Digital LCD Wrist Blood Pressure Monitor
BVDWBPMTRKA
User Manual

Please read this user manual carefully and thoroughly to ensure the safe and accurate use of this product. Keep a copy of the manual handy for future reference.

Table of Contents

General Description

This blood pressure monitor features blood pressure measurement, pulse rate measurement and result storage. Readings taken using this device are the equivalent to those obtained by a trained observer using the cuff and stethoscope auscultation method.

Features

- Systolic blood pressure
- Diastolic blood pressure
- Memory function holds 60 measurements

The Blood Pressure Monitor is digital LCD monitors intended for use in measuring blood pressure and heartbeat rate with wrist circumference ranging from 13.5cm to 21.5 cm (about $5^{1}/_{3}$″ -$8^{1}/_{2}$″). It is intended for adult indoor use only.

Sold in Australia by Kogan Australia Pty Ltd,
(GPO Box 2679 Melbourne VIC 3001)
ARTG Number: ARTG 286504

Manufactured by: Guangdong Transtek Medical Electronics Co.,Ltd
(Zone A, No.105 Dongli Road Torch Development District, Zhongshan, Guangdong 528437 China)

Product Labels

The labels below may appear in the labelling on the product.

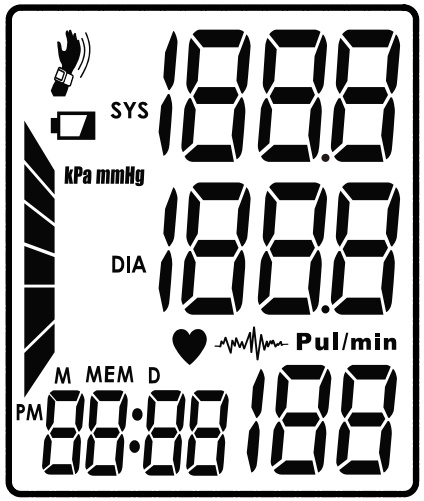
	Symbol for “THE OPERATION GUIDE MUST BE READ”		Symbol for “TYPE BF APPLIED PARTS”
	Caution: These notes must be observed to prevent any damage to the device.		Symbol for “ENVIRONMENT PROTECTION - Electrical waste products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice”
	Symbol for “MANUFACTURE DATE”		
	Symbol for “SERIAL NUMBER”		
	Symbol for “DIRECT CURRENT”		

⚠ Caution

- This device is intended for adult use only.
- This device is intended for non-invasive measurement and monitoring of arterial blood pressure.
- It is not intended for use on extremities other than the wrist, or for functions other than obtaining a blood pressure measurement.
- Do not confuse self-monitoring with self-diagnosis. This unit allows you to monitor your blood pressure. Do not begin or end medical treatment without asking a physician for treatment advice. If you are taking medication, consult with your physician to determine the most appropriate time to measure your blood pressure. Never change a prescribed medication without consulting with your physician.

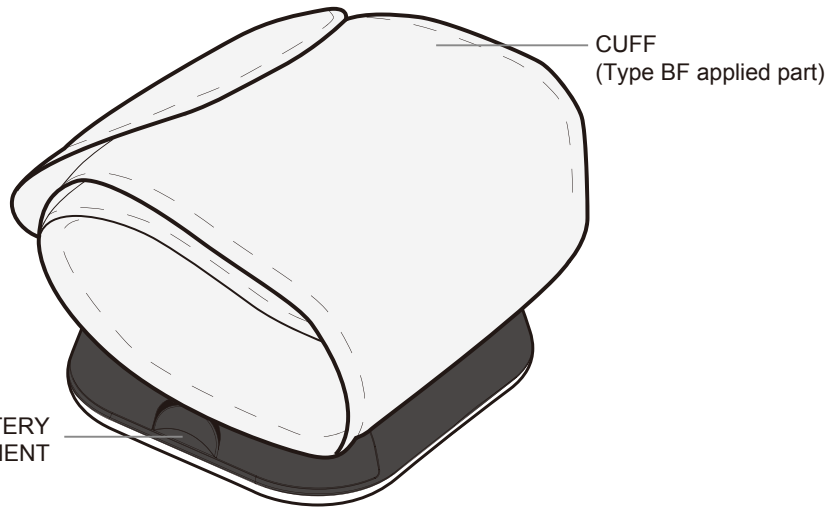
- When this device is used to measure patients who have common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, accurate results from the device may still occur with deviations. Please consult with your physician about the results.
- If the cuff pressure exceeds 40kPa (300 mmHg), the unit will automatically deflate. Should the cuff not deflate when the pressure exceeds 40 kPa (300 mmHg), detach the cuff from your wristand press the START/STOP button to stop inflation.
- This equipment is not AP/APG equipment and not suitable for use in the presence of a flammable anaesthetic mixture of air with oxygen or nitrous oxide.
- The operator must not touch the battery output and the patient simultaneously.
- To avoid measurement errors, please avoid strong electromagnetic fields, radiating interference signals or electrical fast transient/burst signals.
- The user must check that the equipment is functioning safely, checking that the product is in working order before use.
- This device should not be used by pregnant women, or women who suspect they may be pregnant. It will provide inaccurate readings and the effects upon a fetus is untested.
- This device is not suitable for continuous monitoring during medical emergencies or operations. Prolonged use can cause the patients wristand fingers to become swollen and turn purple due to the lack of blood flow.
- During use, the patient will be in contact with the cuff. The materials of the cuff have been tested and found to comply with requirements of ISO 10993-5:2009 and ISO 10993-10:2010. It will not cause any irritation or hyper-sensitivity.
- Please do not use extra accessories that have not been supplied by Kogan.com.
- If you have any problems or questions regarding the use of the device, please contact the Kogan.com customer support team.
- Please use the soft cloth to clean the whole unit. Don't use any abrasive or volatile cleaners.
- The maximum temperature that the applied part can be achieved is 42.5℃ while the environmental temperature is 40℃.

