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Distributed by:

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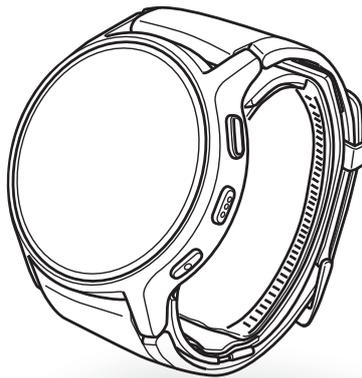
OMRON®

HeartGuide™

WRIST BLOOD PRESSURE MONITOR

Model BP8000-M

Instruction Manual



All for Healthcare

HJ034-0195

TABLE OF CONTENTS

Introduction	3
Safety Instructions	3
Intended Use	4
Receiving and Inspection.....	4
Symbols glossary	4
Important Safety Information.....	5
1. Know Your Monitor	13
1.1 Contents	13
1.2 Monitor	14
1.3 Display and Symbols	15
1.4 Classification of BP (Blood Pressure).....	18
2. Preparation.....	19
2.1 Charging the Battery.....	19
2.2 Wearing the Monitor on the Left Wrist.....	21
2.3 Turn Your Monitor On.....	22
3. Using Your Monitor without a Smart Device.....	24
3.1 Taking a Blood Pressure Measurement.....	24
4. Using Your Monitor with a Smart Device.....	32
4.1 Pairing Your monitor with a Smart Device	32
4.2 Taking a Blood Pressure Measurement	34
4.3 Taking Activity Measurements	35
4.4 Taking Sleep Measurements.....	38
4.5 Receiving Notification from Your Smart Device	40
4.6 Receiving a Reminder.....	41
5. Recording an Event.....	42

6. Viewing the Readings Stored in Memory	43
Readings Details.....	45
Sleep Mode Details	46
7. Settings	47
7.1 Function settings	47
7.2 Bluetooth settings.....	49
7.3 Restoring Your Monitor to the Default Settings.....	51
7.4 Turning Off Your Monitor.....	52
8. Error Messages and Troubleshooting.....	53
8.1 Error Messages.....	53
8.2 Troubleshooting	57
9. Maintenance	59
9.1 Maintenance	59
9.3 Cleaning	60
9.4 Disposal	60
10. Optional Accessories	61
11. Specifications	62
12. FCC Statement	67
13. Limited Warranty	68
14. Guidance and Manufacturer’s Declaration.....	69

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.

Important Safety Information

- 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; pre-eclampsia 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**[®] 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.

Important Safety Information

- 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 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.

Important Safety Information

- 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.
- Ensure that this monitor has acclimated to room temperature before

Important Safety Information

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 this monitor for any purpose other than measuring blood pressure.
- This monitor is not used to diagnose sleep disorders or other similar illnesses.
- 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.

Important Safety Information

- 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.

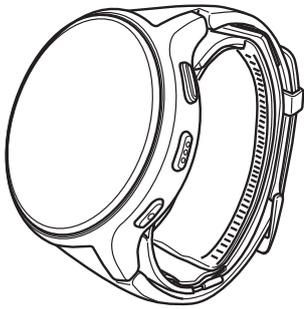
Rechargeable Battery Handling and Usage

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

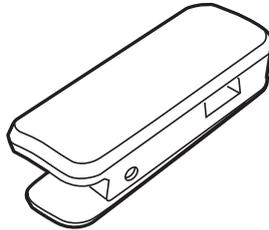
1. Know Your Monitor

1.1 Contents

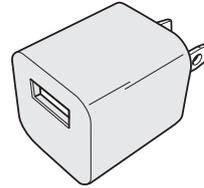
Monitor



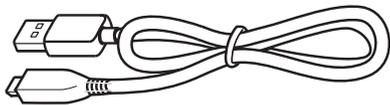
Charging clip
(HEM-CLIP-01)



AC adapter
(HHP-AM02)



Charging cable
(HHX-CB07U)



