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HeartGuide M RIST BLOOD PRESSURE MONITOR

Model BP8000-M Instruction Manual



4615954-8A

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## Introduction

Thank you for purchasing the OMRON BP8000-M Wrist Blood Pressure Monitor. This blood pressure monitor is to be worn on your wrist. This blood pressure monitor uses the oscillometric method of blood pressure measurement. When the band inflates, the monitor senses the pressure pulsations of the artery underneath the band. The pulses are called oscillometric pulses. The electronic pressure sensor displays a digital reading of blood pressure.

This monitor can also track measurements such as steps, calories burned, hours slept and awake time.

## **Safety Instructions**

This instruction manual provides you with important information about the OMRON BP8000-M Wrist Blood Pressure Monitor. To ensure the safe and proper use of your monitor, READ and UNDERSTAND all of the safety and operating instructions. If you do not understand these instructions or have any questions, contact 1-800-634-4350 before attempting to use your monitor. For specific information about your own blood pressure, contact your physician.

## Intended Use

The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 6.3 to 7.5 inches (16 to 19 cm).

The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.

Environments of Use :

Home Patient Population : Adult

## **Receiving and Inspection**

Remove this monitor from the packaging and inspect for damage. If this monitor is damaged, DO NOT USE and contact 1-800-634-4350.

## **Symbols Glossary**

For symbol information, visit: OmronHealthcare.com/symbols-glossary

## Contraindications

## **Blood Pressure Measurement Usage**

- The monitor is contraindicated for use in ambulatory environments.
- The monitor is contraindicated for use on aircraft.

## **Important Safety Information**

# Read the Important Safety Information in this instruction manual before using this monitor.

Follow this instruction manual thoroughly for your safety. Keep for future reference. For specific information about your own blood pressure, CONSULT WITH YOUR PHYSICIAN.

## Warning Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

- DO NOT use this monitor on infants, toddlers, children or persons who cannot express themselves.
- DO NOT adjust medication based on blood pressure readings from this blood pressure monitor. Take medication as prescribed by your physician.
- ONLY a physician is qualified to diagnose and treat high blood pressure.
- DO NOT use this monitor on an injured wrist or a wrist under medical treatment.
- DO NOT wear this monitor on your wrist while on an intravenous drip or blood transfusion.
- DO NOT use this monitor in areas containing high frequency (HF) surgical equipment, magnetic resonance imaging (MRI) equipment, computerized tomography (CT) scanners. This may result in incorrect operation of the monitor and/or cause an inaccurate reading.
- DO NOT use this monitor in oxygen rich environments or near flammable gas.

- Consult with your physician before using this monitor if you have common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation; arterial sclerosis; poor perfusion; diabetes; pregnancy; preeclampsia or renal disease. NOTE that any of these conditions in addition to patient motion, trembling, or shivering may affect the blood pressure measurement reading.
- NEVER diagnose or treat yourself based on your readings. ALWAYS consult with your physician.
- To help avoid strangulation, keep the charging cable away from infants, toddlers or children.
- This product contains small parts that may cause a choking hazard if swallowed by infants, toddlers or children.

### **Data Transmission**

• This product emits radio frequencies (RF) in the 2.4 GHz band. DO NOT use this product in locations where RF is restricted, such as on an aircraft or in hospitals.

Turn off the **Bluetooth**<sup>®</sup> feature in this monitor when in RF restricted areas. For further information on potential restrictions refer to documentation on the Bluetooth usage by the FCC.

### AC Adapter / Charging Cable Handling and Usage

• DO NOT use the AC adapter if the monitor or the charging cable is damaged. If this monitor or the charging cable is damaged, turn off the power and unplug the AC adapter immediately.

### Important Safety Information

- Plug the AC adapter into the appropriate voltage outlet. DO NOT use in a multi-outlet plug.
- NEVER plug in or unplug the AC adapter from the electric outlet with wet hands.
- DO NOT disassemble or attempt to repair the AC adapter.
- DO NOT touch (with wet hands) or wet the charging port of the band, terminal of the charging clip and plugs of cables.

## **Rechargeable Battery Handling and Usage**

- The rechargeable battery has been specifically designed for this monitor. DO NOT use it in any other devices.
- DO NOT recharge the rechargeable battery once it has been removed from this monitor.
- DO NOT dispose of the battery in a fire.
- DO NOT crush or puncture the battery because it may cause spontaneous flames.
- DO NOT disassemble or modify the battery.
- DO NOT connect the + and poles using a piece of metal or other conductive objects.
- DO NOT carry it or store it together with item such as necklaces and hair pins.
- DO NOT recharge, use, or leave the battery in any high temperature environment such as in a location near a fire or in direct sunlight. Doing so may cause the battery to overheat, ignite or rupture.

- DO NOT leave the battery that has been removed within the reach of infants, toddlers, children or pets. Doing so may result in an injury or an accident. If liquid comes in contact with the battery, a fire or an accident may occur.
- This monitor has a built-in rechargeable battery. To prevent the risk of overheating, fire or explosion, DO NOT throw into fire, apply heat, puncture or crush, use or leave in a high temperature environment.

# ▲ Caution

Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient, or cause damage to the equipment or other property.

- Stop using this monitor and consult with your physician if you experience skin irritation or discomfort.
- DO NOT use this device if you have a metal allergy.
- Keep this monitor clean. If this monitor is causing skin irritation due to sweat or contamination, stop using it and consult with your dermatologist.
- Prolonged rubbing and pressure may irritate the skin. Give your wrist a break by removing the monitor for a while after extended wear.
- DO NOT let chemical products such as lotions, oils, skin creams or cosmetics collect on the band. To avoid damage to the band material, make sure to wipe off any chemical products that have collected on the band.

