REF TMB-2296-B

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Made in China

kinetik WELLBEING

User Manual

Smart All-In-One Blood Pressure Monitor

REF TMB-2296-B

Arm Type



- Thank you for selecting the Kinetik Wellbeing Smart All-In-One Blood Pressure Monitor.
- Please read the user manual carefully and thoroughly, this is to ensure the safe usage of the product. Please keep the user manual for future reference.

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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…

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

Email:
customercare@kinetikwellbeing.com

Post:
Kinetik Medical Devices Limited
Unit 11, Perrywood Business Park, Honeycrock Lane,
Salfords, Redhill. RH1 5DZ

♥ General Description

Thank you for selecting the Kinetik Wellbeing Smart All-In-One Blood Pressure Monitor. The monitor features blood pressure measurement, pulse rate measurement and the result storage. The blood pressure monitor provides you with two years of reliable service.

Readings taken by the TMB-2296-B 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:

- Digital LCD display
- Systolic, Diastolic Blood Pressure & Pulse Display
- Measuring-during-inflation technology

♥ Indications for Use

This Blood Pressure Monitor is a digital monitor intended for use in measuring blood pressure and pulse rate with arm circumference ranging from 22cm to 32cm (about 8¾″-12½″) or 22cm to 42cm (about 8¾″-16½″).

It is intended for adult indoor use only.

♥ 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 atmospheric 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.

♥ Receiving and Inspecting your Monitor

Check that the device packaging has not been tampered with and make sure that all contents are present. Before use, ensure that there is no visible damage to the device or accessories and that all packaging material has been removed. If you have any doubts, do not use the device and contact Kinetik Wellbeing.

♥ Safety Information

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

	Manufacturer		Type BF applied part
CN	Manufactuer Date and Made in China		Direct Current
		SN	Serial Number
	Recyclable	MD	Medical Device
	For indoor use only		Class II Equipment
REF	Symbol for Commercial Product Code / Model Number	LOT	Symbol for Batch Code
	Refer to instruction manual/booklet To signify that the instruction manual/ booklet must be read. Note: The background color of the symbol is blue.		
	Caution Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.		
	The symbol indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling.		
CE 0123	CE marking indicates that a product has been assessed by the manufacturer and deemed to meet EU safety, health and environmental protection requirements. It is required for products manufactured anywhere in the world that are then marketed in the EU.		
EC REP	Authorized representative in the European Community/ European Union		
IP22	The first characteristic numeral symbol for “Degrees of protection against access to hazardous parts and against solid foreign objects.” The second characteristic numeral symbol for “Degrees of protection against ingress of water.”		

Precaution

* This device is intended for indoor, home use and is not intended for public use.
* This device is portable, but it is not intended for use during patient transport.
* This device is not suitable for continuous monitoring during medical emergencies or operations.
* This device is intended for non-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than the arm, or for any purpose other than obtaining a blood pressure measurement.
* This device is for adults. Do not use this device on neonates or infants. Do not use it on children and adolescents unless otherwise instructed by a healthcare professional.
* Consult with a healthcare professional before using this monitor if you suffer from the following conditions: common arrhythmias such as premature ventricular beats or atrial fibrillation; peripheral arterial disease; implantation with electrical devices; undergoing intravascular therapy; arteriovenous shunt or mastectomy.
  Please note that any of these conditions may affect measurement readings,in addition to patient motion, trembling or shivering.
* Do not use this device for diagnosis or treatment of any health problem or disease. Contact a healthcare professional if you have or suspect any medical problem. Do not change your medications without the advice of a healthcare professional.
* If you are taking medication, consult a healthcare professional to determine the proper time to measure your blood pressure.
* This device may be used only for the intended use described in this manual, the manufacturer shall have no liability for any incidental, consequential, or special damages caused by misuse or abuse.
* Please use the device under the environment which is provided in the user manual. Otherwise, the performance and lifetime of the device will be impacted and reduced.
* The device may require up to 30 minutes to warm up / cool down from the minimum/ maximum storage temperature before it is ready for use.
* The blood pressure monitor, its adapter, and the cuff are suitable for use within the patient environment.
* Do not wash the cuff in a washing machine or dishwasher.
* The device contains sensitive electronic components. To avoid measurement errors, avoid taking blood pressure measurements near a strong electromagnetic field radiated interference signal or electrical fast transient/burst signal.
* Wireless communication equipment, such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies may cause interference that may affect the accuracy of measurements. A minimum distance of 1 foot (30 cm) should be kept from such devices during a measurement.
* This blood pressure monitor is intended for use by medical or non-medical staff. A patient can also be the intended user or operator.

