[redacted]

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**Made in China**

CE 0197 IP22

Kinetik WBP3 UK IB 20210723

kinetik WELLBEING

APPROVED
By cmlam at 2:36 pm, Jul 29, 2021

# wrist blood pressure monitor


- To use the monitor correctly and safely, please read the manual thoroughly.
- Please keep this manual well in order to reference in future.

## Instruction Manual

REF WBP3

TABLE OF CONTENTS

## ♥ General Description

**Thank you for selecting Kinetik wrist type blood pressure monitor (WBP3). The monitor features blood pressure measurement, pulse rate measurement and the result storage. The design provides you with two years of reliable service.**

**Readings taken by the WBP3 are equivalent to those obtained by a trained observer using the cuff and stethoscope auscultation method.**

**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:

- Systolic blood pressure
- Diastolic blood pressure
- Pulse rate
- 60 records for each user

## ♥ Indications for Use

The Kinetik Wrist Blood Pressure Monitor is a digital monitor intended for use in measuring blood pressure and heartbeat rate with a wrist circumference ranging from 13.5cm to 21.5 cm ( about 5⅓″-8½″ ).

It is intended for adult indoor use only.





## ♥ Contraindications

1.The device should not be used by any person who may be suspected of,or is pregnant .

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 point" equivalent to the atmospheric pressure. Then it starts inflating the cuff. Meanwhile, the unit detects pressure oscillation generated by beat-to-beat pulsatile, which is used to determine the systolic pressure and diastolic pressure as well as 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 | Symbol for "COMPLIES WITH MDD 93/42/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" |
|  | Symbol for "RECYCLE" | 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. |
|  | The Green Dot is the license symbol of a European network of industry-funded systems for recycling the packaging materials of consumer goods. | | |





### ⚠ 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 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 your physician to determine the most appropriate time to measure your blood pressure. Never change a prescribed medication without consulting your physician.
* 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.
* 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.

## CAUTION

*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 wrist 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 wrist 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 maximum temperature that the applied part can be achieved is 42.5℃ while the environmental temperature is 40℃.
* 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.





## CAUTION

* The patient can measure data and change batteries 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.
* If you experience discomfort during a measurement, such as pain in the wrist or other complaints, press the START/STOP button to release the air immediately from the cuff. Loosen the cuff and remove it from your wrist.
* 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 wrist 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.
* The service life of this product is 2 years.
* 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.

## CAUTION

* 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 80MHz 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.





## CAUTION

* 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 wrist where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present; inflating the cuff on the side of a mastectomy.
* Please dispose of ACCESSORIES, detachable parts, and the ME EQUIPMENT according to the local guidelines.

## ♥ LCD Display Symbol

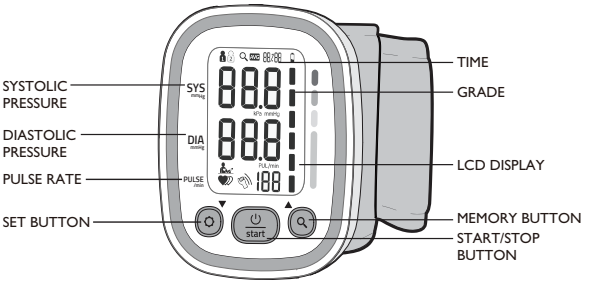

| SYMBOL | DESCRIPTION | EXPLANATION |
|---|---|---|
| SYS | Systolic pressure | High blood pressure |
| DIA | Diastolic pressure | Low blood pressure |
| PUL | Pulse display | Pulse in beats per minute |
| | Motion indicator | Motion may result in an inaccurate measurement |
| +Lo | Low battery | Batteries are low and need to be replaced |

| SYMBOL | DESCRIPTION | EXPLANATION |
|---|---|---|
| kPa | kPa | Measurement unit of the blood pressure (1kPa=7.5mmHg) |
| mmHg | mmHg | Measurement unit the blood pressure (1mmHg=0.133kPa) |
| | Irregular heartbeat | Blood pressure monitor is detecting an irregular heartbeat during measurement. |
| 88:88 | Current time | Month/Day,Hour/Minute |
| AVG | Average value | The average value of latest 3 groups blood pressure value. |
| | Heartbeat | Blood pressure monitor is detecting a heartbeat during measurement. |
| | Memory | Indicate it is in the memory mode |
| | User 1 | Start measurement and save the results for user 1 |
| 2 | User 2 | Start measurement and save the results for user 2 |
| | Blood pressure level indicator | Indicate the blood pressure level |
| | Positioning symbol | The correct position gives you an accurate measurement. |



