KINETIK medical

BPM5TL Series

# Fully Automatic Blood Pressure Monitor User Manual

## Index


| | | | |
|---|---|---|---|
| Important Information | 2 | Body Posture During Measurement | 16 |
| Contents and Display Indicators | 3 | Taking Your Blood Pressure Reading | 17 |
| Intended Use | 4 | Displaying Stored Results | 19 |
| Contraindication | 4 | Deleting Measurements from the Memory | 21 |
| Product Description | 5 | Assessing High Blood Pressure for Adults | 22 |
| Specifications | 6 | Troubleshooting (1) | 23 |
| Notice | 8 | Troubleshooting (2) | 24 |
| Setup and Operating Procedures | 12 | Maintenance | 25 |
| Battery Loading | 12 | Explanation of Symbols on Unit | 26 |
| Clock and Date Adjustment | 13 | Electromagnetic Compatibility Information | 28 |
| Connecting the Cuff to the Monitor | 14 | | |
| Applying the Cuff | 15 | | |

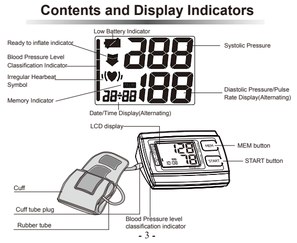



## Important Information
## Normal Blood Pressure Fluctuation

All physical activity, excitement, stress, eating, drinking, smoking, body posture and many other activities or factors (including taking a blood pressure measurement) will influence blood pressure value. Because of this, it is unusual to obtain identical multiple blood pressure readings.
Blood pressure fluctuates continually ----- day and night. The highest value usually appears in the daytime and lowest one usually at midnight. Typically, the value begins to increase at around 3:00AM, and reaches to highest level in the daytime while most people are awake and active.
Considering the above information, it is recommended that you measure your blood pressure at approximately the same time each day.
Too many measurements may cause injury due to blood flow interference, please always relax a minimum of 1 to 1.5 minutes between measurements to allow the blood circulation in your arm to recover. It is rare to obtain identical blood pressure readings each time.



## Contents and Display Indicators






## Intended Use

This Fully Automatic Electronic Sphygmomanometer is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 22cm-48cm (approx. 8 21/32"~18 29/32").

## Contraindication

⚠ It is inappropriate for people with serious arrhythmia to use this Electronic Sphygmomanometer.



## Product Description

Based on Oscillometric methodology and a silicon integrated pressure sensor, blood pressure and pulse rate can be measured automatically and non-invasively. The LCD display will show blood pressure and pulse rate. The most recent 60 measurements for two users can be stored in the memory with date and time stamp. The monitor can also show the average reading of the last three measurements. This Electronic Sphygmomanometer corresponds to the following standards: IEC 60601-1:2005/EN 60601-1:2006/AC:2010 (Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance), IEC60601-1-2: 2007/EN 60601-1-2:2007 /AC:2010 (Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests), EN 1060-1: 1995 + A1: 2002 + A2: 2009 (Non-invasive sphygmomanometers - Part 1: General requirements), EN 1060-3: 1997 + A1: 2005 + A2: 2009 (Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems).



## Specifications

1. Product name: Blood Pressure Monitor
2. Model: BPM5TL
3. Classification: Internally powered, Type BF Applied Part, IPX0, No AP or APG, Continuous Operation
4. Machine size: Approx. 138mm × 98mm × 48mm (5 7/16"x 3 27/32"x 1 7/8")
5. Cuff circumference: 22cm-30cm (8 21/32"-11 13/16"), 30cm-42cm (11 13/16"-16 17/32") (Optional), 42cm-48cm (16 17/32"-18 29/32") (Optional)
6. Weight: Approx. 211g (7 7/16 oz.) (exclude batteries and cuff)
7. Measuring method: Oscillometric method, automatic inflation and measurement
8. Memory volume: 2 x 60 with time and date stamp
9. Power source: batteries: 4 × 1.5V⎓ SIZE AA
10. Measurement range:
    Cuff pressure: 0-300 mmHg
    Systolic: 60-260 mmHg
    Diastolic: 40-199 mmHg
    Pulse rate: 40-180 beats/minute



## Specifications

11. Accuracy:
    Pressure: ±3 mmHg
    Pulse rate: ±5%
12. Environmental temperature for operation: 10ºC～40ºC(50ºF～104ºF)
13. Environmental humidity for operation: ≤90%RH
14. Environmental temperature for storage and transport: -20ºC～55C(-4ºF～131ºF)
15. Environmental humidity for storage and transport: ≤90%RH
16. Environmental pressure: 80KPa-105KPa
17. Battery life: Approx 500 measurements

Note: These specifications are subject to change without notice.