⚠ Caution

* Do not attempt to repair the unit yourself if it malfunctions. Only have repairs carried out by authorised service centers.
* It is recommended that the performance should be checked after repair, maintenance, and every two years of use, by retesting the requirements in limits of the error of the cuff pressure indication and air leakage (testing at least at 50 mmHg and 200 mmHg). Please contact Kinetik Wellbeing for authorised service personnel.
* Store your device, cuff and adapter in a clean and dry place, protect it against extreme moisture, heat, lint, dust and direct sunlight. Never place any heavy objects on it.
* Make sure the rubber tube of the cuff is not squeezed, stretched, or kinked during storage.
* Dispose of accessories, detachable parts, and the device according to any local guidelines.

Warning

* Do not apply the cuff on an arm that has an intravenous drip or a blood transfusion attached.
* Do not kink, fold, stretch, compress, or otherwise deform the tube during measuring, as the cuff pressure might continuously increase, which could prevent blood flow and result injury.
* Taking blood pressure measurements too frequently could disrupt blood circulation and cause injuries.
* Do not apply cuff to areas on patient where skin is delicate or damaged. Check cuff site frequently for irritation.
* Do not place the cuff on the arm of a person whose arteries or veins are undergoing medical treatment, i.e. intra-vascular access or intra-vascular therapy or an arteriovenous (A-V) shunt, which could disrupt blood circulation and cause injuries.
* Do not place the cuff on the arm on the same side of a mastectomy (especially when lymph nodes have been removed), it is recommended to take measurements on the unaffected side.
* Do not wrap the cuff on the same arm to which another monitoring device is applied. One or both devices could temporarily stop functioning if you try to use them at the same time.
* Please check (for example, by observation of the limb concerned) that the operation of the device does not result in prolonged impairment of patient blood circulation.
* On the rare occasion of a fault causing the cuff to remain fully inflated during measurement, loosen and remove the cuff immediately. Prolonged high pressure applied to the arm (cuff pressure >300 mmHg or constant pressure >15 mmHg for more than 3 minutes) might lead to bruising and discolored skin.
* Do not use this device with high-frequency (HF) surgical equipment at the same time.
* This device is not used in conjunction with oxygen rich environments, not intended for use with flammable anaesthetics, not intended for use in conjunction with flammable agents.
* Do not touch output of the batteries/adapter and the user simultaneously.
* The power cord is considered the disconnect device for isolating this equipment from supply mains. Do not position the equipment so that it is difficult to reach or disconnect.
* Do not use this device if you are allergic to polyester, nylon, or plastic.
* Only use accessories approved by manufacturer. Using unapproved accessories might cause damage to the unit and injure users.
* If you experience discomfort during a measurement, such as pain in the arm or other complaints, press the Power button immediately to release the air from the cuff.
* Do not use the device while under maintenance, or being serviced.
* The air tube poses a risk of strangulation. Furthermore, the small parts of product and batteries present a choking hazard if swallowed. They should therefore always be kept away from infants/children.
* Sensor degradation or looseness may reduce performance of device or cause other problems.

Notice

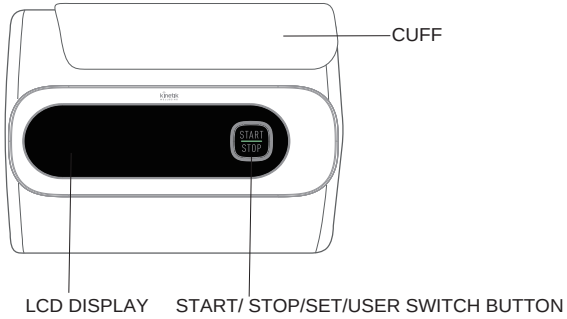
* You can use this device to take your own measurement, no third-party operator is required.
* Adapter is specified as a part of the ME (Medical Electrical) Equipment.
* At the request of authorised service personnel, circuit diagrams, component part lists, descriptions, and calibration procedures will be made available by Kinetik Wellbeing.
* The expected lifetime of the cuff may vary by the frequency of washing, skin condition, and storage state.
* Please report to the manufacturer and the competent authority of the country in which you are established about any serious incident that has occurred in relation to this device.