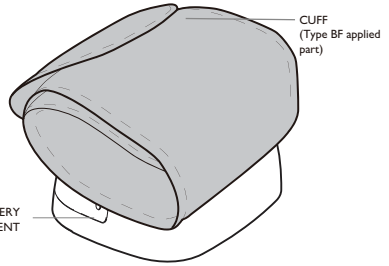


## ♥ Monitor Components



Component list pressure measuring system:

1. PCBA;
2. Air Pipe;
3. Pump;
4. Valve;
5. Cuff.




## ♥ List

1) Blood Pressure Monitor WBP3
2) 2×AAA alkaline batteries (Not Included)
3) User manual

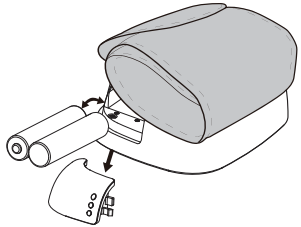




## ♥ Installing and Replacing the Batteries

- Slide off the battery cover.
- Install the batteries by matching the correct polarity, as shown below. Always use the correct battery type (2×AAA alkaline batteries.)
- Replace the cover.

The typical service life of the new and unused batteries is 60 measurements for the operation time is 60s.



Replace the batteries whenever the below happen

- 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.

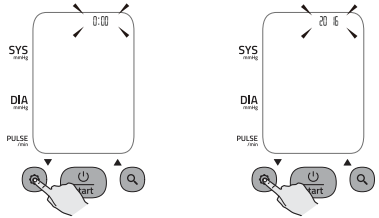




## ♥ Setting Date, Time, Positioning Symbol and Measurement Unit

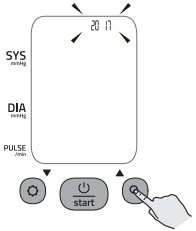
**It is important to set the clock before using your blood pressure monitor, so that a time stamp can be assigned to each record that is stored in the memory. (The setting range of year is 2016 ~ 2056. Time format: 24H)**

1. When the monitor is off, press " SET " button, it will display the time. Then press and hold " SET " button to enter the mode for year setting.

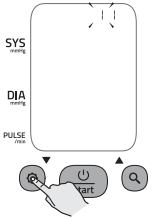


Notes:
1. During the process of setting, you can press " START/STOP " button to stop setting at any time.
2. If there is no operation during the process of setting, it will turn off.

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



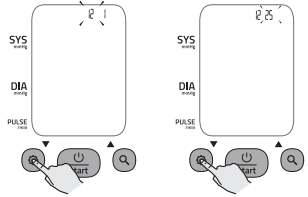

**3.** When you get the right year, press " SET " button to confirm and it will turn to next step.



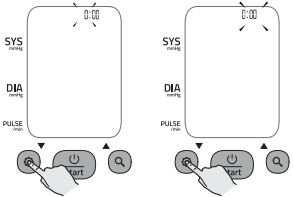




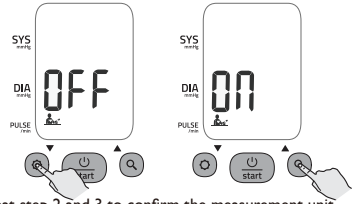

**4.** Repeat step 2 and 3 to confirm [MONTH] and [DAY].



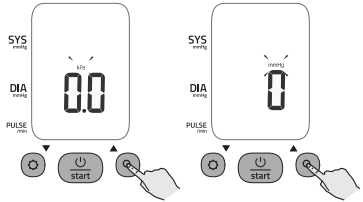

**5.** Repeat step 2 and 3 to confirm [HOUR] and [MINUTE].



**6.** Repeat step 2 and 3 to confirm [Positioning symbol] on or off.



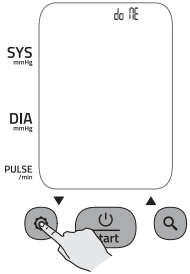

**7.** Repeat step 2 and 3 to confirm the measurement unit.







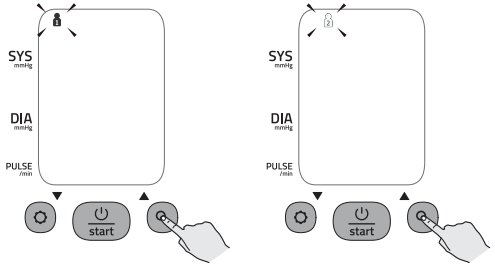

**8.** After confirming the meausrement unit, the LCD will display “donE”, then display all the settings you have done one by one and then the monitor will turn off.