### Important Safety Information

- Consult with your physician before using this monitor on a wrist where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present because of temporary interference to blood flow which could result in injury.
- Consult with your physician before using this monitor if you have had a mastectomy.
- Consult with your physician before using this monitor if you have severe blood flow problems or blood disorders as cuff inflation can cause bruising.
- DO NOT take blood pressure measurements more often than necessary because bruising, due to blood flow interference, may occur.
- ONLY inflate the cuff when the band is applied to your wrist.
- Remove the band if it does not start deflating during a blood pressure measurement.
- During measurement, make sure that no mobile device or any other electrical device that emits electromagnetic fields is within 12 inches (30 cm) of this monitor. This may result in incorrect operation of the monitor and/or cause an inaccurate reading.
- DO NOT disassemble or attempt to repair this monitor or other components. This may cause an inaccurate reading.
- DO NOT use in a location where there is moisture or a risk of water splashing this monitor. This may damage this monitor.

- The monitor, AC adapter and charging cable are not designed for use in water or wet environments.
- DO NOT use this monitor in a moving vehicle such as in a car.
- DO NOT drop or subject this monitor to strong shocks or vibrations.
- DO NOT use this monitor in places with high or low humidity or high or low temperatures. Refer to section 11.
- Ensure this monitor is not impairing blood circulation by observing the wrist while blood pressure measurement is occurring.
- DO NOT use this monitor in high-use environments such as medical clinics or physician offices.
- DO NOT use this monitor with other medical electrical (ME) equipment simultaneously. This may result in incorrect operation of the monitor and/or cause an inaccurate reading.
- Avoid bathing, drinking alcohol or caffeine, smoking, exercising and eating for at least 30 minutes before taking a blood pressure measurement.
- Rest for at least 5 minutes before taking a blood pressure measurement.
- Remove tight-fitting and thick clothing and any accessories from your wrist while taking a blood pressure measurement.
- Remain still and DO NOT talk while taking a blood pressure measurement.
- ONLY use this monitor on persons whose wrist circumference is within the specified range of the cuff.

### Important Safety Information

- Ensure that this monitor has acclimated to room temperature before taking a measurement. Taking a measurement after an extreme temperature change could lead to an inaccurate reading. OMRON recommends waiting for approximately 2 hours for the monitor to warm up or cool down when the monitor is used in an environment within the temperature specified as operating conditions after it is stored either at the maximum or at the minimum storage temperature. For additional information of operating and storage/transport temperature, refer to section 11.
- DO NOT use this monitor after the durable period has ended. Refer to section 11.
- DO NOT crease the band excessively.
- DO NOT use the blood pressure measuring function for any other purpose.
- DO NOT use this monitor to diagnose sleep disorders.
- Consult with your physician or healthcare provider if you begin a weight reduction or exercise program.

## AC Adapter / Charging Cable Handling and Usage

- DO NOT plug the charging cable into any device other than this monitor.
- Fully insert the AC adapter into the outlet.
- When unplugging the AC adapter from the outlet, be sure to safely pull from the AC adapter. DO NOT pull from the charging cable.

- When handling the charging cable:
  - DO NOT damage it. -DO NOT break it.
  - DO NOT tamper with it. -DO NOT forcibly bend or pull it.
  - DO NOT twist it. -DO NOT use it if it is gathered in a bundle.
  - DO NOT pinch it. -DO NOT place it under heavy objects.
- Wipe any dust off of the AC adapter.
- Unplug the AC adapter when not in use.
- Unplug the AC adapter before cleaning this monitor.
- ONLY use the AC adapter and charging cable specified for this monitor. Use of unsupported AC adapters or cables may damage and/or may be hazardous to this monitor.

### **Rechargeable Battery Handling and Usage**

• DO NOT charge the battery when the AC adapter is wet.

## **1. Know Your Monitor**

## 1.1 Contents

□ Monitor



Charging cable Model: HHX-CB07U



Charging clip Model: HEM-CLIP-01



 Replacement cuff sleeve Model: HEM-CUCV-01

(2 pcs.)



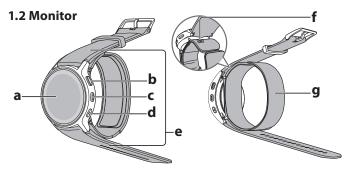
AC adapter Model: HHP-AM02



□ Instruction manual

- □ Quick start guide
- □ Paper sizing guide

### 1. Know Your Monitor



a	Display		e	Band
b	0	[START/STOP] button	f	Charging port
c	8	[FORWARD] button	g	Cuff
d	0	[HOME] button Press this button from any screen to go back to HOME screen.		

#### 1.3 Display and Symbols <HOME screen> **Battery symbol** Appears when any button is Α D pressed or battery is low. Date WED 4 Refer to page 17. 12:35 Time Sync symbol B Appears when your data needs to be transferred because the stored memory 🕯 off 与 🚥 is either almost or completely full. Once you pair your E. Ε monitor with your smart Sleep mode symbol device, transfer your readings Appears when your monitor immediately before the is in sleep mode. Refer to monitor deletes the oldest reading. Refer to page 17 sub-section 4.4 (page 38). for each internal memory. Bluetooth symbol Bluetooth OFF symbol Appears when your В \*of Appears when Bluetooth is readings are being disabled transferred. F **Reminder symbol** Disconnect symbol Appears when a reminder is Appears when your monitor is С set. Refer to sub-section 4.6 not connected with your smart (page 41). device and Bluetooth is enabled.

	<b>Movement error symbol</b> Appears along with a blood pressure reading when your body is moving during a blood pressure measurement. If it appears, check if the band is applied correctly. Refer to sub-section 2.3 (page 21). After applying the band correctly, wait for 2 to 3 minutes. Then, remain still and take another measurement.		
	Heart zone error symbol Appears when your monitor is not positioned at heart level during a measurement. Refer to page 30 for more information about heart zone indicator.		
0	Irregular heartbeat symbol Appears along with readings when an irregular rhythm is detected 2 or more times during a blood pressure measurement. An irregular heartbeat rhythm is defined as a rhythm that is 25 % less or 25 % more than the average rhythm detected while your monitor is measuring the blood pressure. The irregular heartbeat symbol may be displayed when the monitor detects arm movements. Refer to section 8 to solve the problem. If it continues to appear, we recommend you consult with and follow the directions of your physician.		
	Heartbeat symbol Flashes while taking a blood pressure measurement.		
Blood pressure level indicator (color) When your systolic or diastolic blood pressure is above the AHA guideline, the number			

When your systolic or diastolic blood pressure is above the AHA guideline, the number will be shown in red. Refer to sub-section 1.4 (page 18) for more information.