LCD Display



SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic pressure	High blood pressure
DIA	Diastolic pressure	Low blood pressure
Pul/min	Pulse display	Pulse in beats per minute
	Motion indicator	Motion may result in an inaccurate measurement.
	Low battery	Batteries are low and need to be replaced
kPa	kPa	Measurement unit of the blood pressure (1kPa=7.5mmHg)
mmHg	mmHg	Measurement unit of the blood pressure (1mmHg=0.133kPa)
	Irregular heartbeat	Blood pressure monitor is detecting an irregular heartbeat during measurement.
	Current time	Year/Month/Day,Hour : Minute
	Blood pressure level indicator	Indicate the blood pressure level
	Heartbeat	Blood pressure monitor is detecting a heartbeat during measurement.
	Memory	Indicate it is in the memory mode and which group of memory it is.

Product Layout

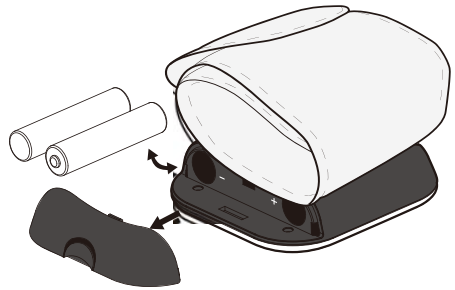


List

1) Wrist Blood Pressure Monitor BVDWBPMTRKA
2) 2×AAA batteries
3) User manual

Before Use

Installing/Replacing Batteries



1. Slide the battery cover off.
2. Install the batteries as indicated in the battery compartment, taking care to match the polarities as shown.
   (The unit uses two x AAA batteries)
3. Replace the battery cover.

The batteries should be replaced whenever any of the following occurs:

- The 'Lo+▭' symbol shows.
- The display is dim.
- The display does not light up.

⚠ CAUTION
Do not use new and used batteries together.
Do not use different types of batteries together.
Do not dispose of the batteries in a fire. Batteries may explode or leak.
Remove batteries if the device is not likely to be used for some time.
Worn batteries are harmful for the environment. Do not dispose with the household garbage.