## ♥ Select the User ID

Before you start the measurement, please select the desired user ID first.

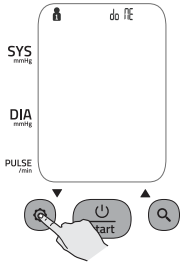
1. When the blood pressure monitor is off, press and hold " MEM " button until the user ID blinks. Then press "MEM " button to change the user ID between user 1 and user 2. Press " SET " button to confirm your selection.







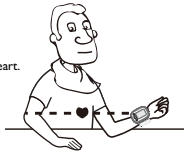

2. After confirming the user ID, the LCD will display "User ID+donE" and then turn off. Then you can start your measurement now.



## ♥ Tie the Cuff

1. Remove all accessories (watch, bracelet, etc) from your wrist. If your physician has diagnosed you with poor circulation in your wrist, use the other one.
2. Roll or push up your sleeve to expose the skin.
3. Apply the cuff to your wrist with your palm facing up.
4. Position the edge of the cuff about 1cm~1.5cm from 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. Sit comfortably with your tested wrist 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.
7. Patients with Hypertension:
   The middle of the cuff should be at the level of the right atrium of the heart; Before starting measurement, please sit comfortably with legs uncrossed, feet flat on the floor, back and wrist supported.

- Rest for 5 minutes before 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.
- Do not cross your legs and keep your feet 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 wrist, or as directed by a physician.



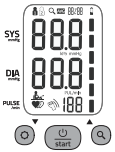




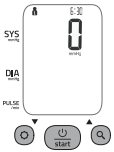
## ♥ Start the Measurement

1. When the monitor is off, press " START/STOP " button to turn on the monitor, and it will finish the whole measurement. (Take user 1 for example.)

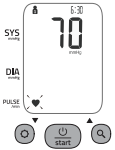

LCD display



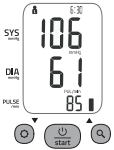

Adjust the zero.




Inflating and measuring.




Display and save the result. The year, date and time will display alternately.



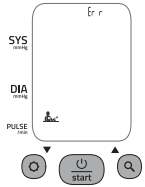
**2.** Press " START/STOP " button to power off, otherwise it will turn off within 1 minute.


Tips:
1. There are two users in total. Each user has 60 records.
2. You can press "START/STOP " button to stop measuring during the process of the measurement at any time.
3. If the measurement result is out of the measurement range (SYS: 60mmHg to 230mmHg; or DIA: 40mmHg to 130mmHg; or Pulse: 40-199 pulse/minute), the LCD will display "out".

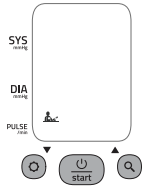
Notes: If you have set the [Positioning Symbol] on, when you start the measurement, the blood pressure monitor will detect the position first. The wrist must beat the angle between 30° and 45°. If it's out of this angle, the LCD won't start any measurements and will display + Err until you have the correct position.





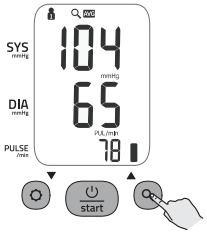



If you get the correct position, it will display for about 3 seconds, and then finish the whole measurement.

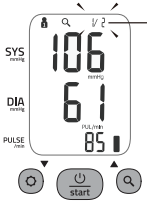


## ♥ Recall the Records

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




2. Press " MEM " button or " SET " button to get the record you want.



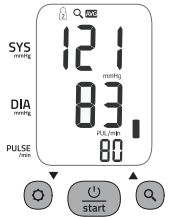


The record number, date and time of the measurement records will display alternately.





3. If you want to check the other user's measurement records, please press " START/STOP " button to turn off the blood pressure monitor. Then press and hold "MEM " button to enter the selecting user mode, press " MEM " again to change the user, when the desired user ID blinks, press " SET " button to confirm. Then press " MEM " button to check the records of the selected user.



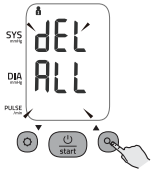

**CAUTION**

The most recent record (1) is shown first. Each new measurement is assigned to the first (1) record. All other records are pushed back one digit (e.g., 2 becomes 3, and so on), and the last record (60) is dropped from the list.

