kinetik
WELLBEING

Blood Pressure Monitor

Instruction Manual

REF WBP1

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Support

Our manual should provide you with all the information you need to set up and use this product.

If you have a question, have a look at our Troubleshooting page!

For further assistance, why not contact our Customer Care team directly? We're here to help!

Our Customer Care team are available from 9am-5pm, Monday to Friday (excluding bank holidays).

We promise to respond to all queries and will ensure to resolve any issue you may be having.

You can reach us by...

Phone:
+44 1483 937969

Live Chat:
Simply visit www.kinetikwellbeing.com and send us a message.

Email:
customercare@kinetikwellbeing.com

Post:
Kinetik Medical Devices Limited
Unit 3, Perrywood Business Park, Honeycrock Lane,
Salfords, Redhill. RH1 5DZ

General Description

Thank you for selecting Kinetik arm type blood pressure monitor (WBP1). The monitor features blood pressure measurement, pulse rate measurement and the result storage.

This manual contains important safety and care information, and provides step by step instructions for using the product.

Read the manual thoroughly before using the product.

Features:

- 65mm×50mm Digital LCD display
- 90 readings
- 3rd Generation Technology: Measuring during inflation

Indications for Use

The Kinetik Blood Pressure Monitor is digital monitors intended for use in measuring blood pressure and heartbeat rate with arm circumference 22cm to 42cm (about 8¾"-16½"). It is intended for adult indoor use only.

Contraindications

1. The device is not suitable for use on may be pregnant women or pregnant women.
2. The device is not suitable for use on patients with implanted, electrical devices, such as cardiac pacemakers, defibrillators.

Measurement Principle

This product uses the Oscillometric Measuring method to detect blood pressure. Before every measurement, the unit establishes a "zero pressure" equivalent to the air pressure. Then it starts inflating the arm cuff, meanwhile, the unit detects pressure oscillations generated by beat-to-beat pulsatile, which is used to determine the systolic and diastolic pressure, and also pulse rate.

Safety Information

The signs below might be in the user manual, labeling or other component. They are the requirement of standard and using.

	Read the instructions (actual symbol colours are white on a blue background).		Symbol for “TYPE BF APPLIED PARTS”
CE 0197	This product complies with MDD93/42/EEC requirements.		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 “MANUFACTURER”		
SN	Symbol for “SERIAL NUMBER”		
	Symbol for “DIRECT CURRENT”	EC REP	Symbol for “Authorised Representative in the European Community”
	Symbol for “MANUFACTURE DATE”		Caution: These notes must be observed to prevent any damage to the device.
IP21	Classification for water ingress and particulate matter		

⚠ CAUTION

* This device is intended for adult use in homes only.
* The device is not suitable for use on neonatal patients, pregnant women,patients with implanted, electronical devices, patients with pre-eclampsia, premature ventricular beats, atrial fibrillation, peripheral, arterial disease and patients undergoing intravascular therapy or arterio-venous shunt or people who received a mastectomy. Please consult your doctor prior to using the unit if you suffer from illnesses.
* The device is not suitable for measuring the blood pressure of children. Ask your doctor before using it on older children.
* The device is not intended for patient transport outside a healthcare facility.
* The device is not intended for public use.
* This device is intended for no-invasive measuring and monitoring of arterial blood pressure.It is not intended for use on extremities other than the arm 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 your physician to determine the most appropriate time to measure your blood pressure. Never change a prescribed medication without consulting your physician.