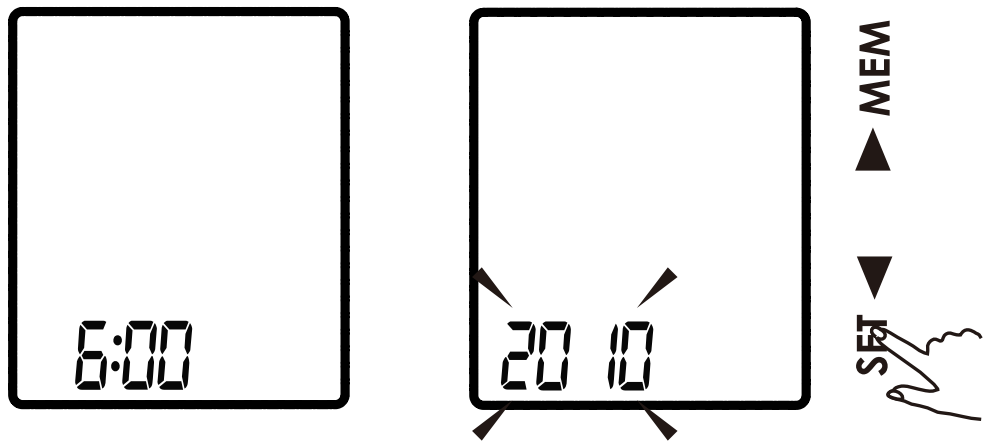
Measurement Principle

This product uses the oscillometric measurement method to detect blood pressure.
Before each measurement, the unit will establish a “zero pressure” equivalent to the air pressure. Then it will start inflating the arm cuff, while the unit will detect pressure oscillations generated by the beat-to-beat pulsatile. This will determine the systolic and diastolic pressure, and also your pulse rate.
The device also compares the longest and shortest time intervals for detected pulse waves, to calculate the mean time interval, and then calculates your standard deviation. The unit will display a warning signal with the reading to indicate the detection of an irregular heartbeat if the difference in the time intervals is over 25%.

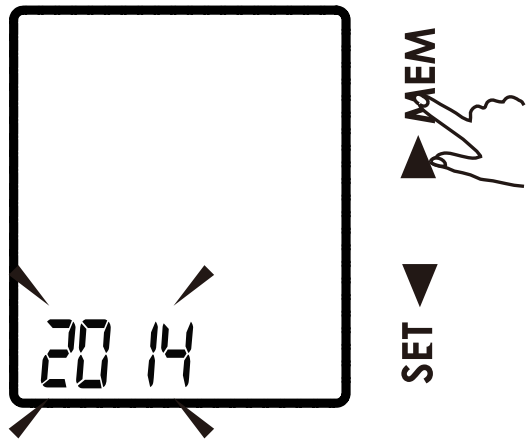
Setting Date, Time and Measurement Units

It is important to set the clock before using the blood pressure monitor, so that a time stamp can be assigned to each record that is stored in the memory. (The setting range for years is 2010 ~ 2050, and time format is 24H/12H).

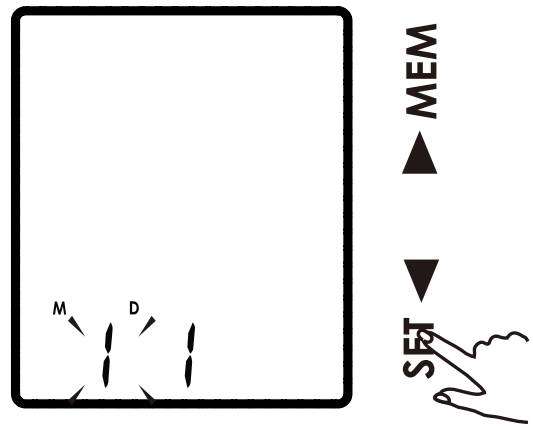
1. When the monitor is off, press the SET button once to display the time, then hold the SET button to enter the year setting mode.



2. Press MEM to change the [YEAR]. Each press will increase the numeral by one. The numbers will cycle back if you accidentally pass the current year.