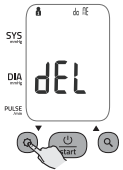
## ♥ Delete the Records

**If you did not get the correct measurement, you can delete all the results for the selected user by following steps. (Take user 1 for example.)**

1. In the memory mode, hold pressing " MEM " button about 3 seconds, the flash display "dEL All" + User ID will show.




2. Press " SET " button to confirm deleting, the LCD displays " User ID+dEL doNE " and then turns off.

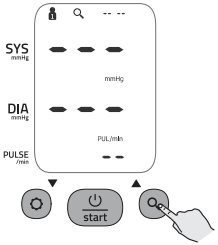



Note: To exit out of delete mode without deleting any records, press " START/STOP " button before pressing " SET " button to confirm any delete commands.





3. If there is no record, when you press " MEM " button to check the record, the display will show.



## ♥ Tips for Measurement

**Measurements may be inaccurate if taken in the following circumstances.**

Within 1 hour
after dinner or drinking

Immediate measurement
after tea, coffee, smoking

Within 20 minutes
after taking a bath

When talking or
moving your fingers

In a very cold environment

When you want to
discharge urine





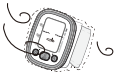
## ♥ Maintenance

**To obtain the best performance, please follow the instructions below.**

Put in a dry place and
avoid the sunshine

Avoid touching water,
clean it with a dry cloth in case.

Avoid intense shaking and collision.



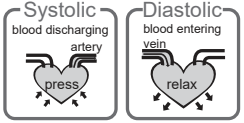
Avoid dusty and unstable-
temperature environment.

Using wet cloths to remove dirt.

Avoid washing the cuff

## ♥ What are systolic pressure and diastolic pressure?

When ventricles contract and pump blood out of the heart, blood pressure reaches its maximum value, the highest pressure in the cycle is known as systolic pressure. When the heart relaxes between heartbeats, the lowest blood pressure is diastolic pressure.

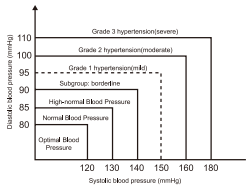



## ♥ What is the standard blood pressure classification?

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 |

## ♥ Irregular Heartbeat Detector

An irregular heartbeat is detected when a heartbeat rhythm varies while the device is measuring systolic pressure and diastolic pressure. During each measurement, blood pressure monitor will keep a record of all the pulse intervals and calculate the average value of them. 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%, then the irregular heartbeat symbol will appear on the display with the measurement result.

**⚠ CAUTION**

The appearance of the IHB icon indicates that a pulse irregularity consistent with an irregular heartbeat 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 tie 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.

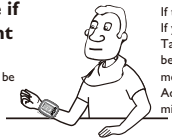
3. Wait at least 3 minutes for another measurement.

## ♥ 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.

## ♥ Is the result the same if measuring on the right wrist?

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



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 wrist.
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.





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

| PROBLEM | SYMPTOM | CHECK THIS | REMEDY |
|---|---|---|---|
| **No power** | Display is dim or will not light up. | Batteries are exhausted. | Replace with new batteries |
| | | Batteries are inserted incorrectly. | Insert the batteries correctly |
| **Low batteries** | +Lo Show on the display | 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 wrist and then measure again. |
| | E 04 shows | Measure incorrectly. | Relax for a moment and then measure again. |

## TROUBLESHOOTING

| PROBLEM | SYMPTOM | CHECK THIS | REMEDY |
|---|---|---|---|
| **Error message** | EExx,shows on the display. | A calibration error occurred. (XX can be some digital symbol,such as 01,02,etc., if this similarsituation appear, all belong to 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: 2*AAA batteries (3V DC) |
| **Display mode** | Digital LCD V.A. 45mm x 33mm |
| **Measurement mode** | Oscillographic testing mode |
| **Measurement range** | Rated cuff pressure:<br>0mmHg ~ 299mmHg (0kPa ~ 39.9kPa)<br>Measurement pressure:<br>SYS: 60mmHg ~ 230mmHg (8.0kPa ~ 30.7kPa)<br>DIA: 40mmHg ~ 130mmHg (5.3kPa ~ 17.3kPa)<br>Pulse value: (40-199) beat/minute |
| **Accuracy** | Pressure: 5°C-40°C within±3mmHg (0.4kPa)<br>Pulse value: ±5% |
| **Normal Working condition** | A temperature range of: +5°C to +40°C<br>A relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa<br>An atmospheric pressure range of: 700 hPa to 1060 hPa |
| **Storage & transportation condition** | Temperature: -20°C to +60°C<br>A relative humidity range of ≤ 93%, non-condensing, at a water vapour pressure up to 50hPa |
| **Measurement perimeter of the wrist** | About 13.5cm-21.5cm |
| **Weight** | Approx.100g (Excluding the batteries) |
| **External dimensions** | Approx. 86mm × 66mm × 22mm (Excluding the cuff) |
| **Attachment** | 2×AAA alkaline batteries (Not Included), User manual |