♥ LCD display signal



SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic blood pressure	High pressure result
DIA	Diastolic blood pressure	Low pressure result
PULSE /min	Pulse display	Pulse in beats per minute
mmHg	mmHg	Measurement unit of blood pressure
OK	Cuff wearing	The cuff is secured.
	Pulse rate	Pulse rate dectetion during measurement
	Hand shaking	Hand shaking makes results inaccurate
	Battery Indicator	Indicate the current battery
	Irregular pulse rate	Irregular pulse rate
	Data transmitting	Data is transmitting
	Bluetooth icon	Indicate the bluetooth is working.

♥ Product Components

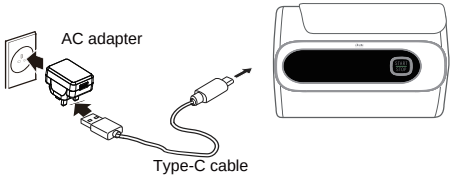


♥ Contents/Product Includes

- **Blood Pressure Monitor (TMB-2296-B)**
- **Cuff (Type BF applied part)**
  Upper arm cuff: 22-42cm.
- **User manual**
- **Type-C cable & Adapter (Optional!)**

♥ Power Supply and Charge Power

1. This blood pressure monitor has a built-in, rechargeable li-polymer battery. The battery current is 1000 mAh.
2. Please use the Type-C cable and AC adapter to charge the battery, just like the following picture:



Charging the power under following circumstances:

- + bAt Lo displays on the LCD
- The LCD display is dim.
- When powering on the monitor, the LCD doesn't light up.

⚠ CAUTION

- The battery of TMB-2296-B is a built-in rechargeable lithium-ion battery, please do not disassemble it.
* If the battery is not recharging, or the blood pressure monitor is not working as usual, please contact Kinetik Wellbeing. When fully charged, the blood pressure monitor will take 100 measurements.
* Ensure to store and use the blood pressure monitor in cool, dry and ventilated environments. Avoid storing or using the device near an open fireplace or heat source, as it could cause the battery to explode.
* Only can use the authorised AC Adaptor (Model: BLJ06L050100U-B) to charge. You cannot use the blood pressure monitor whilst charging.
* Whilst charging, the LED indicator of the START/STOP button will light up. When charging is complete, the LED indicator will stop lighting up. Please unplug the blood pressure monitor from the charging socket.

⚠ CAUTION

- Do not attempt to replace your blood pressure monitor's battery. It is built-in and not changeable.
- Only charge the battery in accordance with the user instructions supplied with the blood pressure monitor.
- Avoid charging your blood pressure monitor in extremely high or low temperatures.
- Do not use your blood pressure monitor while you are charging it.
- Do not attempt to disassemble the blood pressure monitor or force open the built-in battery.
- Do not clean the blood pressure monitor when it is being charged. Always unplug the charger first before cleaning the blood pressure monitor.
- Do not dispose of your blood pressure monitor in a fire. The battery could explode causing injury or death.

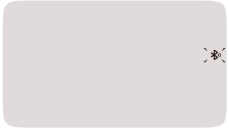
♥ Activate Your Blood Pressure Monitor

When you first use the Blood Pressure Monitor, the first thing you must do is activate it. Press and hold the "START/STOP" button for about 5 seconds to activate the device.

♥ Pair a smart device with the monitor

You are the intended operator of this blood pressure monitor. After measuring your blood pressure, data will automatically be sent to a smart device (such as smartphone or tablet), so long as there is Bluetooth connectivity. If there isn't, the blood pressure monitor will store up to 2 user x 199 measurements. The blood pressure monitor will automatically send the measurements once a connection is re-established.

1. **Download the Blood Pressure Diary by MedM app or the MedM Health app from the App store or Google Play.**
2. **Enable Bluetooth and the MedM Health app on your smart device.** Make sure both Bluetooth and app are ON when pair-up is proceeding.
3. **When the monitor is off, press and hold the "MEM" button to start pair-up, the bluetooth symbol will flash.**



4. **If successful**, the bluetooth symbol will not flash any more and the monitor will automatically shut off after several seconds.
5. **In the app, select the menu in the top left corner of the screen. Then select 'My Devices'.**
6. **At the bottom of the screen select 'Add New'. This will automatically start scanning for a new device.**

   When detected, select the TMB-2296-B.
7. **Once selected you will be asked if you would like to receive data automatically. If no, you will need to manually input results. If yes, you will then be asked if you want to receive data in the background.**

Note:
1. The date and time on your monitor will automatically be set after paired with your smart device successfully.
2. The device can also enter the Bluetooth pairing automatically when the battery is installed for the first time.