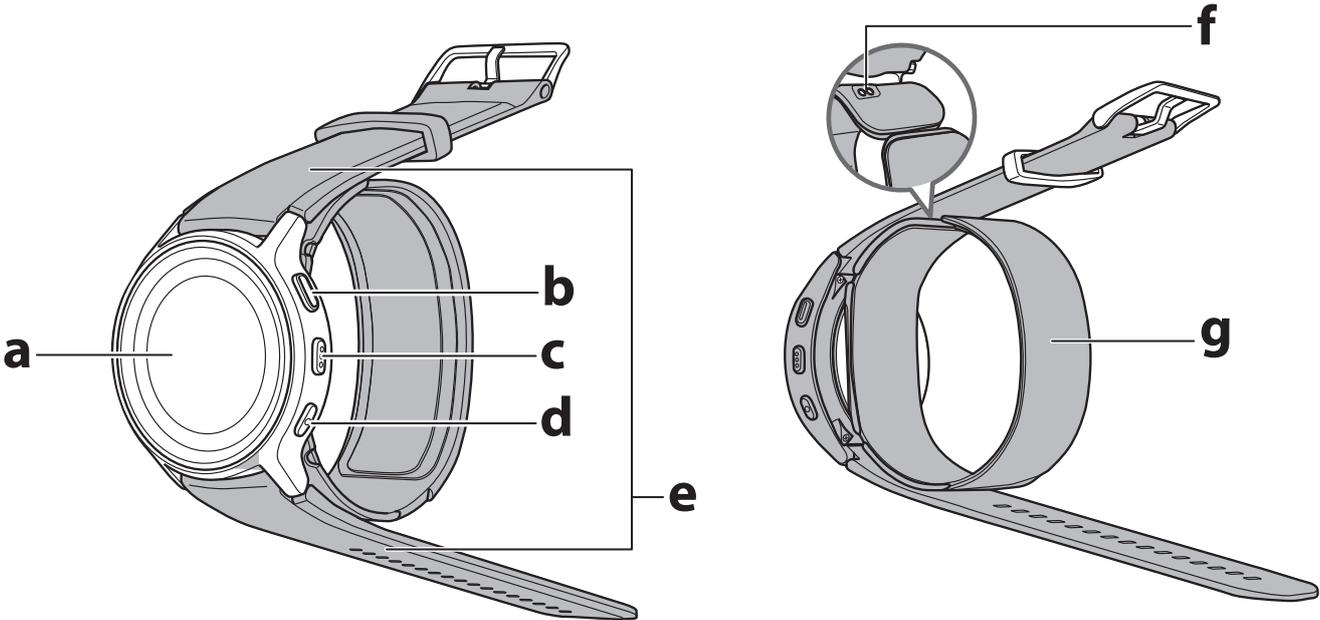
Paper sizing guide

Cuff cover

Instruction manual

Quick start guide

1.2 Monitor



a	Display	
b		[START/STOP] button
c		[FORWARD] button
d		[HOME] button

e	Band	
f	Charging port	
g	Cuff	

1. Know Your Monitor

1.3 Display and Symbols



A		Sleep mode symbol Appears when your monitor is in sleep mode. Refer to sub-section 4.4 (page 38).
B		Bluetooth symbol Appears when your readings are being transferred.
C		Reminder symbol Appears when a reminder is set. Refer to sub-section 4.7 (page 41).

D		Battery symbol Appears when any button is pressed or battery is low. Refer to page 17.
E		Sync symbol Appears when your data needs to be transferred because the stored memory is either almost, or completely full. Once you pair your monitor with your smart device, transfer your readings immediately before the monitor deletes the oldest reading. Refer to page 17 for each internal memory.
F		Bluetooth OFF symbol Appears when Bluetooth is disabled.
		Disconnect symbol Appears when your monitor is not paired with your smart device and Bluetooth is enabled.