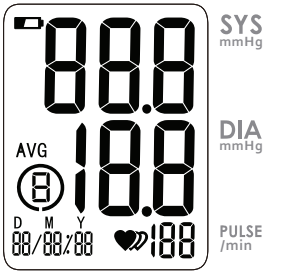
⚠ CAUTION

* Do not take any therapeutic measures on the basis of a self measurement. Never alter the dose of a medicine prescribed by a doctor. Consult your doctor if you have any question about your blood pressure.
* When the device was used to measure patients who have common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, the best result may occur with deviation. Please consult your physician about the result.
* Don't kink the connection tube during use, otherwise, the cuff pressure may continuously increase which can prevent blood flow and result in harmful injury to the PATIENT.
* When using this device, please pay attention to the following situation which may interrupt blood flow and influence blood circulation of the patient, thus cause harmful injury to the patient: connection tubing kinking too frequent and consecutive multiple measurements; the application of the cuff and its pressurization on any arm where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present; inflating the cuff on the side of a mastectomy.
* Warning: Do not apply the cuff over a wound;otherwise it can cause further injury.
*Do not inflate the cuff on the same limb which other monitoring ME equipment is applied around simultaneously, because this could cause temporary loss of function of those simultaneously-used monitoring ME equipment.
*On the rare occasion of a fault causing the cuff to remain fully inflated during measurement, open the cuff immediately. Prolonged high pressure (cuff pressure > 300mmHg or constant pressure > 15mmHg for more than 3 minutes) applied to the arm may lead to an ecchymosis.
*Please check that operation of the device does not result in prolonged impairment of patient blood circulation.
* When measurement, please avoid compression or restriction of the connection tubing.
* The device cannot be used with HF surgical equipment at the same time.
* The ACCOMPANYING DOCUMENT shall disclose that the SPHYGMOMANOMETER was clinically investigated according to the requirements of ISO 81060-2:2013.
* To verify the calibration of the AUTOMATED SPHYGMOMANOMETER, please contact the manufacturer.
* This device is contraindicated for any female who may be suspected of, or is pregnant. Besides providing inaccurate readings, the effects of this device on the fetus are unknown.
* Too frequent and consecutive measurements could cause disturbances in blood circulation and injuries.
* This unit is not suitable for continuous monitoring during medical emergencies or operations.Otherwise, the patient's arm and fingers will become anaesthetic, swollen and even purple due to a lack of blood.
* When not in use, store the device in a dry room and protect it against extreme moisture, heat, lint, dust and direct sunlight. Never place any heavy objects on the storage case.
* This device may be used only for the purpose described in this booklet. The manufacturer cannot be held liable for damage caused by incorrect application.
*This device comprises sensitive components and must be treated with caution. Observe the storage and operating conditions described in this booklet.
* The equipment is not AP/APG equipment and not suitable for use in the presence of a flammable anesthetic mixture with air of with oxygen or nitrous oxide.
* Warning: No servicing/maintenance while the ME equipment is in use.
* The patient is an intended operator.
* The patient can measure data and change battery under normal circumstances and maintain the device and its accessories according to the user manual.
* To avoid measurement errors, please avoid the condition of strong electromagnetic field radiated interference signal or electrical fast transient/burst signal.
* The blood pressure monitor and the cuff are suitable for use within the patient environment. If you are allergic to polyester, nylon or plastic, please don't use this device.
* 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 potential sensization or irritation reaction.