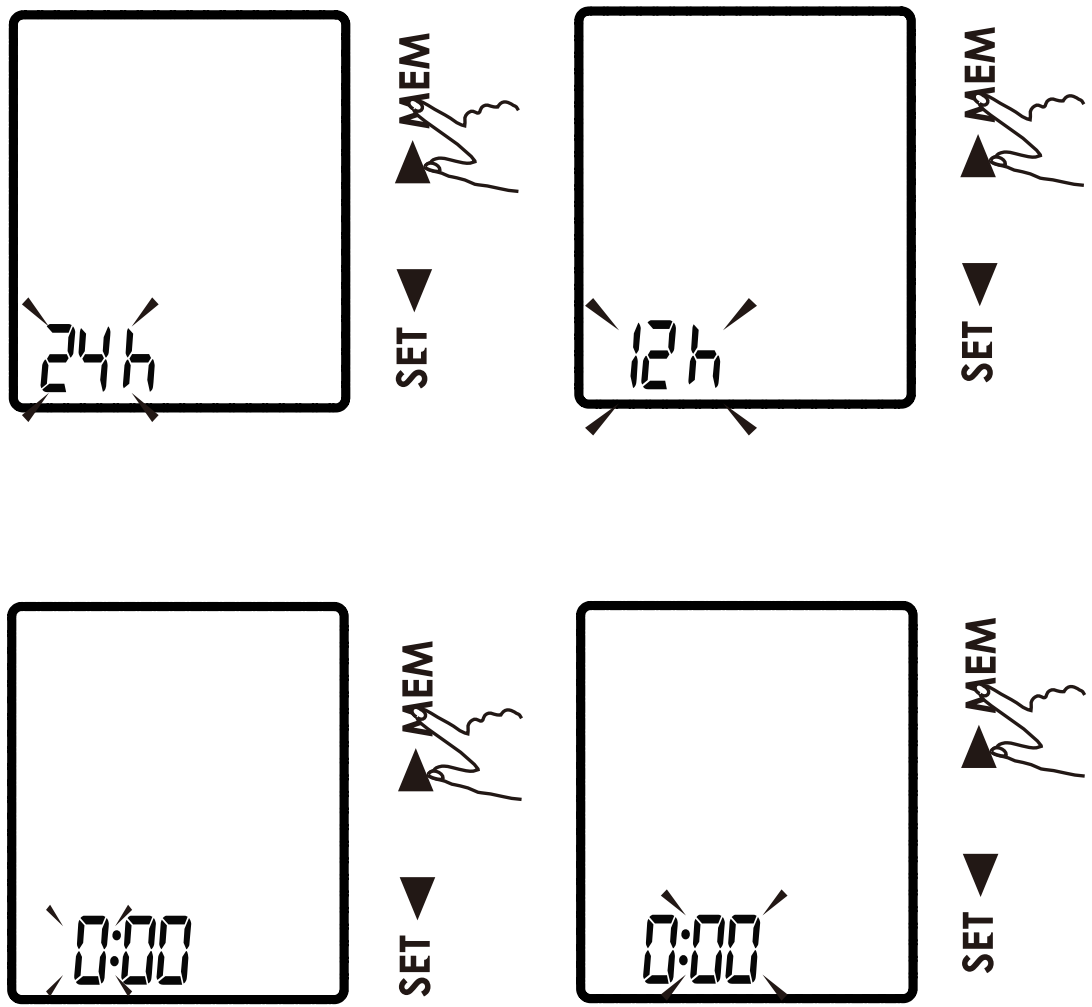


3. When you get the right year, press the SET button to select the year, then go to the next step.

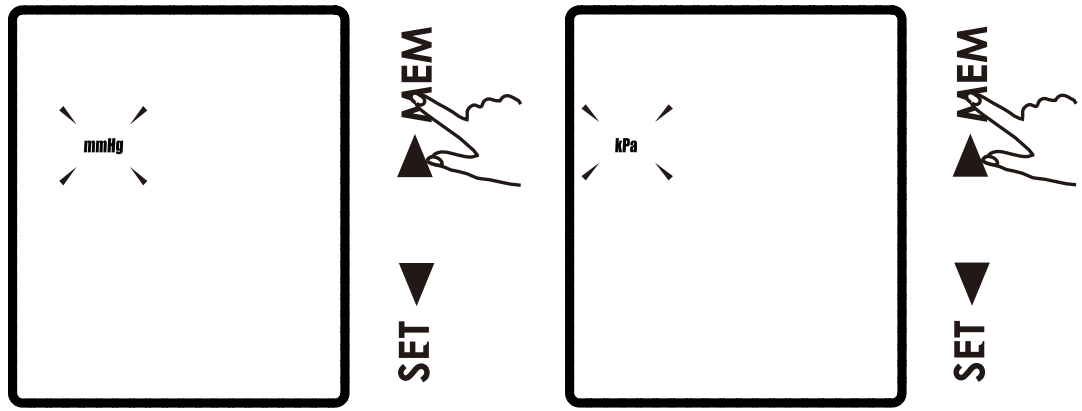


4. Repeat steps 2 and 3 to set the [MONTH] and [DAY].

5. Repeat steps 2 and 3 to set the time format, then the [HOUR] and [MINUTE].



6. Repeat steps 2 and 3 to set the measurement [UNIT]



7. After confirming the meausrement unit, the LCD will display all the settings you have done one by one and then shut off,

Tying the Cuff

1. Remove all accessories (watches, bracelets etc) from your wrist. If your doctor has diagnosed you with poor circulation in a wrist, use the other one to take the measurement.
2. Roll or push up your sleeve to expose the skin.
3. Apply the cuff to your wrist, with your palm facing upwards.
4. Position the edge of the cuff about 1 ~ 1.5cm from the wrist joints.
5. Fasten the wrist cuff around your wrist, leaving no extra room between the cuff and your skin. If the cuff is too loose, the measurement will not be accurate.
6. Place your elbow on a table so that the cuff is at the same level as your heart. Turn your palm upwards. Sit upright in a chair, and take 5-6 deep breaths.