## Notice ⚠

1. Read all of the information in the operation guide and any other literature in the box before operating the unit.
2. Stay still, calm and rest for 5 minutes before blood pressure measurement.
3. The cuff should be placed at the same level as your heart.
4. During measurement, neither speak nor move your body and arm.
5. Measure on same arm for each measurement.
6. Please always relax at least 1 to 1.5 minutes between measurements to allow the blood circulation in your arm to recover. Prolonged over-inflation (cuff pressure exceeds 300 mmHg ) of the bladder may cause bruising or swelling of your arm.
7. Consult your physician if you have any doubt about the following :
1) The application of the cuff over a wound or inflammation.
2) The application of the cuff on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present.
3) The application of the cuff over the arm on the side of a mastectomy.
4) Simultaneously used with other monitoring medical equipment on the same limb.
5) If you suffer with poor circulation.



## Notice ⚠

8.⚠ This Electronic Sphygmomanometer is designed for adults and should never be used on infants or young children. Consult your physician or other health care professionals before use on older children.
9. Do not use this unit in a moving vehicle. This may result in erroneous measurement.
10. Blood pressure measurements determined by this monitor are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultation method, within the limits prescribed by the American National Standard Institute, Electronic or automated sphygmomanometers.
11. For information regarding potential electromagnetic or other interference between the blood pressure monitor and other devices together with advice regarding avoidance of such interference, please see part ELECTROMAGNETIC COMPATIBILITY INFORMATION.
12. If Irregular Heartbeat (IHB) brought by common arrhythmias is detected during a measurement, the ((•)) will be displayed. Please ignore the results and try again after a few minutes.



## Notice ⚠

Note: This monitor is designed to detect Premature Ventricular Contractions, also known as a Premature Ventricular Complex (or complexes), Ventricular Premature Contractions (or complex or complexes), Ventricular Premature Beats, or Extrasystoles. It is not designed to detect Atrial Fibrillation or Atrial Premature Beats.
13. Please only use the cuff supplied.
14.⚠This monitor might not meet its performance specifications or cause a safety hazard if stored or used outside the specified temperature and humidity ranges in the specifications section.
15. ⚠ To avoid cross contamination, do not share this cuff with anyone suffering with a contagious illness.



## Notice ⚠

16. This blood pressure monitor is verified by auscultatory method. It is recommended that you check annex B of ANSI/AAMI SP-10:2002+A1:2003+A2: 2006 for details of verification method if you need.



## Setup and Operating Procedures

### 1. Battery Loading

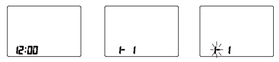
a. Open battery cover at the back of the monitor.
b. Load four "AA" size batteries. Please pay attention to polarity.
c. Close the battery cover.
When LCD shows battery symbol ▬ , replace all batteries with new ones.
Rechargeable batteries are not suitable for this monitor.
Remove the batteries if the monitor will not be used for a month or more to avoid battery leakage.
⚠ Avoid getting battery fluid in your eyes. If it should get in your eyes, immediately rinse with plenty of clean water and contact a physician.

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



### 2. Clock and Date Adjustment

a. Once you install the battery or turn off the monitor, it will enter Clock Mode, and LCD will display time and date (alternating). See picture 2&2-1.



picture 2 picture 2-1 picture 2-2

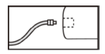
b. While the monitor is in Clock Mode, pressing both the "START" and "MEM" button simultaneously, a beep is heard and the month will blink at first. See picture 2-2. Press the button "START" repeatedly, the day, hour and minute will blink in turn. While the number is blinking, press the button "MEM" to increase the number. Pressing and hold the "MEM" button will advance the number quickly.
c. You can turn off the monitor by pressing the "START" button, when the minute is blinking the time and date is confirmed.



d. The monitor will turn off automatically after 1 minute of no operation, with the time and date unchanged.
e. Once you change the batteries, you should adjust the time and date.