⚠ CAUTION

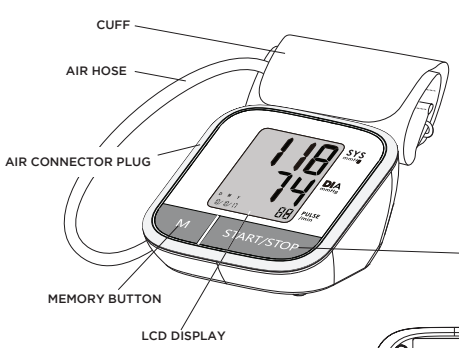
* If you experience discomfort during a measurement, such as pain in the arm or other complaints, press the START/STOP button to release the air immediately from the cuff. Loosen the cuff and remove it from your arm.
* If the cuff pressure reaches 40 kPa (300 mmHg), the unit will automatically deflate. Should the cuff not deflate when pressures reaches 40 kPa (300 mmHg), detach the cuff from the arm and press the START/STOP button to stop inflation.
* Before use, make sure the device functions safely and is in proper working condition. Check the device, do not use the device if it is damaged in any way. The continuous use of a damaged unit may cause injury, improper results, or serious danger.
* Do not wash the cuff in a washing machine or dishwasher!
* The service life of the cuff may vary by the frequency of washing, skin condition, and storage state. The typical service life is 10000 times.
* It is recommended that the performance should be checked every 2 years and after maintenance and repair, by retesting at least the requirements in limits of the error of the cuff pressure indication and air leakage (testing at least at 50mmHg and 200mmHg).
* Please dispose of ACCESSORIES, detachable parts, and the ME EQUIPMENT according to the local guidelines.
* Manufacturer will make available on request circuit diagrams, component part lists, descriptions, calibration instructions,etc., to assist to service personnel in parts repair.
* The operator shall not touch output of batteries and the patient simultaneously.
* Cleaning :Dust environment may affect the performance of the unit. Please use the soft cloth to clean the whole unit before and after use. Don't use any abrasive or volatile cleaners.
* The device doesn't need to be calibrated within two years of reliable service.
* If you have any problems with this device, such as setting up, maintaining or using, please contact the SERVICE PERSONNEL of Harvard Medical Devices. Don't open or repair the device by yourself in the event of malfunctions. The device must only be serviced, repaired and opened by individuals at authorized sales/service centers.
* Please report to Harvard Medical Devices if any unexpected operation or events occur.
* Keep the unit out of reach of infants, young children or pets to avoid inhalation or swallowing of small parts. It is dangerous or even fatal.
* Be careful to strangulation due to cables and hoses, particularly due to excessive length.
* At least 30 min required for ME equipment to warm from the minimum storage temperature between uses until it is ready for intended use. At least 30 min required for ME equipment to cool from the maximum storage temperature between uses until it is ready for intended use.
* This equipment needs to be installed and put into service in accordance with the information provided in the ACCOMPANYING DOCUMENTS;
* Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance d away from the equipment. The distance d is calculated by the MANUFACTURER from the 80 MHz to 5.8 GHz column of Table 4 and Table 9 of IEC 60601-1-2:2014, as appropriate.
* Please use ACCESSORIES and detachable partes specified/ authorised by MANUFACTURE. Otherwise, it may cause damage to the unit or danger to the user/patients.
* There is no luer lock connectors are used in the construction of tubing, there is a possibility that they might be inadvertently connected to intravascular fluid systems, allowing air to be pumped into a blood vessel.
* Please use the device under the environment which was provided in the user manual. Otherwise, the performance and lifetime of the device will be impacted and reduced.

LCD display signal



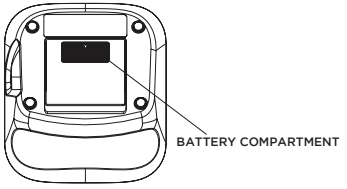
SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic pressure	High blood pressure
DIA	Diastolic pressure	Low blood pressure
PUL/min	Pulse display	Pulse in beats per minute
mmHg	mmHg	Measurement Unit of the blood pressure (1mmHg=0.133kPa)
	Blood pressure level indicator	Indicate the blood pressure level
Lo+	Low battery	Batteries are low and need to be replaced
	Irregular heartbeat	Blood pressure monitor is detecting an irregular heartbeat during measurement.
D M Y	Current Time	Year/Month/Day, Hour : Minute
	Heartbeat	Blood pressure monitor is detecting a heartbeat during measurement.
AVG	Average value	The average value of blood pressure

Monitor Components



Component list of pressure measuring system

1. Cuff
2. Air pipe
3. PCBA
4. Pump
5. Valve



List

1. Blood Pressure Monitor (WBP1)

2. Cuff (Type BF applied part)

(22cm~42cm)

(Please use Kinetik authorized cuff. The size of the actual cuff please refer to the label on the attached cuff.)

3. 4×AAA batteries

4. User manual

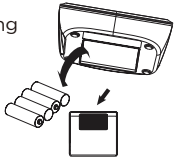
Power Supply

1 Battery powered mode:
6VDC 4×AAA batteries

> ⚠ CAUTION
>
> In order to get the best effect and protect your monitor,please use the right battery.

Installing and Replacing the Batteries

- Open the battery cover.
- Install the batteries by matching the correct polarity, as shown.
- Replace the battery cover.



Replace the batteries whenever the below happens

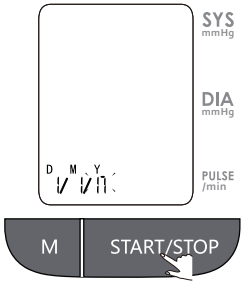
- The Lo+ shows
- The display is dim
- The display does not light up.

> ⚠ CAUTION
>
- Do not use new and used batteries together.
- Do not use different types of batteries together.
- Do not dispose the batteries in fire. Batteries may explode or leak.
- Remove batteries if the device is not likely to be used for some time.
- Worn batteries are harmful to the environment. Do not dispose with daily garbage.
- Remove the old batteries from the device following your local recycling guidelines.