### **1. Know Your Monitor**

## **Storable Readings of Each Measurement**

Your monitor can store readings in its internal memory as follows:

Blood pressure measurements	Up to 100 readings
Activity data	Up to 7 days
Sleep data	Up to 7 times
Event data	Up to 100 items

## **Battery Symbols**

Indicates current battery remaining.

Remaining	Full	Low	Depleted
Symbols			

## 1.4 Classification of BP (Blood Pressure)

ACC/AHA 2017 Hypertension guidelines define categories of BP in adults as below.

### Categories of BP in Adults\*

BP Category	Systolic BP		Diastolic BP	
Normal	< 120 mmHg	and	< 80 mmHg	
Elevated	120-129 mmHg	and	< 80 mmHg	
Hypertension				
Stage 1	130-139 mmHg	or	80-89 mmHg	
Stage 2	≥ 140 mmHg	or	≥ 90 mmHg	
Hypertensive crisis	> 180 mmHg	and/or	> 120 mmHg	

\* Individuals with Systolic BP and Diastolic BP in 2 categories should be designated to the higher BP category.

BP indicates blood pressure (based on an average of  $\geq$  2 careful readings obtained on  $\geq$  2 occasions).

Source: ACC/AHA 2017 High Blood Pressure Clinical Practice Guideline

## A Warning

NEVER diagnose or treat yourself based on your readings. ALWAYS consult with your physician.

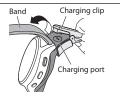
## 2. Preparation

## 2.1 Charging the Battery

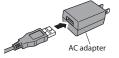
We recommend charging the battery to a full 100 % charge. Once fully charged, the battery will last for approximately 2 days. It takes about 2.5 hours to fully charge once the battery is empty.

- 1. Plug the smaller end of the charging cable into the charging clip.
- 2. Lift the band and connect the clip to the charging port of your monitor.

Make sure the cuff sleeve does not cover the charging port.



3. Plug the larger end of the charging cable into the AC adapter.



# 4. Plug the AC adapter into an electrical outlet.

The charging screen shown as the image on the right will appear.



### Note

If your monitor has not been used for 3 months, recharge it. Do not charge the battery in environments where there is high heat or cold temperatures.

## **Charging Status**



## **Battery Life**

Your monitor will last up to 2 days per charge, depending on use and storage condition. Refer to "Battery Life Information" (page 65) for the terms of the battery life.

- The battery life will eventually get shorter due to recharging the monitor repeatedly. When the battery life becomes extremely short, it is coming to the end of its service life. For disposal information, refer to sub-section 9.5 (page 61).
- Temperature during the battery charging should be 50 to 95 °F (10 to 35 °C).

### 2. Preparation

## 2.2 Installing the Cuff Sleeve

To use your monitor comfortably, install the cuff sleeve to the cuff of the monitor. **Note** 

- Install the cuff sleeve correctly, otherwise the blood pressure readings may not be accurate.
  - 1. Insert the longer side of the cuff to the replacement cuff sleeve's hole from inside as the illustration shown on the right.
  - 2. Cover the cuff by pulling the cuff sleeve toward the charging port.
  - **3.** Cover the charging port.





## 2.3 Wearing the Monitor on the Left Wrist

Blood pressure can differ between the right and left wrists, and readings can be different. OMRON recommends always using the same wrist when measuring blood pressure. Consult with your physician to determine which wrist you should use for your measurements.

## **A**Caution

Remove tight-fitting and thick clothing and any accessories from your wrist while taking a blood pressure measurement.

### Note

 Your monitor does not have water-resistant functionality. Do not immerse your monitor in water.

# Position the monitor and leave approximately 1 inch (2.5 - 3 cm) between the band and the bottom of your palm.

Use your forefinger and middle finger as a guide. If you cannot determine which hole is appropriate, use the "paper sizing guide".

### Note

- Your monitor must have a snug fit prior to measuring; not too tight, not too loose. Your index finger should NOT easily slide between the band and your wrist.
- Make sure that the cuff is positioned correctly. When the upper and lower sides of the cuff are overlapped, the lower side should be positioned under the upper side. Refer to the illustration.

## Wearing the Monitor on the Right Wrist

Your monitor can also be worn on your right wrist. Configure the Right / Left Wrist setting. Refer to sub-section 7.1.2 (page 48).



<Not correct>





### 2. Preparation

## 2.4 Turn Your Monitor On

# Press and hold the [FORWARD] button for more than 3 seconds.

The monitor turns on and the screen below appears on the display.





- You can use your monitor without pairing to your smart device. Refer to section 3 (page 24).
- To take activity measurements and sleep measurements, pair your monitor with your smart device. Refer to sub-section 4.1 (page 32).
- If the monitor does not turn on or the screen below appears on the display, charge the battery. Refer to sub-section 2.1 (page 19).



You can use your monitor as a blood pressure monitor without pairing to a smart device. To pair your monitor with a smart device, refer to sub-section 4.1.

## **A**Caution

- DO NOT use this monitor with other medical electrical (ME) equipment simultaneously. This may result in incorrect operation of the monitor and/or cause an inaccurate reading.
- Remain still and DO NOT talk while taking a blood pressure measurement.

- When using your monitor without a smart device, you can take only blood pressure measurements.
- When using your monitor without a smart device, you will not be able to view your prior readings that have been stored in memory.