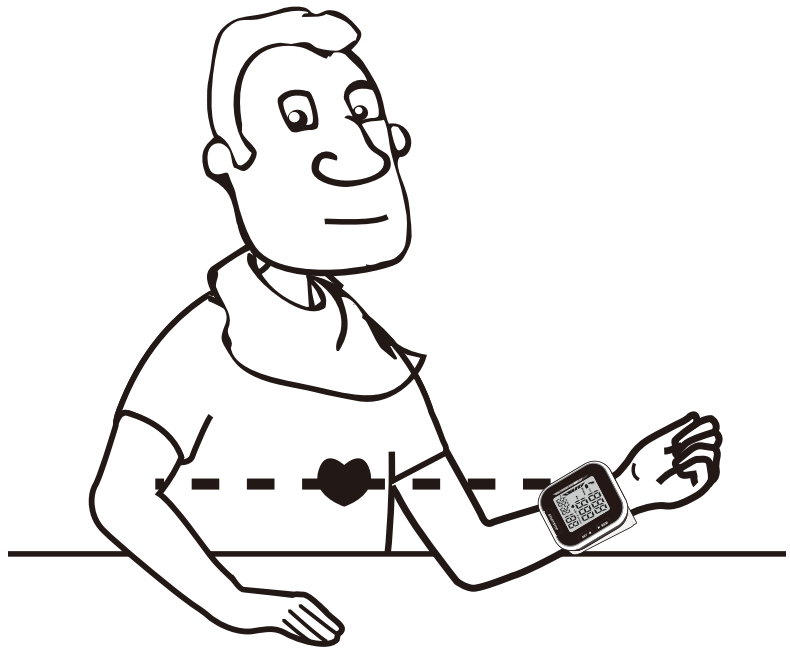
- Rest for 5 minutes before measurement.
- Wait for at least 3 minutes between each measurement. This will allow your blood circulation to recover.

- Take the measurement in a quiet room.

- Do not move or talk when taking the measurement.

- The cuff should be maintained at the save level as the right atrium of your heart.

- Do not cross your legs, keeping your feet flat on the ground.



- Keep your back up against the backrest of your chair.

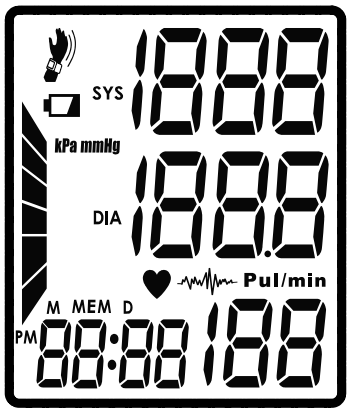
- For a meaningful comparison, try to take the measurements under similar conditions. For example, take daily measurements at approximately the same time, on the same wrist, or as directed by your doctor.

Measurement

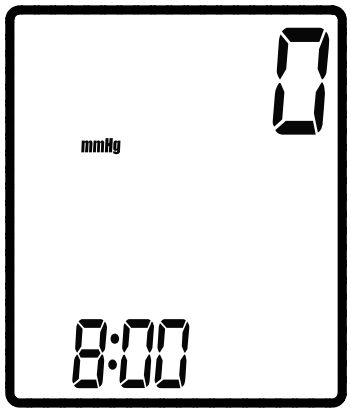
Starting the Measurement

Step One: When the monitor is off, press START/STOP to turn the monitor on, and it will then complete the whole measurement process.