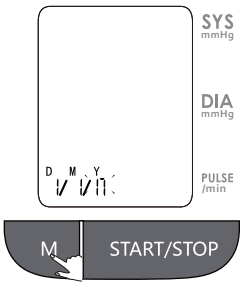
Setting Date and Time.

It is important to set the clock before using your blood pressure monitor, so that a time stamp can be assigned to each reading that is stored in the memory. (The setting range of the year :2017—2057; Time format:24H)

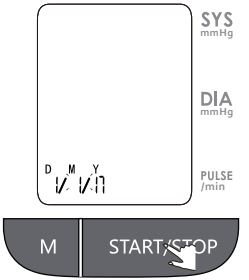
1. When the monitor is off, hold pressing " START/STOP " for 3 seconds to enter the mode for year setting.



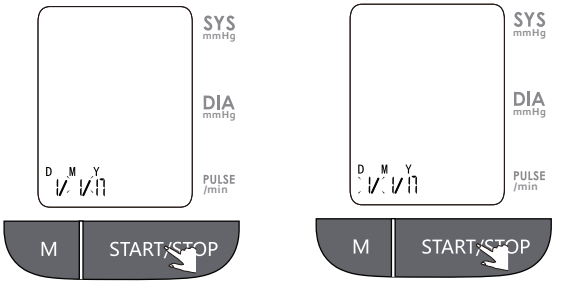
2. Press " M " button to change the [YEAR]. Each press will increase the numeral by one in a cycling manner.



3. Press " START/STOP " button to confirm [YEAR]. Then the monitor diverts to [MONTH] and [DAY] setting.

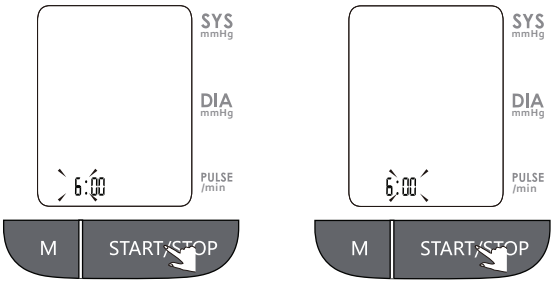


4. Repeat steps 2 and 3 to set the [MONTH] and [DAY].

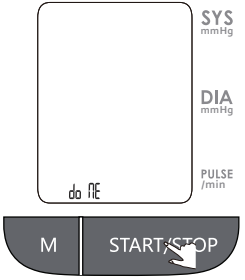


Power Supply

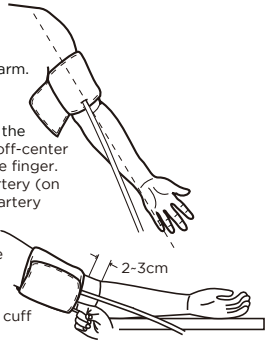
5. Repeat steps 2 and 3 to set the [HOUR] and [MINUTE].



6. After hour and minute are set, the LCD will display “donE” and the monitor will turn off.



Fitting the cuff



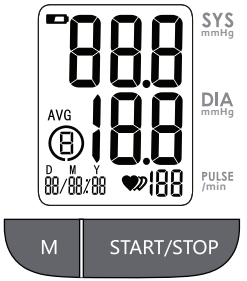
1. Remove all Jewellery, such as watches and bracelets from your left arm.
   Note: If your doctor has diagnosed you with poor circulation in your left arm, use your right arm.
2. Roll or push up your sleeve to expose the skin. Make sure your sleeve is not too tight.
3. Hold your arm with your palm facing up and tie the cuff on your upper arm, then position the tube off-center toward the inner side of arm in line with the little finger. Or position the artery mark ϕ over the main artery (on the inside of your arm). Note: Locate the main artery by pressing with 2 fingers approximately 2 cm above the bend of your elbow on the inside of your left arm. Identify where the pulse can be felt the strongest. This is your main artery.
4. The cuff should be snug but not too tight. You should be able to insert one finger between the cuff and your arm.
5. Sit comfortably with your tested arm resting on a flat surface. 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.
6. Helpful tips for Patients, especially for Patients with Hypertension:

- Rest for 5 minutes before first measuring.
- Wait at least 3 minutes between measurements. This allows your blood circulation to recover.
- Take the measurement in a silent room.
- The patient must relax as much as possible and do not move and talk during the measurement procedure.
- The cuff should maintain at the same level as the right atrium of the heart.
- Please sit comfortably. Do not cross your legs and keep your feet flat on the ground.
- Keep your back against the backrest of the chair.
- For a meaningful comparison, try to measure under similar conditions. For example, take daily measurements at approximately the same time, on the same arm, or as directed by a physician.