## 3.1 Taking a Blood Pressure Measurement 3.1.1 Blood Pressure Measurement Tips

To help ensure an accurate reading, be aware of the following:

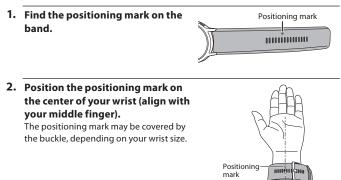
- Stress raises blood pressure. Avoid taking measurements during stressful times.
- Measurements should be taken in a quiet place.
- It is important to take measurements at the same times each day. Taking measurements in the morning and in the evening is recommended.
- Remember to have a record of your blood pressure and pulse readings for your physician.
- A single measurement does not provide an accurate indication of your true blood pressure. You need to take and record several readings over a period of time.

## **∕**∆Caution

- Avoid bathing, drinking alcohol or caffeine, smoking, exercising and eating for at least 30 minutes before taking a blood pressure measurement.
- Rest for at least 5 minutes before taking a blood pressure measurement.

## 3.1.2 Positioning the Band

To take an accurate blood pressure measurement, the position of the band is important.



## 3.1.3 Sitting Correctly

To take a blood pressure measurement, you need to be relaxed and comfortably seated in a room with a comfortable temperature.

- Keep your upper arm next to the body.
- Sit in a comfortable chair with your back supported.
- Keep your feet flat and your legs uncrossed.
- Relax your wrist and hand. Do not bend your wrist back, clench your fist or bend your wrist forward.

## 3.1.4 Taking a Blood Pressure Measurement

## Note

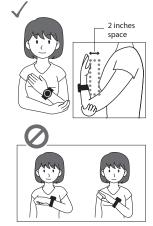
- To stop the measurement, press the [START/STOP] button once to deflate the cuff.
  - 1. Press the [START/STOP] button.

The heart zone indicator will appear.



### 2. Adjust the position of your wrist.

Place your monitor over your heart while a measurement. Once the heart zone indicator appears, raise or lower your wrist until it is at heart level. Make sure your wrist is about 2 inches apart from your chest. When your wrist is in the proper position, your monitor will vibrate once. After approximately 2 seconds, the monitor will start a measurement and the cuff will start to inflate. If the monitor is too high above your heart, your blood pressure will be artificially low. If the monitor is too low below your heart, your blood pressure will be artificially high.



- DO NOT make the band and your body touch while taking a measurement.
- After approximately 5 seconds your monitor will start a measurement and the cuff will start to inflate, even when your monitor is not positioned properly.
- For more information about the heart zone indicator, refer to "Heart Zone Indicator" on page 30.

# 3. Remain still and do not move or talk until the entire measurement process is completed.

As the cuff inflates, your monitor automatically determines your ideal inflation level. Your monitor detects your blood pressure and pulse rate during inflation. The heatbeat symbol flashes at every heartbeat.

After your monitor has detected your blood pressure and pulse rate, the cuff automatically deflates. Your blood pressure and pulse rate are displayed. If either the systolic or the diastolic reading is high (refer to sub-section 1.4), the number and indicator will be shown in red.



- To stop a measurement, press any button.
- Wait 2-3 minutes between measurements. The wait time allows the arteries to decompress and return to their pre-measurement state. You may need to increase the wait time depending on your individual physiological characteristics.

### **Heart Zone Indicator**

Your monitor has a built-in heart zone indicator that is used as an aid in determining if your monitor is at the correct height and position. It has been designed to work with most people so that when your wrist is at the correct position relative to your heart, your monitor will vibrate once. If it does not vibrate, your monitor may not be at the correct height and position relative to your heart.

Due to differences in individual size and physique, this feature may not be helpful in all cases and you may wish to turn off this feature. If you feel the position of the wrist, according to the heart zone indicator's guidance, does NOT match your heart level, please turn off this feature and follow your judgment. To disable this feature, refer to sub-section 7.1 (page 47).

## **Error Symbols**

If the error screens below are displayed, please take another measurement. Refer to sub-section 1.3 (page 16).



## A Warning

- DO NOT adjust medication based on your readings from this blood pressure monitor. Take medication only as prescribed by your physician. ONLY a physician is qualified to diagnose and treat high blood pressure.
- NEVER diagnose or treat yourself based on your readings. ALWAYS consult with your physician.

## 4.1 Pairing Your Monitor with a Smart Device

Pairing your monitor with the "HeartAdvisor" app on your smart device will set the date and time on the monitor. Once you have paired with the app, all future measurements will include the date and time when you transfer. If you do not pair the monitor, any measurements you take will not include the date and time.

Review the list of compatible smart devices at OmronHealthcare.com.

- 1. Enable Bluetooth on your smart device.
- 2. Download and install the free "HeartAdvisor" app onto your smart device.



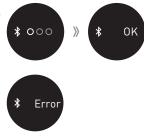


3. Open the app and follow the pairing instructions shown on your smart device.

## 4. Confirm that your monitor is connected successfully.

If your monitor is connected successfully to your smart device, "OK" flashes on the display.

If "Error" flashes on the display, follow the instructions in the "HeartAdvisor" app. If it still appears after checking the app, contact customer service. Refer to section 13 (page 69).



- "HeartAdvisor" is the only app that we recommend that you use with your monitor to transfer data correctly.
- Be aware that OMRON will not be responsible for the loss of data and/or information in the app.
- If you change your smart device that was paired with your monitor, delete the pairing information from your old smart device to avoid communication issue.

## 4.2 Taking a Blood Pressure Measurement

### 1. Take a measurement.

Refer to sub-section 3.1 (page 25) to start a measurement.

# 2. Your reading will be transferred to your smart device automatically.

Past readings cannot be viewed on either of the monitor's displays. Open the app on your smart device and follow the instructions.

- Make sure your monitor is within 16 ft. (5 m) of your smart device.
- When the Bluetooth OFF symbol ( 101) appears on the display of your monitor, enable Bluetooth. Refer to sub-section 7.2 (page 49).
- Once you transfer your readings to the app, your readings cannot be sent again to any app or smart device.

### 4.3 Taking Activity Measurements

Your monitor automatically measures your activities when you are wearing your monitor. The following items will be measured:

- Steps
- Calories burned
- Distance
- Aerobic steps

Refer to "Readings Details" in section 6 (page 45) for more information.