### 3. Connecting the Cuff to the Monitor

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

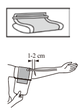


⚠ Avoid compression or restriction of the connection tubing during measurement, which may cause inflation error, or harmful injury due to continuous cuff pressure.



### 4. Applying the Cuff

a. Pulling the cuff end through the medal loop (the cuff is packaged like this already), turn it outward (away from your body) and tighten it and close the Velcro fastener.
b. Place the cuff around a bare arm 1-2cm above the elbow joint.
c. While seated, place palm upside in front of you on a flat surface such as a desk or table. Position the air tube in the middle of your arm in line with your middle finger.
d. The cuff should fit comfortably, yet snugly around your arm. You should be able to insert one finger between your arm and the cuff.




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



5. Please keep the cuff clean. If the cuff becomes dirty, remove it from the monitor and clean it by hand in a mild detergent, then rinse it thoroughly in cold water. Never dry the cuff in clothes dryer or iron it.

### 5. Body Posture During Measurement

**Seated**
a. Be seated with your feet flat on the floor, and don't cross your legs.
b. Place palm upside in front of you on a flat surface such as a desk or table.
c. The middle of the cuff should be at the level of the right atrium of the heart.

**Lying Down**
a. Lie on your back.
b. Place your arm straight along your side with your palm upside.
c. The cuff should be placed at the same level as your heart.

### 6. Taking Your Blood Pressure Reading

a. After applying the cuff and ensuring your body is in a comfortable position, press the "START" button. A beep is heard and all display characters are shown for self-test. See picture 6. Please contact your retailer if any segments are missing.
b. The current memory bank (U1 or U2) will blink. See picture 6-1. Press "MEM" button to change over to other bank. See picture 6-2. Confirm your selection by pressing "START" button. The current bank can also be confirmed automatically after 5 seconds with no operation.

picture 6 picture 6-1 picture 6-2

c. After selecting the memory bank, the monitor starts to seek zero pressure. See picture 6-3.



d. The monitor inflates the cuff until sufficient pressure has built up for a measurement. Then the monitor slowly releases air from the cuff and carries out the measurement. Finally the blood pressure and pulse rate will be calculated and displayed on the LCD screen separately. Irregular heartbeat symbol (if any) will blink. See picture 6-4&6-5. The result will be automatically stored in the current memory bank.

picture 6-3 picture 6-4 picture 6-5

e. After measurement, the monitor will turn off automatically after 1 minute of no operation. Alternatively, you can press the "START" button to turn off the monitor manually.
f. During measurement, you can press the "START" button to turn off the monitor manually.
Note: Please consult a health care professional for interpretation of pressure measurements.



### 7. Displaying Stored Results

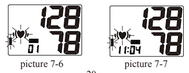
a. After the measurement, you can review the measurements in the current memory bank by pressing button "MEM". The LCD will display the number of the results in the current bank. See picture 7.

picture 7 picture 7-1 picture 7-2

b. Alternatively, press "MEM" button in Clock Mode to display the stored results. The current memory bank will blink and the amount of results in this bank will be displayed. See picture 7-1. Press "START" button to change over to other bank. See picture 7-2. Confirm your selection by pressing "MEM" button. The current bank can also be confirmed automatically after 5 seconds with no operation.
c. After selecting the memory bank, the LCD will display the average value of the last three results in this bank, See picture 7-3 & 7-4. If no result stored, LCD will show dashes as picture 7-5.

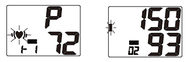
picture 7-3 picture 7-4 picture 7-5

d. When the average is displayed, press the "MEM" button, the most recent result will be shown. See picture 7-6. Followed by, the blood pressure and pulse rate will be shown separately. Irregular heartbeat symbol (if any) will blink. See picture 7-7&7-8. Press "MEM" button again to review the next result. See picture 7-9. In this way, repeatedly pressing the "MEM" button displays the respective results measured previously.



picture 7-6 picture 7-7





picture 7-8 picture 7-9

e. When displaying the stored results, the monitor will turn off automatically after 1 minute of no operation. You can also press the button "START" to turn off the monitor manually.