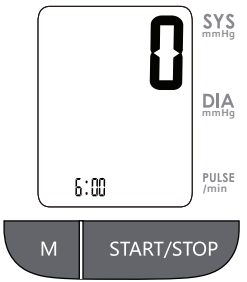
Start the Measurement

1. When the monitor is off, press " START/STOP " button to turn on the monitor, and it will finish the whole measurement.

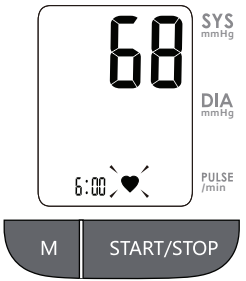
LCD display



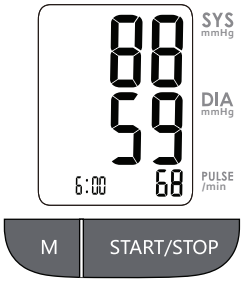
Adjust the zero.



Inflating and measuring.



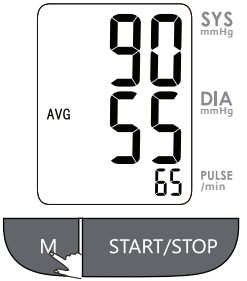
Display and save the measurement result.



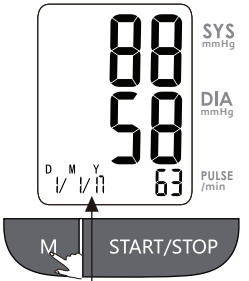
2. Press the " START/STOP " to power off, otherwise it will turn off within 1 minute.

Check the memory

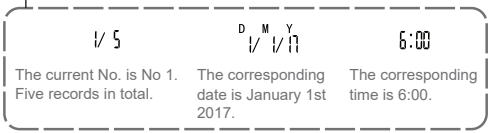
1. When the monitor is off, please press " M " button to show the average value of the latest three records.If the records are less than 3 groups, it will display the latest record instead.



2. Press the " M " to get the record you want.



The date and time of the record will be shown alternately.

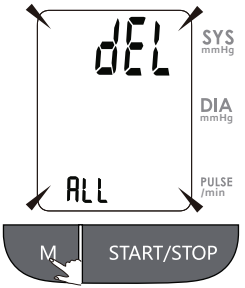


Delete the Readings

If you did not get the correct measurement, you can delete all results for the selected user by following steps below.

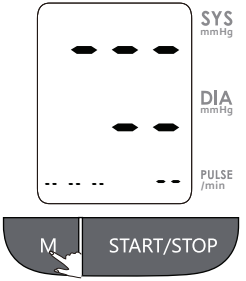
1. Hold pressing " M " button for 3 seconds when the monitor is in the memory recall mode, the flash display "dEL ALL" will show.

2. Hold Press " START/STOP " button to confirm deleting and the monitor will turn off.



Note: To exit out of delete mode without deleting any records, press " START/STOP " button.

3. If there is no record, press "M" button, the right display will show.



Tips for Measurement

Measurements may be inaccurate if taken in the following circumstances.

1. Within 1 hour after drinking or eating.
2. Immediate measurement after tea, coffee or smoking
3. Within 20 minutes after taking a bath
4. When talking or moving your fingers
5. In a very cold Environment
6. When you need the bathroom

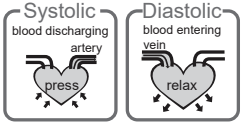
Maintenance

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

1. Put in a dry place and avoid the sunlight
2. Avoid contact with water, clean it with a dry cloth in case.
3. Avoid intense shaking and collisions
4. Avoid dusty and unstable temperature environment
5. Use wet cloths to remove dirt
6. Do not attempt to clean the reusable cuff with water and never immerse the cuff in water.

