mode, press “MEM” button, the last result will be displayed with date and time. Irregular heartbeat symbol (if any) and the indicator of blood pressure classification will blink at the same time. If the voice function is on, the monitor will announce each result displaying on the screen. Press “MEM” button repeatedly to review the results measured previously.

b. When displaying the stored results, the monitor will turn off automatically after 2 minutes of no operation. You can also press the button “START” to turn off the monitor manually.

9. Deleting Measurements From The Memory

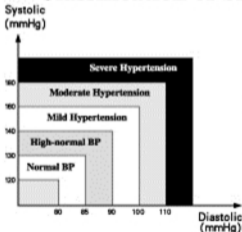
When any result is displaying, keeping on pressing button “MEM” for three seconds, all results will be deleted after three “beep”. Press the button “MEM” or “START”, the monitor will turn off.



10. 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.

11. 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.

Troubleshooting (1)

Problem	Possible Cause	Solution
LCD Display shows battery symbol	Low Battery	Change all the batteries
LCD Display shows "EE"	Arm or blood pressure monitor was moved during testing	Re-test taking care to not move your arm or the blood pressure monitor
	The cuff does not inflate properly or pressure falls quickly during testing	Make certain the plugs and brackets of the cuff are securely attached to the monitor.
	Irregular heartbeat (arrhythmia)	It is inappropriate for people with serious arrhythmia to use this blood pressure monitor.

Troubleshooting (2)

Problem	Possible Cause	Solution
LCD Display shows "EE"	The cuff was not properly applied.	Review the cuff applying and testing sections of the instructions and re-test.
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 and testing 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
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. 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.
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.

Maintenance

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.

11. 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.

12. 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.

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”

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

 Symbol for “DATE OF MANUFACTURE”

EC REP Symbol for “EUROPEAN REPRESENTATION”

SN Symbol for “SERIAL NUMBER”

 Symbol for “KEEP DRY”

IP20 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”

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

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, \pm 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		

Date of issue: Aug 13, 2019