1. Know Your Monitor

	<p>Movement error symbol</p> <p>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 2.2 (page 21). After applying the band correctly, wait for 2 to 3 minutes. Then, remain still and take another measurement.</p>
	<p>Heart zone error symbol</p> <p>Appears when your monitor is not positioned at heart level during a measurement. Refer to sub-section 3.1 (page 30) for more information about heart zone indicator.</p>
	<p>Irregular heartbeat symbol</p> <p>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. Irregular heartbeat symbol may be displayed when the monitor detects arm movements. Refer to section 7 for more information.</p> <p>If it continues to appear, we recommend you to consult with and follow the directions of your physician.</p>
	<p>Heartbeat symbol</p> <p>Flashes while taking a blood pressure measurement.</p>
<p>Blood pressure level indicator (color)</p> <p>When your systolic or diastolic blood pressure is above the AHA guideline, the number will be shown in red. About AHA guideline, refer to sub-section 1.4 (page 18).</p>	

1. Know Your Monitor

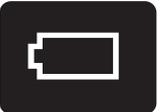
Storable Readings of Each Measurement

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				
Symbols				

1.4 Classification of BP (Blood Pressure)

AHA (American Heart Association) defines categories of BP in adults as below.

Categories of BP in Adults*

BP Category	Systolic BP	and	Diastolic BP
Normal	< 120 mmHg		< 80 mmHg
Elevated	120-129 mmHg		< 80 mmHg
Hypertension	Stage 1 130-139 mmHg	or	80-89 mmHg
	Stage 2 ≥ 140 mmHg	or	≥ 90 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 ≥ 2 careful readings obtained on ≥ 2 occasions).

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

Warning

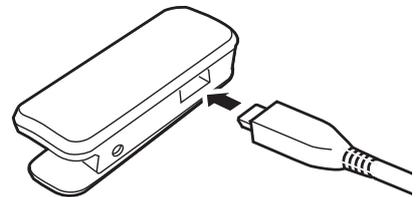
NEVER diagnose or treat yourself based on your readings. ALWAYS consult with your physician.

2. Preparation

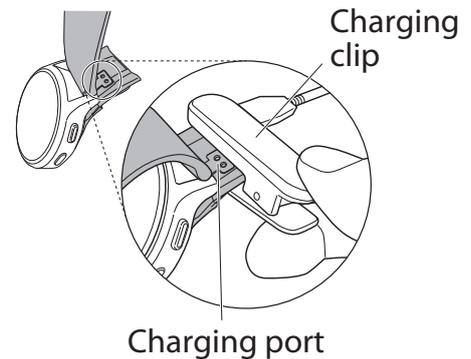
2.1 Charging the Battery

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.

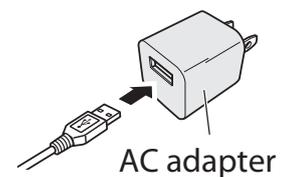
1. **Plug the smaller end of the charging cable into the charging clip.**



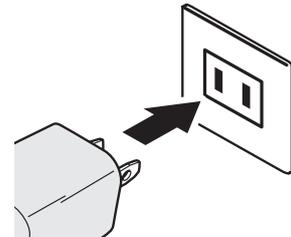
2. **Connect the clip to the charging port of your monitor.**



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



4. Plug the AC adapter into an electrical outlet.



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

Remaining	Low  Full			
Symbols				

Battery Life

Your monitor will last up to 2 days per charge, depending on use and storage condition.

Note

- 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 section 10 (page 60).
- Temperature during the battery charging should be 50 to 95 °F (10 to 35 °C).

2. Preparation

2.2 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.

Caution

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

Note

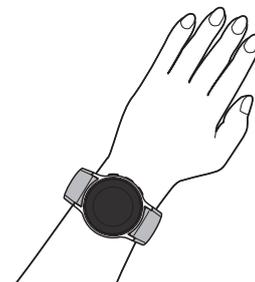
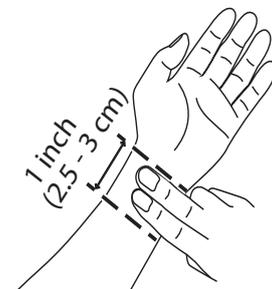
- Your monitor does not have water-resistant functionality. Do not immerse your monitor in water.

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.

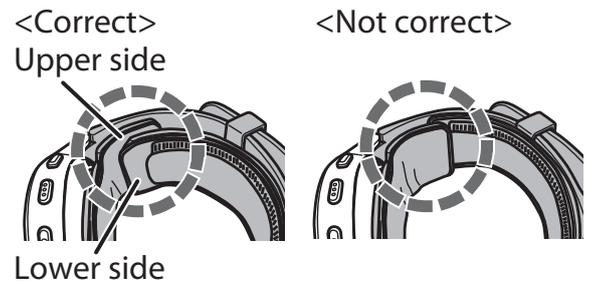
Note

- In order to secure an accurate measurement, adjust the band to fit firmly if it feels too loose or too tight.