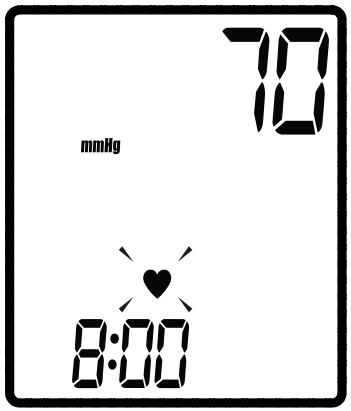
LCD Display



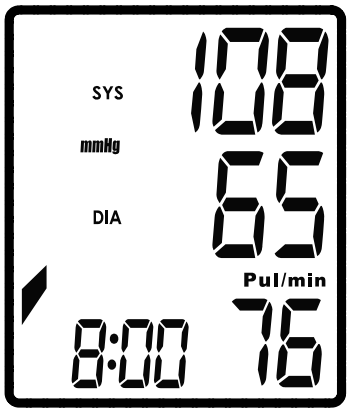
Adjust to Zero



Inflating and Measuring



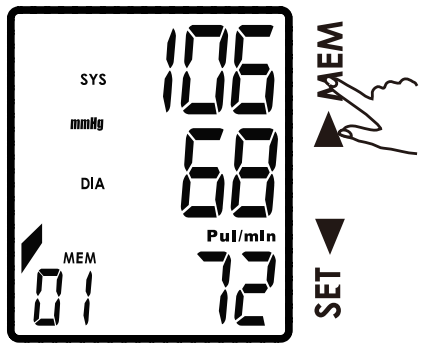
Display/Save Results



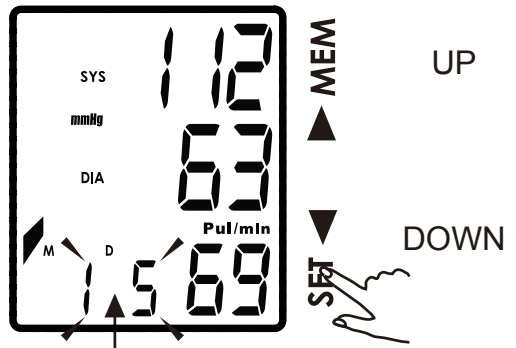
Step Two: Press START/STOP to power off, otherwise the unit will automatically turn off after one minute of inactivity.

Recalling Records

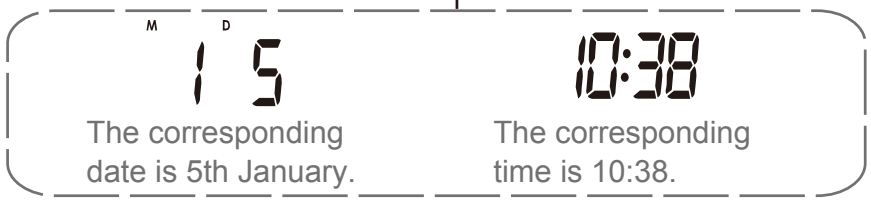
Step One: When the monitor is off, press "MEM" button to show the latest measurement record.



Step Two: Press MEM or SET to access the specific record you want.



Date and time will display alternately.



⚠ CAUTION

The most recent record (1) is shown first. Each new measurement will take the (1) position, with older records shuffled back. (2) will become (3) and so on.
The last record (60) will be dropped from the list.

Deleting Records

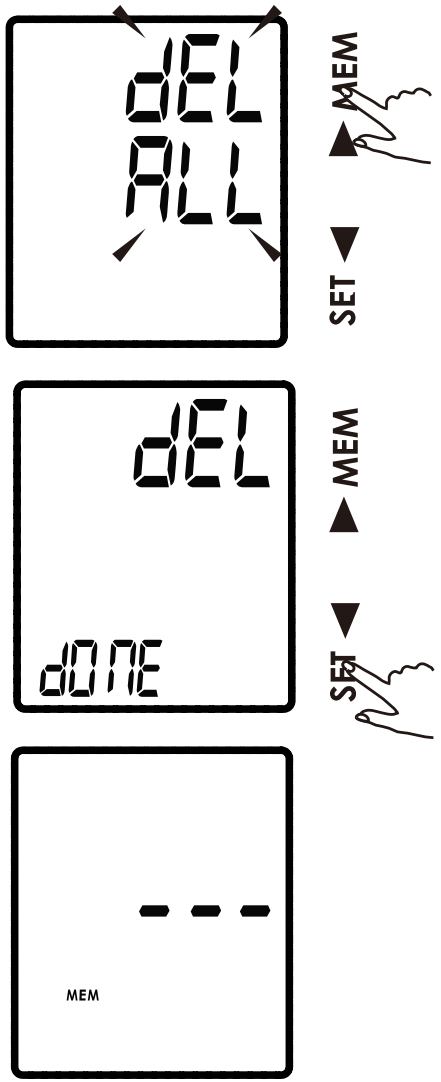
If you are not satisfied with your measurement, you can delete all saved records be following these steps.

1. Hold the MEM button down for 3 seconds when the monitor is in memory recall mode. The unit will flash, showing the display to the right.

2. Press SET to confirm deletion. The monitor will then turn off.

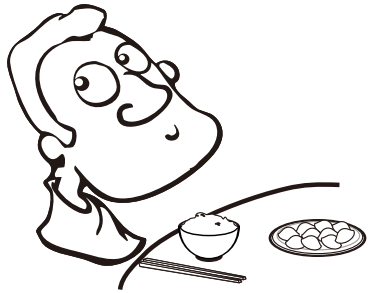
   Note: to exit of out of the deletion mode without deleting any records, press START/STOP before pressing SET to confirm the delete instruction.

3. If there are no records to delete, the following screen will display.



Measurement Tips

Measurements may be inaccurate if taken under the following conditions.