If unsuccessful within 60 seconds, it is judged timeout and the monitor will shut off.

Specifications for Bluetooth Transmission		
Bluetooth	Throughput	2.5K-5K
	Latency	50ms
	PER	＜10%
	Operating Frequency	2400-2480MHz
	Transmission Power	0dBm
	Transmission Distance	10m

Note:
1. The necessary Quality of Service (QoS) is fully considered here for wirelessly enabled functions.
2. Interference may occur in the vicinity of equipment marked with the following symbol . And TMB-2296-B may interfere the vicinal electrical equipment.
3. Keep the monitor at least 20 centimeters away from the human body (especially the head) when data transmission is proceeding after measurement.
4. To enable the data transmission function, this device shall be paired to an appropriate BT mobile terminal.

Warning

About a wireless communication interference

The monitor operates in the unlicensed ISM band at 2.4 GHz. In case it is used around the other wireless devices including microwave and wireless LAN, which operate at the same frequency band as the monitor, there is a possibility that interference occurs between the monitor and such other devices. If such interference occurs, please stop the operation of other devices or relocate the monitor before using it or do not use it around the other wireless devices.

List of compatible devices:

For iOS devices:
The operating system must be iOS 13.0 or more.

For Android devices:

The operating system must be Android 5.0 or more.

♥ Setting a user ID

There are 2 user ID available. User 1 and User 2, each with 199 memory spaces, this means that 2 different people can save their measured values separately.

1. When the monitor is off, press the “START/STOP” button to display the current user ID and flash. Press the “START/STOP” button again to switch the user ID between the User 1 and User 2.



User 1



User 2

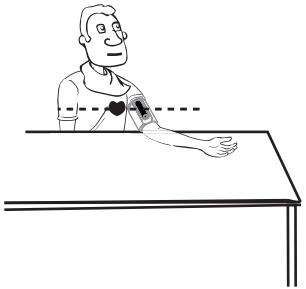
2. When you have selected the correct User ID, do not press anything, simply wait a moment until the User ID is no longer flashing. The blood pressure monitor will start the measurement in a few seconds.

♥ Tie the Cuff

Only use a cuff that has been approved by Kinetik Wellbeing.
Before use, please confirm if it fits your arm circumference.

1. Remove all accessories (watch, bracelet, etc) from your arm. If your physician has diagnosed you with poor circulation in your arm, use the other one.
2. Roll or push up your sleeve to expose skin.
3. Apply the cuff to your arm with your palm facing up.
4. Position the edge of the cuff about 2cm~3cm from elbow.
5. Fasten the cuff around your arm, 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 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.
7. Helpful tips for Patients, especially for Patients with Hypertension:

- Rest for 5 minutes before first measurement.
- 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 healthcare professional.



♥ Start the Measurement

You can use your monitor without pairing to a smart device. To pair your monitor with a smart device refer to page 12.

1. When the monitor is off, press the "START/STOP" button, the current user ID will flash.

When you have selected the correct User ID, do not press anything, simply wait a moment until the User ID is no longer flashing. The blood pressure monitor will start the measurement in a few seconds.

Remain still and do not talk until the full measurement is complete. (Take User 1 for example.)



Select user ID



Cuff wrap detection.
symbol " " flash.



Cuff wrap ok.
Inflating and measuring.



Display and save the measurement result

2. Press the button to turn off the monitor, or it will shut off after about 1 minute.

3. If your monitor is already paired with your smart device and both Bluetooth and app are ON, the measurement result will start transmitting.

If data transmission successful, the symbol " " will disappear first , after several seconds, " " will also disappear, and then the monitor will turn off automatically.



If unsuccessful within 60 seconds, after 60 seconds of inactivity, the blood pressure monitor will turn off.

Note

1. If you want to stop the measurement at any time, you can press the "START/ STOP" button manually.
2. If there are previous untransmitted measurements, the symbol will display on the screen at the beginning of the measurement.
3. Both User 1 and User 2 can store a maximum of 199 measurements on the monitor. You can view your readings in the MedM Blood Pressure Diary or MedM Health app, if your monitor is already paired with your smart device.