### Note

Do not wear your monitor other than on your wrist.

### 1. Pair your monitor with your smart device.

Refer to sub-section 4.1 (page 32). The personal information you are asked to provide on the app is to help calculate measurements accurately. You can also set your daily target steps on the app.

### 2. Set your stride length.

The initial stride length displayed on the app is an estimated value calculated by your height setting.

You may choose to adjust your stride length by adding the new value in the app. For instructions on calculating your stride manually, refer to the instructions below.

- 1. Walk 10 steps with your normal stride as illustrated below.
- 2. Measure the distance from START to END in inches.
- 3. Calculate your stride length by dividing the total distance by 10.

#### Example: Total distance = 320" $320 \div 10 = 32''$ (2 feet 8 inches) **Conversion Chart** 12 inches = 1 foot END START 24 inches = 2 feet 3 10 36 inches = 3 feet 320 inches 48 inches = 4 feet

#### 3. Wear your monitor wherever you go. When your target steps are achieved, the achievement screen appears.



4. Press the [FORWARD] button to view the readings stored in the memory.

Refer to section 6 (page 43) for more information.



#### Your monitor may not track your activity data correctly:

#### Improperly Wearing

- · Wearing your monitor somewhere other than your wrist.
- · Putting your monitor inside a bag or pocket.

#### Moving Irregularly

- Placing your monitor inside or attached to a bag and the bag moves irregularly.
- Moving your arm continuously when not walking.
- Carrying a bag
- · Extremely slow arm movements.
- · Doing housework without walking.

#### Walking at an Inconsistent Pace

- Shuffling or wearing sandals.
- · Constantly starting and stopping walking or moving at some other inconsistent pace.
- · Walking extremely slowly.

#### Moving Up and Down

- Standing up and sitting down.
- Playing sports other than walking.
- · Going up or down stairs or a steep slope.

#### Vibrations from a Moving Vehicle

• When you are on a bicycle, automobile, train or bus.

### 4.4 Taking Sleep Measurements

Your monitor measures your sleep by detecting movement of your body while you sleep. The following items will be measured:

- Sleep period time
- Awake time

Refer to "Readings Details" in section 6 (page 45) for more information.

#### Note

- Only wear your monitor on your wrist.
- During the sleep mode, your monitor does not count your steps.
- If you set the sleep mode manually, you cannot take a blood pressure measurement or change settings.
  - 1. Pair your monitor with your smart device.

Before taking a measurement, pair your monitor with your smart device. Refer to sub-section 4.1 (page 32).

You can also set your target sleep period time on the app.

2. Go to sleep with your monitor on. To detect and track your sleep automatically, set your approximate daily bedtime and wake-up time on the app first.

#### Note

- When you take a measurement, do not place your monitor on the floor, bed or shelf.
- To enable the sleep mode manually, refer to the "Heart Advisor" app.
- If the "Auto sleep" function is disabled, press and hold the [START/STOP] button to start the sleep measurement.



### 3. Get up.

Your monitor will detect rising and disable the sleep mode automatically.

#### Note

 If the "Auto sleep" function is disabled, press and hold the [START/STOP] button to stop the sleep measurement.

### Your monitor may not track your sleep data in the following instances:

- Wearing your monitor somewhere other than your wrist.
- Wearing your monitor too loosely, so that you can insert more than one pointer finger in between your wrist and the band.
- Sleeping in a chair or on a couch

### 4.5 Receiving Notification from Your Smart Device

Your monitor receives a notification (phone call, message and email) from your smart device.

When your monitor receives a notification, your monitor vibrates. Press any button to close the notification.



### Note

- Refer to "HeartAdvisor" for compatible email apps or any other information.
- Your monitor cannot receive a notification from your smart device during the following:
  - When taking a blood pressure measurement.
  - When the Bluetooth function of your monitor or smart device is disabled.
- Only English alphabets and digits can be displayed correctly on your monitor.
- Your monitor may not able to receive a notification for any reason other than your monitor or the app.
- For more details, refer to the app.

### 4.6 Receiving a Reminder

The reminder function will alert you at a specific time of day with vibration and the "Reminder" icon on the display. The reminder can only be set on the app.



### Note

- To stop the vibration, press any button.
- If the reminder time comes while taking a blood pressure measurement, the alert will start after the measurement.
- The reminder will not alert you when the monitor is being charged or the battery is depleted.

# 5. Recording an Event

You can record the time of your action or activity as an "Event", such as time you ate, took a medicine, exercised or had another event.

### Note

The recorded time of your events can be viewed on the app only.

- 1. Press and hold the [FORWARD] button for more than 3 seconds.
- 2. "Record" appears on the display.

Record



# 6. Viewing the Readings Stored in Memory

Only your latest reading can be viewed on the monitor's display. Use the "HeartAdvisor" app to view all the readings stored in the memory.

1. Press the [FORWARD] button.

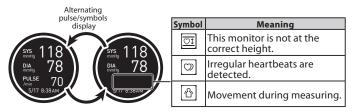


### 2. Press the [FORWARD] button one by one.

The display of your readings changes as below. For activities and sleep, the ring around the reading describes the level of achievement against your target.



If this monitor detects any errors during a measurement, the following symbols will appear on the display.



### Meaning of each display item

<Activities>

<Sleep>



Calories burned

Sleep period time



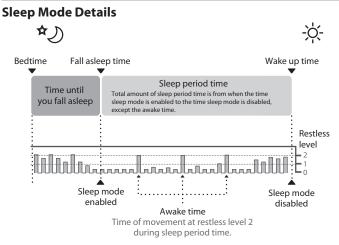
Percent achieved

Target sleep period time

#### 6. Viewing the Readings Stored in Memory

#### **Readings** Details **Calories burned** Indicates the amount of calories burned by measuring the intensity of your activity. Distance Indicates you distance traveled by using your step count. Note If you have logged, climbed up or down stairs, or walked at brisk walking pace, some errors may occur in the value. **Aerobic steps** Aerobic steps are the physical exercise that helps us stay healthy. Aerobic steps are counted separately when walking more than 60 steps per minute and more than 10 minutes successively. If a rest of less than 1 minute is taken after a continuous walk of more than 10 minutes, this will be regarded as part of "a continuous walk". Note Aerobic steps can be viewed on the app only. Sleep period time Indicates your actual time asleep. Awake time Indicates the time of movement at "restless level 2" after vou fell asleep. For more information on restless levels, refer to "Sleep Mode Details" on the next page. Note Awake time can be viewed on the app only.