Within 1 hour of eating/drinking

After drinking tea, coffee or smoking

Within 20 minutes of bathing

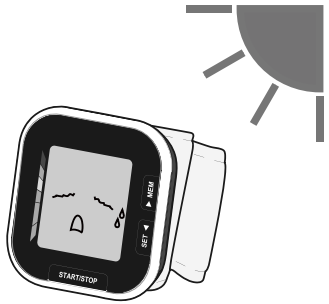
When talking or moving fingers

In a cold environment

When you need to go to the toilet

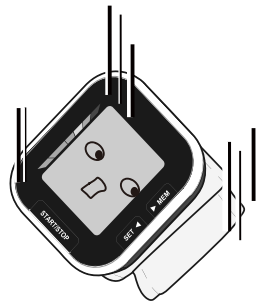
Maintenance

In order to get the best performance, please follow these instructions.

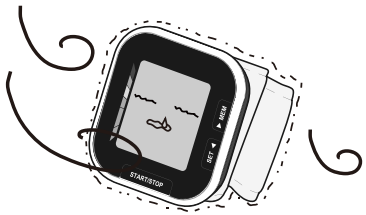


Place in a dry location out of sunshine

Avoid contact with water

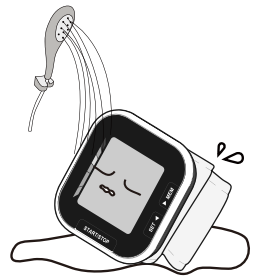


Avoid intense shaking/knocks/drops



Avoid dusty, hot locations

Use a soft, dry cloth to remove dirt

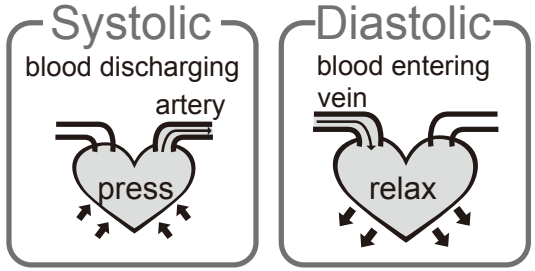


Do not clean cuff or unit with water

Information

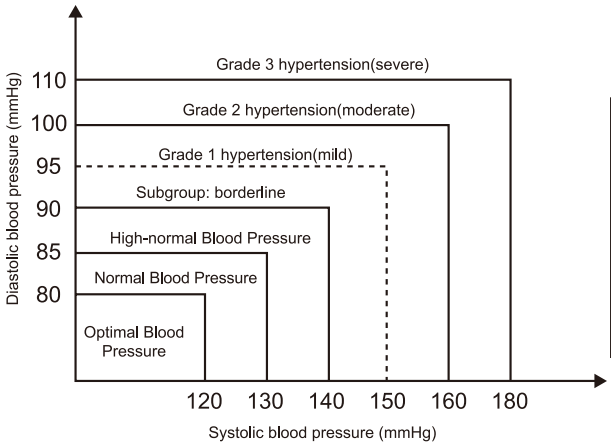
What are systolic pressure and diastolic pressure?

When ventricles contract and pump blood out of the heart, the blood pressure reaches its maximum value in the cycle, which is called systolic pressure. When the ventricles relax, the blood pressure reaches its minimum value in the cycle, which is called diastolic pressure.



What is the standard blood pressure classification?

The blood press classification published by the World Health Organisation (WHO) and the International Society of Hypertension (ISH) in 1999 is as follows:



Blood Pressure (mmHg) \ Level	Optimal	Normal	High-normal	Mild	Moderate	Severe
SYS	<120	120~129	130~139	140~159	160~179	⩾180
DIA	<80	80~84	85~89	90~99	100~109	⩾110

⚠ **CAUTION**: Only your doctor can tell you your normal BP range. Please contact your doctor if your measuring results fall outside of this range. Please note that only your doctor can tell you if your blood pressure value has reached a dangerous level.

Irregular Heartbeat Detector

An irregular heartbeat (IHB) is detected when a heartbeat rhythm varies while the unit is measuring the systolic and diastolic blood pressure. During each measurement, the monitor records the heartbeat intervals and calculates the average. If any average is larger than or equal to 25%, the irregular heartbeat symbol will appear on the display when the measurement results appear.

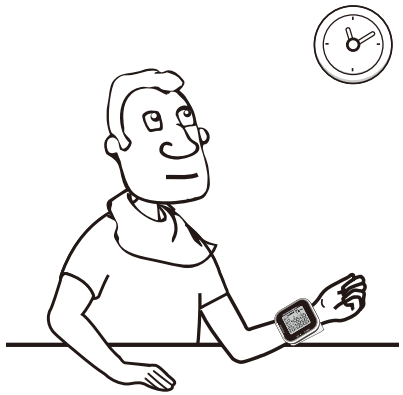
⚠ CAUTION: The appearance of the IHB icon indicates that a pulse irregularity consistent with irregular heartbeat was detected during the measurement. Usually this is NOT a cause for concern. However, if the symbol appears often, we recommend you seek medical advice. Please note that this device does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

Why does my blood pressure fluctuate through the day?