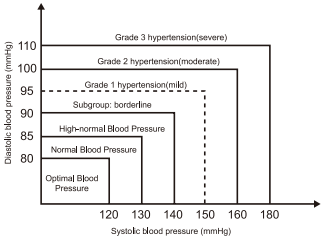
What are systolic pressure and diastolic pressure?

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 pressure classification published by World Health Organization (WHO) and International Society of Hypertension (ISH) in 1999 is as follows:



CAUTION

Only a physician can tell your normal BP range. Please contact a physician if your measuring result falls out of the range. Please note that only a physician can tell whether your blood pressure value has reached a dangerous point.

Blood Pressure (mm Hg) \ 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
Ⓑ		Ⓟ	Ⓟ	①	②	③

Irregular Heartbeat Detector

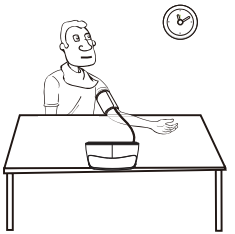
An irregular heartbeat is detected when a heartbeat rhythm varies while the unit is measuring the systolic and diastolic blood pressure.During each measurement, the monitor records all the pulse intervals and calculate the average ; if there are two or more pulse intervals ,the difference between each interval and the average is more than the average value of ±25% , or there are four or more pulse intervals, the difference between each interval and the average is more than the average value of ±15%,the irregular heartbeat symbol appears on the display when the measurement results are appeared.

CAUTION

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

Why does my blood pressure fluctuate throughout the day?

1. Individual blood pressure varies multiple times everyday. It is also affected by the way you wear your cuff and your measurement position, so please take the measurement under the same conditions.
2. If the person takes medicine, the pressure will vary more.
3. Wait at least 3 minutes for another measurement.



Why do I get a different blood pressure at home compared to the hospital?

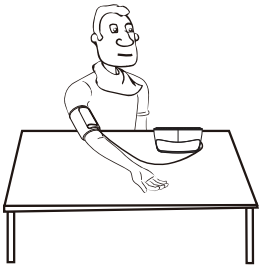
The blood pressure is different even throughout the day due to weather, emotion, exercise etc, Also, there is the "white coat" effect, which means blood pressure usually increases in clinical settings.

What you need to pay attention to when you measure your blood pressure at home:

If the cuff is tied properly.
If the cuff is too tight or too loose.
If the cuff is tied on the upper arm.
If you feel anxious.
Taking 2-3 deep breaths before beginning will be better for measuring.
Advice: Relax yourself for 4-5 minutes until you calm down.

Is the result the same if measuring on the right arm?

It is ok for both arms, but there will be some different results for different people. We suggest you measure the same arm every time.



TROUBLE SHOOTING

This section includes a list of error messages and frequently asked questions for problems you may encounter with your blood pressure monitor. If the product is not operating as you think it should, check here before arranging for servicing.

PROBLEM	SYMPTOM	CHECK THIS	REMEDY
No power	Display will not light up.	Batteries are exhausted.	Replace with new batteries
		Batteries are inserted incorrectly.	Insert the batteries correctly
Low batteries	Display is dim or show	Batteries are low.	Replace with new batteries
Error message	E 01 shows	The cuff is too tight or too loose.	Refasten the cuff and then measure again.
	E 02 shows	The monitor detected motion while measuring.	Movement can affect the measurement.Relax for a moment and then measure again.
	E 03 shows	The measurement process does not detect the pulse signal.	Loosen the clothing on the arm and then measure again.
	E 04 shows	The treatment of the measurement failed.	Relax for a moment and then measure again.
	EExx, shows on the display.	A calibration error occurred. (XX can be some digital symbol, such as 01, 02,etc., if this similar situation appears, it is a calibration error.)	Retake the measurement. If the problem persists, contact the retailer or our customer service department for further assistance.Refer to the warranty for contact information and return instructions.
Warning message	“out ” shows	Out of measurement range	Relax for a moment. Refasten the cuff and then measure again. If the problem persists, contact your physician.