4. About the irregular pulse rate and excessive body motion during the measurement.

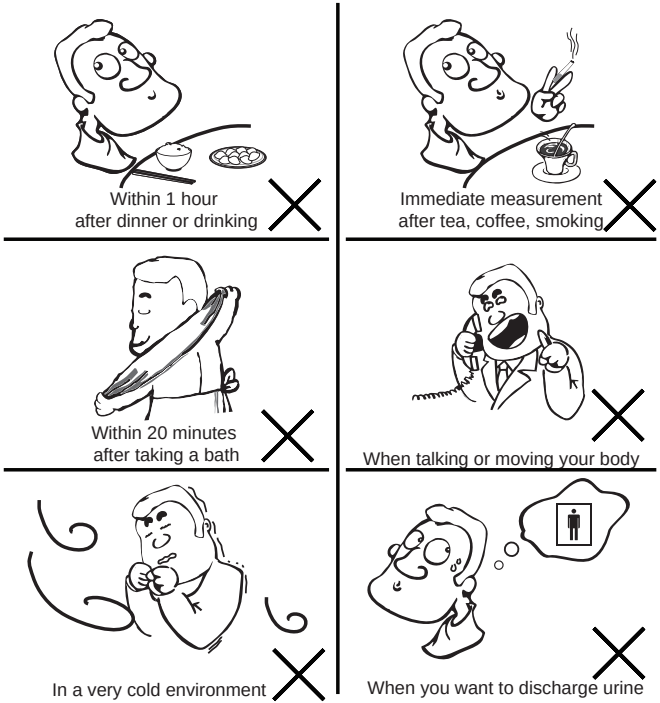
- During a measurement, if an irregular pulse rate is detected, the symbol will display in the measurement result. See page 21 for more information.
- During a measurement, if excessive body motion is detected, the symbol will flash for about 5 seconds and repeat the measurement. If it is no longer detected, the symbol will disappear. If still detected, the symbol will be shown in the measurement result.

Note
The measured blood pressure reading may not be accurate if this symbol is displayed.



♥ Tips for Measurement

Measurements may be inaccurate if taken in the following circumstances.



♥ Maintenance

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

1. Cleaning Process:

Step 1: Make sure to switch off and unplug the device prior to cleaning.
Step 2: Use a soft cloth and dampen it with soapy water to clean the cuff first, and then use a soft cloth and damped it with clear water to remove residual soap until there is no visible residual contaminants. Attention shall be paid to avoid liquid leaking into the cuff.
Step 3: Use a dry soft cloth to wipe the cuff, in order to remove residual moisture.
Step 4: Dry the cuff in a well-ventilated area after cleaning.

2. Disinfection Process:

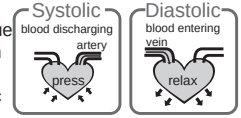
Step 1: Make sure to switch off and unplug the device prior to disinfection.
Step 2: Use a soft cloth with 70% isopropanol to disinfect the cuff for about 10 minutes. Attention shall be paid to avoid liquid leaking into the cuff.
Step 3: Use a clean dry cloth or towel to wipe off the disinfectant until there is no visible residue.
Step 4: Dry the cuff in a well-ventilated area after disinfection.

• Suggestion:

Frequency of Cleaning and Disinfection:
For single patient multiple use, it's recommended to clean the device surface once a month or whenever it's necessary.
For multiple patient multiple use, it's recommended to clean the device every time before and after usage. Maintenance procedures shall be taken as per instruction.

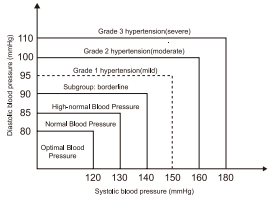
♥ What are systolic pressure and diastolic pressure?

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:



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

♥ Irregular Pulse Rate Detector

An irregular pulse rate is detected when a pulse rate 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 pulse rate symbol appears on the display when the measurement results are appeared.

⚠ CAUTION

The appearance of the ♥ icon indicates that a pulse irregularity consistent with an irregular pulse rate 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 user 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?

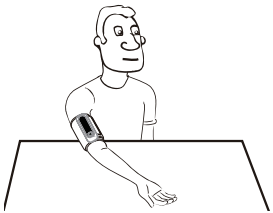
The blood pressure is different even throughout the day due to weather, emotion, exercise etc. Also, there is the “white coat” effect, which means blood pressure usually increases in clinical settings.

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 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.