### 8. Deleting Measurements from the Memory

While any result (except average reading of the last three results) is displayed, press the "MEM" button for three seconds, all results in the current memory bank will be deleted after three beeps.The LCD will show picture 8. Press the button "MEM" or "START" to turn the monitor off.

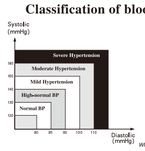
picture 8



### 9. Assessing High Blood Pressure for Adults

The following guidelines for assessing high blood pressure (without regard to age or gender) have been established by the World Health Organization (WHO). Please note that other factors (e.g. diabetes, obesity, smoking, etc.) need to be taken into consideration. Consult with your physician for accurate assessment, and never change your treatment by yourself.

**Classification of blood pressure for adults**




| BLOOD PRESSURE CLASSIFICATION | SBP mmHg | DBP mmHg |
|---|---|---|
| Optimal | <120 | <80 |
| Normal | 120-129 | 80-84 |
| High-Normal | 130-139 | 85-89 |
| Grade 1 Hypertension | 140-159 | 90-99 |
| Grade 2 Hypertension | 160-179 | 100-109 |
| Grade 3 Hypertension | ≥ 180 | ≥ 110 |

*WHO/ISH Definitions and Classification of Blood Pressure Levels*



## Troubleshooting (1)

| Problem | Possible Cause | Solution |
|---|---|---|
| LCD Display shows abnormal result | The cuff position was not correct or it was not properly tightened | Apply the cuff correctly and try again |
| | Body posture was not correct during testing | Review the "BODY POSTURE DURING MEASUREMENT" sections of the instructions and re-test. |
| | Speaking, arm or body movement, angry, excited or nervous during testing | Re-test when calm and without speaking or moving during the test |
| | Irregular heartbeat (arrhythmia) | It is inappropriate for people with serious arrhythmia to use this Electronic Sphygmomanometer. |



## Troubleshooting (2)

| Problem | Possible Cause | Solution |
|---|---|---|
| LCD shows low battery symbol ▬ | Low Battery | Change the batteries |
| LCD shows "Er 0" | Pressure system is unstable before measurement | Don't move and try again. |
| LCD shows "Er 1" | Fail to detect systolic pressure | |
| LCD shows "Er 2" | Fail to detect diastolic pressure | |
| LCD shows "Er 3" | Pneumatic system blocked or cuff is too tight during inflation | Apply the cuff correctly and try again |
| LCD shows"Er 4" | Pneumatic system leakage or cuff is too loose during inflation | |
| LCD shows "Er 5" | Cuff pressure above 300mmHg | Measure again after five minutes. If the monitor is still abnormal, please contact the local distributor or the factory. |
| LCD shows "Er 6" | More than 3 minutes with cuff pressure above 15 mmHg | |
| LCD shows "Er 7" | EEPROM accessing error | |
| LCD shows "Er 8" | Device parameter checking error | |
| LCD shows "Er A" | Pressure sensor parameter error | |
| No response when you press button or load battery. | Incorrect operation or strong electromagnetic interference. | Take out batteries for five minutes, and then reinstall all batteries. |



## Maintenance

1.⚠ Do not drop this monitor or subject it to strong impact.
2.⚠ Avoid high temperature and direct sunlight. Do not immerse in water as this will result in damage to the monitor.
3. If this monitor is stored in cold temperatures, allow it to acclimate to room temperature before use.
4.⚠ Do not attempt to disassemble this monitor.
5. If you do not use the monitor for a long time, please remove the batteries.
6. Clean the monitor with a dry, soft cloth or a soft cloth squeezed well after moistened with water, diluted disinfectant alcohol, or diluted detergent.
7. This blood pressure monitor is calibrated at the time of manufacture. If the blood pressure monitor is used according to the instructions, periodic recalibration is not required. If at any time you question the accuracy of the measurement, please contact the retailer immediately.
8. The monitor can maintain the safety and performance characteristics for a minimum of 10,000 measurements or three years, the cuff can maintain the performance characteristics for a minimum of 1000 measurements.