SPECIFICATIONS

Power supply	Battery powered mode: 6VDC 4×AAA batteries
Display mode	Digital LCD display V.A.65mm×50mm
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0mmHg-299mmHg Measurement pressure: SYS: 60mmHg-230mmHg DIA: 40mmHg-130mmHg Pulse value: 40-199 beats/minute
Accuracy	Pressure: 5°C - 40°C within33mmHg(0.4kPa) Pulse value:±5%
Normal working condition	A temperature range of :+5°C to +40°C A relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa An atmospheric pressure range of : 700 hPa to 1060 hPa
Storage & transportation condition	Temperature:-20°C to +60°C A relative humidity range of ≤ 93%, non-condensing, at a water vapour pressure up to 50hPa
Measurement perimeter of the upper arm	22cm~42cm
Weight	Approx.225g(Excluding the dry cells and cuff)
External dimensions	Approx.120.2mm×108.2mm×68.5mm
Attachment	4×AAA batteries, user manual
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Protection against ingress of water	IP21 It means the device could protected against solid foreign objects of 12.5mm and greater, and protect against vertically falling water drops.
Device Classification	Battery Powered Mode: Internally Powered ME Equipment
Software Version	A04

WARNING: No modification of this equipment is allowed.

Manufacturer Information

Manufactured by: Harvard Medical Devices Ltd. HK
Company: Harvard Medical Devices Ltd. HK
Address: 1002, Railway Plaza, TST, HK

Authorized European Representative:
Company: Share Info Consultant Service LLC Repräsentanzbüro
Address: Heerdter Lohweg 83, 40549 Düsseldorf

Product may be returned if faulty, please contact the Retailer or Kinetik directly if you're experiencing issues with your product. This does not affect your statutory rights. Please note the retailer's own return policy may still be valid, contact the retailer for more information.

Complied Standards List

Risk management	EN ISO 14971:2012 / ISO 14971:2007 Medical devices - Application of risk management to medical devices
Labeling	EN ISO 15223-1:2016 / ISO 15223-1:2016 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. Part 1 : General requirements
User manual	EN 1041:2008+A1:2013 Information supplied by the manufacturer of medical devices
General Requirements for Safety	EN 60601-1:2006+A1:2013/ IEC 60601-1:2005+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance EN 60601-1-11:2015/ IEC 60601-1-11:2015 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 60601-1-2:2015/ IEC 60601-1-2:2014 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 IEC 80601-2-30:2009+A1:2013 Medical electrical equipment- Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
Clinical investigation	EN 1060-4:2004 Non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers ISO 81060-2:2013 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type
Usability	EN 60601-1-6:2010+A1:2015/IEC 60601-1-6:2010+A1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices
Software life-cycle processes	EN 62304:2006/AC: 2008 / IEC 62304: 2006+A1:2015 Medical device software - Software life-cycle processes
Bio-compatibility	ISO 10993-1:2009 Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

EMC Guidance

The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments

Warning: Don't 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.

Warning: 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.

Warning: 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."

Warning: Portable RF communications 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 equipment WBP1, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Technical description:

1. all necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the excepted service life.

2. Guidance and manufacturer's declaration-electromagnetic emissions and Immunity

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	**Compliance**
RF emissions CISPR I I	Group I
RF emissions CISPR I I	Class B
Harmonic emissions IEC 61000-3-2	Not application
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not application

Table 2

Guidance and manufacturer's declaration – electromagnetic Immunity		
Immunity Test	**IEC 60601-1-2 Test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	Not application	Not application
Surge IEC61000-4-5	Not application	Not application
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not application	Not application
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conduced RF IEC61000-4-6	Not application	Not application
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
NOTE U_T **is the a.c. mains voltage prior to application of the test level.**		

COMPLIED STANDARDS LIST AND EMC GUIDANCE

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity							
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communica-tions equipment)	**Test Frequency (MHz)**	**Band (MHz)**	**Service**	**Modulation**	**Modulation (W)**	**Distance (m)**	**IMMUNITY TEST LEVEL (V/m)**
	385	380-390	TETRA 400	Pulse modulation b) 18Hz	1.8	0.3	27
	450	430-470	GMRS 460, FRS 460	FM c) ± 5kHz deviation 1kHz sine	2	0.3	28
	710	704-787	LTE Band 13, 17	Pulse modulation b) 217Hz	0.2	0.3	9
	745						
	780						
	810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18Hz	2	0.3	28
	870						
	930						
	1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	Pulse modulation b) 217Hz	2	0.3	28
	1845						
	1970						
	2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
	5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
	5500						
	5785						

Manufactured by Harvard Medical Devices Ltd. HK

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