#### 6. Viewing the Readings Stored in Memory



### 7.1 Function Settings

To change the function settings on your monitor, press and hold both the [START/STOP] button and the [FORWARD] button for more than 3 seconds.



### 7.1.1 Enabling/Disabling Heart Zone Indicator ( 📴 )

1. Press the [START/STOP] button for heart zone indicator setting.

2. Press the [START/STOP] button to enable, or press the [HOME] button to disable.

#### Note

The heart zone indicator is enabled by default. The current setting is shown in the bracket.





# 7.1.2 Selecting Your Wrist to Wear (Left 🕅 or Right 🕅 )

1. Press the [HOME] button for wrist setting.

 Press the [START/STOP] button if you wear your monitor on the left wrist, or press the [HOME] button if you wear the monitor on the right wrist.

#### Note

Left is set by default. Current setting is indicated in the bracket.



### 7.2 Bluetooth Settings

To enter the pairing mode or change Bluetooth setting, follow the instructions below.

### 7.2.1 Entering Pairing Mode

Press and hold the [HOME] button for more than 3 seconds. Refer to sub-section 4.1 (page 32) to pair your monitor with your smart device.



#### Note

Bluetooth will be enabled automatically after pairing with your smart device sucessfully.

### 7.2.2 Disabling/Enabling Bluetooth

### A Warning

This product emits radio frequencies (RF) in the 2.4 GHz band. DO NOT use this product in locations where RF is restricted, such as on an aircraft or in hospitals. Turn off the Bluetooth feature in those areas. For further information on potential restrictions refer to documentation on the Bluetooth usage by the FCC.

Press and hold the [HOME] button for at least 3 seconds when your monitor is in the pairing mode.

When Bluetooth is enabled, this operation will make it disabled.

When Bluetooth is disabled, this operation will make it enabled.

#### Note

· Bluetooth is enabled by default.



### 7.3 Restoring Your Monitor to the Default Settings

To delete all the information stored in your monitor, follow the instructions below.

Press and hold both the [START/STOP] button and the [HOME] button for at least 7 seconds.

When the confirmation screen appears, press the [START/STOP] button to restore your monitor.



#### Note

- Reverting to its default setting of your monitor does not delete the information in the app.
- You will need to re-pair your monitor when using the monitor again. Without repairing, your readings will not be transferred to your app. Refer to sub-section 4.1 (page 32).

### 7.4 Turning Off Your Monitor

Press and hold both the [FORWARD] button and the [HOME] button for more than 7 seconds.



Turn off and restart your monitor if either of the following occurs:

- When "Error" with a number other than 1 to 9 appears on the display.
- · Your monitor cannot be operated even though you pressed a button.

#### Note

- Turning off your monitor will not delete your reading or any information in the monitor and the app, however; your step numbers from the past hour may be lost.
- After restarting, open "HeartAdvisor" app to communicate. The date and time will be set automatically.

When using your monitor without a smart device, you can only take blood pressure measurements.

When using your monitor without a smart device, you will not be able to view your prior readings that have been stored in memory.

• If the "Error" with a number other than 1 to 9 appears on the display after restarting, refer to section 13 (page 69).

In case any of the below problems occur during measurement, first check that no other electrical device is within 12 inches (30 cm). If the problem persists, please refer to the table below.

### 8.1 Error Messages

Display	Cause	Solution
Irregular heartbeat	Irregular heartbeat detected.	Remove your monitor. Wait for 2 - 3 minutes and then take another measurement. Repeat the steps in sub-section 3.1 (page 25). If this error continues to appear, we recommend that you consult with your physician.
Do not move and take another measurement.	Your body moved during a measurement.	Carefully read and repeat the steps in sub- section 3.1 (page 25).
Position device at heart-tevel.	Your monitor is not at the correct height.	Adjust the height of your wrist following the heart zone indicator. Refer to sub-section 3.1 (page 25).

Display	Cause	Solution
12:35	The battery is depleted.	Charge the battery. Refer to sub-section 2.1 (page 19).
* Error	The monitor cannot connect to a smart device or transmit data correctly.	Follow the instructions shown in the "HeartAdvisor" app. If it still appears after checking the app, contact customer service. Refer to section 13 (page 69).
<b>L</b> i	The band is not applied correctly.	Apply the band correctly, then take another measurement. Refer to sub-section 2.3 (page 21).
Please see the manual. Error 1	Air is leaking from the cuff.	Contact customer service. Refer to section 13 (page 69).
	Clothing is interfering with the band.	Remove any clothing interfering with the band. Refer to sub-section 2.3 (page 21).

Display	Cause	Solution
Please see the manual. Error 2	The band may be applied too loosely.	Apply the band correctly, then take another measurement. Refer to sub-section 2.3 (page 21).
Please see the manual. Error 3	The cuff was inflated exceeding the maximum allowable pressure.	Do not touch your monitor while taking a measurement.
Please see the manual. Error 4	You move or talk during a measurement. Vibrations disrupt a measurement.	Remain still and do not talk during a measurement.
Please see the manual. Error 5	The band was not applied correctly or was moved during a measurement.	Apply the band correctly, then take another measurement. Refer to sub-section 2.3 (page 21). Remain still and sit correctly during a measurement. Refer to sub-section 3.1 (page 25).