1. Individual blood pressure varies multiple times every day. It is also affected by the way you tie your cuff and your measurement position, so please take the measurement under the same conditions.

2. If the person is taking medication, the measurements may vary.

3. Wait at least 3 minutes and then take another measurement.



Why do I get different results at home compared to hospital?

Blood pressure can be different throughout the day due to weather, emotional state, exercise etc. Also, there is what is known as the “white coat” effect, which means blood pressure normally increases in clinical settings.

If taking your measurement at home, pay attention to the following:

- Check the cuff is tied properly
- Check if the cuff is too tight or too loose
- Check that the cuff is positioned correctly
- If feeling anxious, take 2-3 deep breaths and relax and take your measurement later

Will the result differ if taken on the other wrist?

Both wrists will be fairly accurate to your current situation, however to ensure that the results are as accurate as possible, please always measure the same wrist.

Troubleshooting

This section contains a list of error messages and frequently asked questions for problems you may encounter with the blood pressure monitor. If the unit is not operating as your think it should, please check this section before contacting the Kogan.com customer support team.

Problem	Symptom	Possible Cause	Possible Solution
No Power	Display will not light up	Batteries are exhausted	Replace batteries
		Batteries inserted incorrectly	Insert batteries correctly
Low Battery	Display is dim or shows 	Batteries are low	Replace with new batteries
Error Message	E1	Cuff is not secure	Refasten the cuff
	E2	Cuff is too tight	Readjust the cuff
	E3	Excess pressure on cuff	Relax and take measurement again
	E10 or E11	Monitor was unable to take measurement due to excess movement or positioning	Relax, get comfortable and take measurement again
	E20	Pulse cannot be detected	Loosen clothing around your wrist and take measurement again
	E21	Measurement failed	Relax and take measurement again
	EExx	Calibration error has occurred	Retake the measurement. If this problem persists, contact the Kogan.com customer support team for further assistance.

Product Specifications

Power supply	2 x AAA batteries
Display mode	Digital LCD V.A 35mm x 41mm
Measurement mode	Oscillographic testing mode
Measurement range	Cuff pressure: 0kPa – 40kPa (0mmHg – 300mmHg) Measurement pressure: 5.3kPa – 30.7kPa (40mmHg – 230mmHg) Pulse value: 40-199 beat/minute
Accuracy	Pressure: 5℃-40℃within±0.4kPa(3mmHg) Pulse value:±5%
Normal working condition	Temperature: 5°C to 40°C Relative humidity: ≤85%RH Atmospheric pressure: 86kPa to 106kPa
Storage/transport condition	Temperature: -20°C to 60°C Relative humidity: 10%RH – 93%RH Atmospheric pressure: 50kPa to 106kPa
Measurement perimeter of wrist	Approx 13.5cm ~ 21.5cm
Net weight	Approx 100g (not including batteries)
External dimensions	Approx 73mm x 67.5mm x 22.5mm
Mode of operation	Continuous operation
Degree of protection	Type BF applied
Protection against water	IP22
Software version	V01
Device classification	Internally Powered ME Equipment

Complied European Standards List

Risk management	EN ISO 14971:2012 Medical devices - Application of risk management to medical devices
Labeling	EN 980:2008 Symbols for use in the labelling of medical devices
User manual	EN 1041:2008 Information supplied by the manufacturer of medical devices
General Requirements for Safety	EN 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance EN 60601-1-11:2010 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
Electromagnetic compatibility	EN 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
Performance requirements	EN ISO 81060-1:2012 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type EN 1060-3:1997+A2:2009 Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems
Clinical investigation	EN 1060-4:2004 Non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers
Usability	EN 60601-1-6:2010 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability EN 62366:2008 Medical devices - Application of usability engineering to medical devices
Software life-cycle processes	EN 62304:2006/AC: 2008 Medical device software - Software life cycle processes

EMC Guidance

1) * This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.
2) * Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.
3) * Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!
4) * Caution: This machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.

Table 1 Guidance and MANUFACTURER's declaration – ELECTROMAGNETIC EMISSIONS- for all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration – electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 2 Guidance and MANUFACTURER's declaration – electromagnetic IMMUNITY – for all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Table 4 Guidance and MANUFACTURER's declaration – electromagnetic IMMUNITY – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	Not applicable 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).

Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	Not applicable 3 V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broad-cast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Table 6 Recommended separation distances between portable and mobile RF communications equipment and the ME EQUIPMENT or ME SYSTEM – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the device.			
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmittters) and the device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2{,}3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance ***d*** in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where ***P*** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.