If any abnormality arises during use, please check the following points:

PROBLEM	SYMPTOM	CHECK THIS	REMEDY
No power	Display can not light up.	Batteries are depleted.	Charge the power.
		Adapter is inserted incorrectly.	Insert the AC adapter correctly.
Low Battery	bAt Lo& shows	The battery is too low.	Charge the power.
Error message	E 1 shows	The cuff is not wrapped or wrapped incorrectly.	Refasten the cuff, then measure again.
	E 2 or shows	Excessive body motion (such as shaking of the arm with the cuff on) or weak Pulse is detected.	Relax for 5 minutes. and then keep still, measure again.
	E 3 shows	Pulse is not detected during measuring.	Loosen the clothing on the arm and measure again.
	E 4 shows	The measurement failed.	Relax for 5 minutes and measure again.
	EEx shows	A calibration error occurred (X can be some digital symbol, such as 1, 2,etc., if this similar situation 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 and then measure again. If the problem persists, contact your physician.

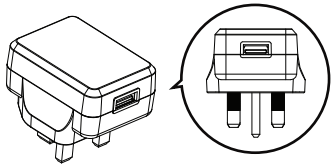
NOTE: If the product still does not work, contact Kinetik Wellbeing. Under no circumstance should you disassemble or attempt to repair the unit by yourself.

Power supply	3.6V 1000mAH Built-in rechargeable li-polymer battery, 5V ⎓ 1A AC Adaptor(Optional!)
Display mode	Digital LCD V.A.72mm × 22mm
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0mmHg~299mmHg Measurement pressure: SYS: 60mmHg~230mmHg DIA: 40mmHg~130mmHg Pulse value: (40-199)beat/minute
Accuracy	Static Pressure: 5°C-40°C within ±3mmHg Pulse value: ±5% Clinical validation: Mean difference within ±5mmHg Standard deviation≤8mmHg
Normal working condition	A temperature range of: +5°C to +40°C A relative humidity range of 15% to 90%, non-condensing, but notrequiring 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 50 hPa An atmospheric pressure range of 500 hPa to 1060 hPa
Measurement perimeter of the upper arm	About 22cm~42cm
Weight	Approx.206g
External dimensions	Approx.123 mm×44 mm×22 mm
Attachment	user manual, type-c cable, adapter (Optional!)
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Protection against ingress of water	IP22 It means the device could be protected against solid foreign objects of 12,5mm Φ and greater, and against vertically falling water drops when enclosure titled up to 15º.
Device Classification	Battery Powered Mode: Internally Powered ME Equipment AC Adaptor Powered Mode: Class II ME Equipment
Software Version	A01
Expected Lifetime	Device(with the cuff): 3 years or 10000 times (may vary based on usage conditions) Battery: About 100 times after fully charged
Types of use/reuse	Multiple patient multiple use

WARNING: No modification of this equipment is allowed.

♥ Authorized Component

Please use the authorized adapter (not included).



Adapter
Type: BLJ06L050100U-B

Input: 100-240V, 50-60Hz, 0.2A max
Output: 5V ⎓ 1000 mA

♥ Contact Information

For more information about our products, please visit:
www.kinetikwellbeing.com

♥ EMC Guidance

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

Essential performance:
Accuracy of measuring blood pressure and pulse rate

Measurement Range	Systolic pressure: 60-230 mmHg Diastolic pressure: 40-130 mmHg Pulse: 40-199 beats/minute
Rated Cuff Pressure	0-299 mmHg (0-39.9 kPa)
Accuracy	Pressure: ±3 mmHg / 0.4 kPa Pulse: ±5%

The Basis Safety of the Blood Pressure Monitor (TMB-2296-B) is as following: Deviation from normal operation that poses an unacceptable risk to the patient or operator.

Warning: Don't be near the 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 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 lifetime.

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 11	Group 1
RF emissions CISPR 11	Class [B]
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations / flicker emissions IEC 61000-3-3	Comply

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, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±2 kV for power supply lines Not applicable 100 kHz repetition frequency
Surge IEC61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	±0.5 kV, ±1 kV differential mode
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% U_T; 1 cycle and 70% U_T; 25/30 cycles; Single phase: at 0°. 0% U_T; 250 / 300 cycle	0% U_T; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% U_T; 1 cycle and 70% U_T; 25/30 cycles; Single phase: at 0°. 0% U_T; 250 / 300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50 Hz / 60 Hz	30 A/m 50 Hz / 60 Hz
Conduced RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz
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.		

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity								
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communicati-ons equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	IEC 60601-1-2 Test Level (V/m)	Compliance level (V/m)
	385	380-390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27	27
	450	430-470	GMRS 460, FRS 460	FM ± 5k Hz deviation 1 kHz sine	2	0.3	28	28
	710	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9	9
	745							
	780							
	810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28	28
	870							
	930							
	1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	Pulse modulation 217 Hz	2	0.3	28	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	28
	5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9	9
	5500							
	5785							