Display	Cause	Solution
Please see the manual. Error 7		Take another measurement making sure not to move your wrist. Refer to sub-section 3.1 (page 25).
	Temperature error is detected.	Wait for few minutes, then take another measurement in a place with moderate room temperature. If the error appears again, contact customer service. Refer to section 13 (page 69).
Please see the manual Fror 8		
Please see the manual. Error 9	The band may be applied too tightly.	Apply the band correctly, then take another measurement. Refer to sub-section 2.2 (page 21).
d	Room temperature is too high to charge the battery.	Charge the battery at a moderate room temperature.
Error	The monitor has malfunctioned.	If the error appears in moderate temperature, contact customer service. Refer to section 13 (page 69).

Display	Cause	Solution
Error 123	malfunctioned.	Turn off and restart your monitor. Refer to sub- section 7.4 (page 52). If the error still appears, contact customer service. Refer to section 13 (page 69).

### 8.2 Troubleshooting

Problem	Cause and Solution
Nothing appears on the display of the monitor.	<ul> <li>Charge the battery. Refer to sub-section 2.1 (page 19).</li> <li>Your monitor is turned off. Refer to sub-section 2.4 (page 23) to turn on your monitor.</li> </ul>
Readings appear too high or too low.	Blood pressure varies constantly. Many factors including stress, time of day, and/or how you apply the band, may affect your blood pressure. Review sub-section 3.1 (page 25).
Any other communication issue occurs.	Follow the instructions shown in the smart device, or visit the "Help" section in the "HeartAdvisor" app for further help. If the problem still persists, contact customer service. Refer to section 13 (page 69).
The monitor cannot be operated.	Turn off and restart your monitor. Refer to sub-section 7.4 (page 52). If your monitor still does not operate, contact customer service. Refer to section 13 (page 69).

Problem	Cause and Solution
adapter is abnormally	The monitor or the AC adapter may be damaged. Unplug the AC adapter from the outlet immediately and contact customer service. Refer to section 13 (page 69).
short, or the monitor does not operate, even	This may be due to the life of the rechargeable battery. The battery cannot be replaced. Contact customer service (refer to section 13 (page 69)) or dispose of your monitor. Refer to sub-section 9.5 (page 61).

# 9. Maintenance

### 9.1 Maintenance

To protect this monitor from damage, please follow the directions below:

• Changes or modifications not approved by the manufacturer will void the user warranty.

### **A**Caution

DO NOT disassemble or attempt to repair this monitor or other

components.

## 9.2 How to Replace the Cuff Sleeve

Clean the cuff sleeve when it becomes dirty (once-a-week cleaning is recommended).

Replace the cuff sleeve to new one in half a year.

1. Detach the cuff sleeve.



2. Refer to sub-section 2.2 (page 21) to install the cuff sleeve.

### 9.3 Storage

- Store your monitor in a clean, safe location.
- Do not store your monitor:
  - If your monitor is wet.
  - In locations exposed to extreme temperatures, humidity, direct sunlight, dust or corrosive vapors such as bleach.
  - In locations exposed to vibrations or shocks.

### 9.4 Cleaning

- Do not use any abrasive or volatile cleaners.
- Use a soft dry cloth or a soft cloth moistened with neutral soap to clean your monitor, and then wipe them with a dry cloth.
- · Do not wash or immerse your monitor in water.
- Do not use gasoline, thinners or similar solvents to clean your monitor.
- Do not use a wet cloth on the plugs of the AC adapter. The charging cable, or the terminal of the charging clip.
- Hand-wash with mild detergent and air-dry the cuff sleeve. Do not soak it in water for long periods of time. Do not use any sterilization chemicals, disinfectants, or softeners.

### 9. Maintenance

### **A**Caution

- Stop using this monitor and consult with your physician if you experience skin irritation or discomfort.
- Prolonged rubbing and pressure may irritate the skin. Give your wrist a break by removing your monitor for a while after extended wear.
- Be careful not to let chemical products such as lotions, oils, skin creams or cosmetics collect on the band. If this happens, wipe them immediately, otherwise it may impact the material and lifetime of product.

# 9.5 Disposal

Dispose of your monitor and other components according to applicable local regulations. Unlawful disposal may cause environmental pollution.

# **10. Optional Accessories**

Charging clip

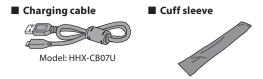


Model: HEM-CLIP-01

### AC adapter



Model: HHP-AM02



Model: HEM-CUCV-01

For further information, visit our website at OmronHealthcare.com.

# 11. Specifications

Model	BP8000-M EEE HEM-6411T-ZM
Display	Transflective memory-in-pixel LCD
Memory	Blood pressure measurement: Up to 100 times Activity measurement: Up to 7 days Sleep measurement: Up to 7 times Event: Up to 100 items
Transmission method	Bluetooth <sup>®</sup> low energy technology
Wireless communication	Frequency range: 2.4 GHz (2400 - 2483.5 MHz) Modulation: GFSK Effective radiated power: <20 dBm
Operation mode	Continuous operation
IP classification	Monitor: IP22 AC adapter: IPX0
Rating	DC 3.8 V 3.0 W
Power source	1 Lithium ion polymer rechargeable battery (3.8 V; Approximately 164 mAh) AC adapter (INPUT AC100-240 V, 50-60 Hz 0.2-0.13 A)
Battery lifespan	Will last for approximately 500 cycles, 8 times/day measurements in normal temperatures of 77.0 °F (25 °C) when new battery fully charged.