2. Preparation

- Make sure that the cuff is positioned correctly. If the upper and lower sides of the cuff are overlapped, the lower side should be positioned under the upper side. Refer to the illustration.



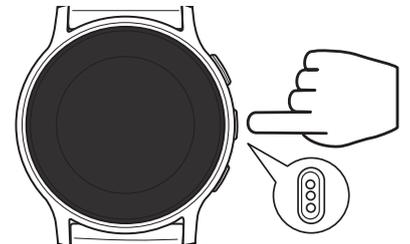
Wearing the Monitor on the Right Wrist

Your monitor can also be worn on your right wrist. Configure the Right / Left Wrist setting. Refer to sub-section 7.1 (page 48).

2.3 Turn Your Monitor On

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

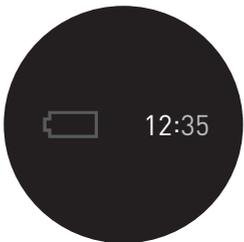
The monitor turns on and the screen below appears on the display.



2. Preparation

Note

- You can use your monitor without pairing with 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).



3. Using Your Monitor without a Smart Device

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.

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.

Note

- 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 the 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.

3. Using Your Monitor without a Smart Device

- 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

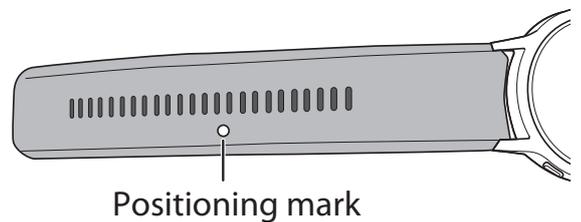
- Avoid bathing, drinking alcohol or caffeine, smoking, exercising and eating for at least 30 minutes before taking a blood pressure measurement.
 - Rest for at least 5 minutes before taking a blood pressure measurement.
-

3. Using Your Monitor without a Smart Device

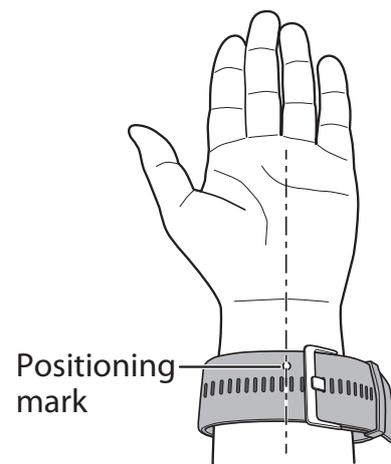
3.1.2 Positioning the Band

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

1. Find the positioning mark on the band.



2. Position the positioning mark on the center of your wrist (align with your middle finger).



3. Using Your Monitor without a Smart Device

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 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.

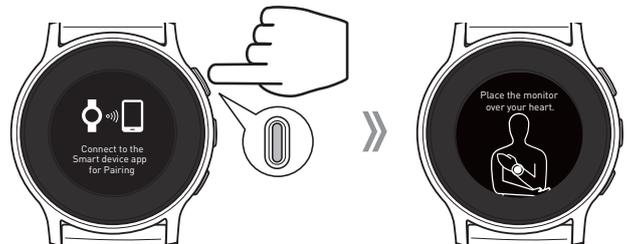
3.1.4 Taking a Blood Pressure Measurement

Note

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

1. Press the [START/STOP] button.

Heart zone indicator will appear.



3. Using Your Monitor without a Smart Device

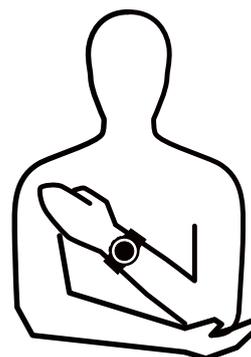
2. Adjust the position of your wrist.

Place your monitor over your heart while a measurement.