9. It is recommended the cuff should be disinfected twice a week if needed (for example, in a hospital or in a clinic). Wipe the inner side of the cuff with a soft cloth moistened with Ethyl Alcohol (75-90%), then dry the cuff by airing.

## Explanation of Symbols on Unit

Symbol for " THE OPERATION GUIDE MUST BE READ"

Symbol for "WARNING"

Symbol for "TYPE BF APPLIED PARTS" (The cuff is type BF applied part)

Symbol for "ENVIRONMENT PROTECTION – Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local Authority or retailer for recycling advice".

Symbol for "MANUFACTURER"

CE 0197 Symbol for "COMPILES WITH MDD93/42/EEC REQUIREMENTS"



Symbol for "DATE OF MANUFACTURE"

EC REP Symbol for "EUROPEAN REPRESENTATIVE"

SN Symbol for "SERIAL NUMBER"

Symbol for "KEEP DRY"

Harvard Medical Devices Ltd.
Unit 1301, 13th Floor, Railway Plaza,
39 Chatham Road South, Tsimshatsui,
Kowloon, Hong Kong.

EC REP Kinetik Medical Devices Ltd.
Mill Road, Rugby, Warwickshire,
United Kingdom, CV21 1PR.



## Electromagnetic Compatibility Information

**Table 1**
**For all ME EQUIPMENT and ME SYSTEMS**

**Guidance and manufacture's declaration - electromagnetic emissions**

The [BPM5TL] is intended for use in the electromagnetic environment specified below. The customer or the user of the [BPM5TL] should assure that it is used in such an environment.

| Emissions test | Compliance | Electromagnetic environment - guidance |
|---|---|---|
| RF emissions CISPR 11 | Group 1 | The [BPM5TL] 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 [BPM5TL] 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: IEC 61000-3-2 | Not applicable | |
| Voltage fluctuations/ flicker emissions: IEC 61000-3-3 | Not applicable | |



**Table 2**
**For all ME EQUIPMENT and ME SYSTEMS**

**Guidance and manufacturer's declaration - electromagnetic immunity**

The [BPM5TL] is intended for use in the electromagnetic environment specified below. The customer or the user of the [BPM5TL] should assure that it is used in such an environment.

| IMMUNITY test | IEC 60601test 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 %. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |



**Table 3**
**For ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING**

**Guidance and manufacturer's declaration - electromagnetic immunity**

The [BPM5TL] is intended for use in the electromagnetic environment specified below. The customer or the user of the [BPM5TL] should assure that it is used in such an environment.

| IMMUNITY test | IEC 60601test level | Compliance level | Electromagnetic environment - guidance |
|---|---|---|---|
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | 3 V/m | Portable and mobile RF communications equipment should be used no closer to any part of the [BPM5TL], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>**Recommended separation distance,**<br>$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz<br>$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz<br>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 meters (m). |

To be continued



continued

**Table 3**

| IMMUNITY test | IEC 60601test level | Compliance level | Electromagnetic environment - guidance |
|---|---|---|---|
| | | | 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 [BPM5TL] is used exceeds the applicable RF compliance level above, the [BPM5TL] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [BPM5TL].
b Over the frequency range 150 MHz to 80 MHz, field strengths should be less than 3 V/m.



**Table 4**
**For ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING**

**Recommended separation distances between portable and mobile RF communications equipment and the [BPM5TL]**

The [BPM5TL] is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the [BPM5TL] can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the [BPM5TL] 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 meters (m) can be determined 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.



KINETIK BPM5TL UK IB 20130910




| | | | |
|---|---|---|---|
| 原稿文件编号 | KINETIK BPM5TL | 版　本 | V3.0 |
| 尺　寸 | 95.0×70.0 | 公　差 | ±1.0mm |
| 材　质 | 60g双胶纸 | 表面处理 | 无 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 设计 | | | 审核 | | | 批准 | |