Battery Life	Up to 2 days (48 hours) battery life* per charge. * Refer to "Battery Life Information" (page 65) for the terms of the battery life.	
Durable period (Service life)	Monitor: 2 years AC adapter: 2 years Cuff sleeve: 0.5 years	
Operating conditions	41 to 104 °F (5 to 40 °C) / 15 to 90 % RH (non-condensing) / 800 to 1060 hPa	
Charging / data transmission conditions	50 to 95 °F (10 to 35 °C)	
Storage conditions	-4 to 104 °F (-20 to 40 °C) / 10 to 90 % RH (non-condensing)	
Transport conditions	-4 to 140 °F (-20 to 60 °C) / 10 to 90 % RH (non-condensing)	
Weight	Approximately 4.1 oz. (115 g)	
Dimensions	Case diameter: Approximately 1.89″ (48 mm) Case thickness: Approximately 0.55″ (14 mm) Band width: Approximately 1.18″ (30 mm)	
Measurable wrist circumference	6.3" to 7.5" (160 to 190 mm)	
Contents	Monitor, charging clip (HEM-CLIP-01), charging cable (HHX-CB07U), AC adapter (HHP-AM02), paper sizing guide, replacement cuff sleeve (HEM-CUCV-01), instruction manual, quick start guide	

#### 11. Specifications

Applied part	Type BF (cuff)
-	Internally powered ME equipment Class II ME equipment (AC adapter)
Maximum temperature of the applied part	Lower than +118.4 °F (+48 °C)

### **Battery Life Information**

The battery life is based on 2 days (48 hours) with the following use: in 23°C environment, 170 mm wrist circumference, 8 times of blood pressure measurement (inflates to 150 mmHg) per day, 16-hour step counting per day, 8-hour sleep measurement per day, 96 times of button pressing per day, 16 times of incoming call per day, 1 time of ringing alarm per day, 16-hour Bluetooth communication per day.

The battery life depends on the terms of use and the environment of storage.

Cuff pressure range	0 to 299 mmHg
Blood pressure	SYS: 60 to 230 mmHg
measurement range	DIA: 40 to 160 mmHg
Pulse measurement	40o 180 beats / min.
range	
Accuracy	Pressure: ±3 mmHg
	Pulse: ±5 % of display reading
Inflation	Automatic by electric pump
Deflation	Automatic rapid deflation
Measurement method	Oscillometric method

### **Blood pressure measurement**

### Activity / Sleep measurement

Measurement range	Steps: 0 to 99,999 steps	
	Distance: 0.0 to 621.3 mile	
	Time: 12:00 AM to 11:59 PM	
	Calories burned: 0 to 59,999 kcal	
Setting range	Time: 12:00 AM to 11:59 PM (0:00 to 23:59)	
	Weight: 22 to 300 lb (in increments of 1 lb)	
	Height: 3' 4" to 6' 6" (in increments of 1 inch)	
	Stride length: 12" to 48" (in increments of 1 inch)	

### Notes

- These specifications are subject to change without notice.
- In the clinical validation study, K5 was used on 85 subjects for determination of diastolic blood pressure.
- This monitor is comply with the requirements of ISO 81060-2:2013.
- This monitor has not been validated for use on pregnant patients.
- IP classification is degrees of protection provided by enclosures in accordance with IEC 60529. This monitor is protected against ingress of dust which would cause issues during a normal operation, and against splashing water which may cause issues during a normal operation.
- This AC adapter is not protected against water.
- Rating indication is printed on the cuff.

### 11. Specifications

### About a wireless communication interference

This product operates in an unlicensed ISM band at 2.4 GHz. In the event this product is used near other wireless devices such as microwave and wireless LAN, which operate on the same frequency band as this product, there is a possibility that interference may occur. If interference occurs, stop the operation of the other devices or relocate this product away from other wireless devices before attempting to use it.

### **Pictogram on the Product**

Indicates the correct positioning for the band on the wrist.
Indicates the correct positioning for the monitor on the wrist.

# 12. FCC Statement

### FCC CAUTION

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

#### Note

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- · Increase the separation between the equipment and receiver.
- · Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult with the dealer or an experienced radio/TV technician for help.

This transmitter must not be co-located or operated in conjunction with any other antenna or transmitter.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) Exposure Guidelines. This equipment has very low levels of RF energy that are deemed to comply without testing of specific absorption ratio (SAR).

# 13. Limited Warranty

Your BP8000-M Wrist Blood Pressure Monitor, excluding AC adapter and charging cable, is warranted to be free from defects in materials and workmanship appearing within 1 year from the date of purchase, when used in accordance with the instructions provided with the monitor. The above warranty extends only to the original retail purchaser. We will, at our option, replace without charge any monitor or band covered by the above warranty. Replacement is our only responsibility and your only remedy under the above warranty.

To obtain warranty service, contact customer service by calling 1-800-634-4350 for the address of the inspection center and the return shipping and handling fee. Enclose the original printed receipt. Include a letter with your name, address, phone number, and description of the specific problem. Pack the product carefully to prevent damage in transit. Because of possible loss in transit, we recommend insuring the product with return receipt requested.

THE FOREGOING IS THE SOLE WARRANTY PROVIDED BY OMRON IN CONNECTION WITH THIS PRODUCT, AND OMRON HEREBY DISCLAIMS ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. IMPLIED WARRANTIES AND OTHER TERMS THAT MAY BE IMPOSED BY LAW, IF ANY, ARE LIMITED IN DURATION TO THE PERIOD OF THE ABOVE EXPRESS WARRANTY.

OMRON SHALL NOT BE LIABLE FOR LOSS OF USE OR ANY OTHER SPECIAL, INCIDENTAL, CONSEQUENTIAL OR INDIRECT COSTS, EXPENSES OR DAMAGES.

This warranty provides you with specific legal rights, and you may have other rights that vary by jurisdiction. Because of special local requirements, some of the above limitations and exclusions may not apply to you.

	For Customer Service
Visit our web site at:	OmronHealthcare.com
Call toll free:	1-800-634-4350
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# 14. Guidance and Manufacturer's Declaration

OMRON Battery-operated Blood Pressure Monitor Information for Accompanying Documents in the Scope of IEC60601-1-2:2014

# Important information regarding Electromagnetic Compatibility (EMC)

BP8000-M manufactured by OMRON HEALTHCARE Co., Ltd. conforms to IEC60601-1-2:2014 Electromagnetic Compatibility (EMC) standard. Further documentation in accordance with this EMC standard is available at OmronHealthcare.com/emc. Refer to the EMC information for BP8000-M on the website.

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