| | |
|---|---|
| **Mode of operation** | Continuous operation |
| **Degree of protection** | Type BF applied part |
| **Device Classification** | Internally Powered ME Equipment |
| **Protection against ingress of water** | IP22: The first number 2: Protected against solid foreign objects of 12,5mm Ø and greater. The second number: Protected against vertically falling water drops when enclosure titled up to 15°. Vertically falling drops shall have no harmful effects when the enclosure is titled at any angle up to 15° on either side of the vertical. |
| **Software Version** | A03 |

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

## ♥ Complied Standards List

| | |
|---|---|
| **Risk management** | EN ISO 14971:2012 Medical devices - Application of risk management to medical devices |
| **Labeling** | EN 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<br>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 disturbances - 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<br>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<br>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<br>EN 62366-1:2015+AC:2015/IEC 62366-1:2015+COR1:2016 Medical devices - Part 1: Application of usability engineering to medical devices |
| **Software life-cycle processes** | EN 62304:2006+A1:2015/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<br>ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity<br>ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization |

# ♥ 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** | | |
|---|---|---|
| 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<br>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<br>CISPR 11 | Class B | The device is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions<br>IEC 61000-3-2 | Class A | |
| Voltage fluctuations/<br>flicker emissions<br>IEC 61000-3-3 | Complies | |

Table 2

| 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 | ±8 kV contact<br>±15 kV air | ±8 kV contact<br>±15 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 | power supply lines: ±2 kV<br>input/output lines: ±1 kV | power supply lines: ±2 kV | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC61000-4-5 | line(s) to line(s): ±1 kV<br>line(s) to earth: ±2 kV<br>100 kHz repetition frequency | line(s) to line(s): ±1 kV<br>100 kHz repetition frequency | 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 | 0% $U_T$ ; 0.5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br>0% $U_T$ ; 1 cycle<br>and<br>70% $U_T$ ; 25/30 cycles<br>Single phase: at 0°<br>0% $U_T$ ; 300 cycle | 0% $U_T$ ; 0.5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br>0% $U_T$ ; 1 cycle<br>and<br>70% $U_T$ ; 25/30 cycles<br>Single phase: at 0°<br>0% $U_T$ ; 300 cycle | Mains power quality should be that of a typical commercial or hospital environment. |
| Power frequency (50Hz/60Hz) magnetic field<br>IEC 61000-4-8 | 30 A/m<br>50Hz/60Hz | 30 A/m<br>50Hz/60Hz | 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 3

| 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 | 150 kHz to 80 MHz: 3 Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz | 150 kHz to 80 MHz: 3 Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz | 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 appropriate for the frequency of the transmitter. Recommended separation distances: $d=0.35\sqrt{P}$ ; $d=1.2\sqrt{P}$ | |
| Radiated RF IEC 61000-4-3 | 10V/m, 80% Am at 1kHz | 10V/m, 80% Am at 1kHz | 80 MHz to 800 MHz: $d=1.2\sqrt{P}$ 800 MHz to 2.7 GHz: $d=2.3\sqrt{P}$ | where, P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, d is the recommended separation distance in meters (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 broadcast 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 4

**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 $d = 3.5\sqrt{P}$ | 80 MHz to 800 MHz $d = 1.2\sqrt{P}$ | 800 MHz to 2.7 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 80 MHz and 800 MHz, 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.





Table 5

**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.

| Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communica-tions equipment) | Test Frequency (MHz) | Band a) (MHz) | Service a) | Modulation b) | Modulation b) (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 b) 217 Hz | 2 | 0.3 | 28 |
| | 5240 | 5100-5800 | WLAN 802.11 a/n | Pulse modulation b) 217 Hz | 0.2 | 0.3 | 9 |
| | 5500 | | | | | | |
| | 5785 | | | | | | |
| NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3. | | | | | | | |
| a) For some services, only the uplink frequencies are included.<br>b) The carrier shall be modulated using a 50% duty cycle square wave signal.<br>c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case. | | | | | | | |
| The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation: $E=\frac{6}{d}\sqrt{P}$<br><br>Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m. | | | | | | | |