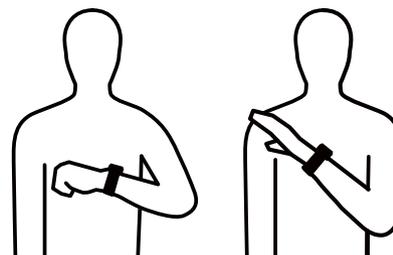
Once the heart zone indicator appears, raise or lower your wrist until it is at heart level. When your wrist is in the proper position, your monitor will vibrate once. After approximately 2 seconds, the monitor will start a measurement and the cuff will start to inflate.

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.

< Correct >



<Not Correct>



Note

- DO NOT make the band and your body touch while a measurement.
- Even when your monitor is not positioned properly, after approximately 5 seconds your monitor will start a measurement and the cuff will start to inflate.
- For more information about the heart zone indicator, refer to "Heart Zone Indicator" on page 29.

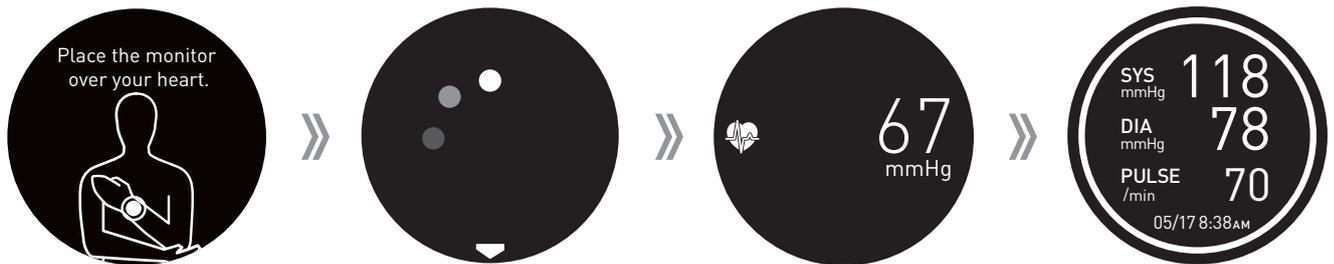
3. Using Your Monitor without a Smart Device

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 heartbeat 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 section 1.4), the number will be shown in red.



Note

- 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. 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 relative to your heart.

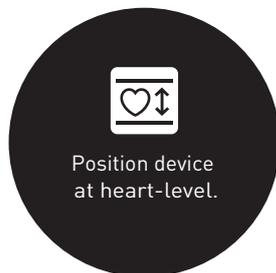
Due to differences in individual size and physique, this feature may not be helpful in all cases and you may wish to turn off this feature. If you feel the position of the wrist, according to the heart zone indicator's guidance, does NOT match your heart level, please turn off this feature and follow your judgment. To disable this feature, refer to sub-section 6.1 (page 37).

3. Using Your Monitor without a Smart Device

Error Symbols

If the error screens below are displayed, please take another measurement. Refer to sub-section 1.3 (page 15).

- Your monitor is not at the correct height.



- Your body was moved during measurement.



- Irregular heartbeats are detected.



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. Using Your Monitor with a Smart Device

4.1 Pairing Your monitor with a Smart Device

Pairing your monitor with the “OMRON connect US/CAN” 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.

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1. **Enable Bluetooth on your smart device.**
 2. **Download and install the free “OMRON connect US/CAN” app onto your smart device.**



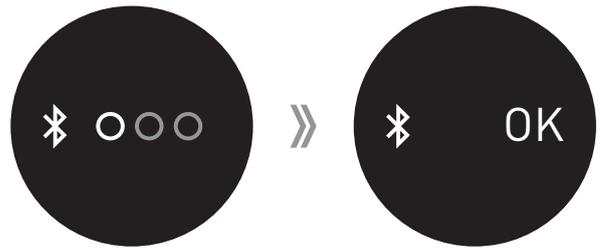
If you already have the “OMRON connect US/CAN” app, and have created your account, open the app and add your new monitor.

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3. **Open the app and follow the pairing instructions shown on your smart device.**
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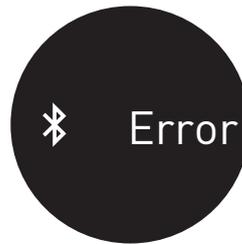
4. Using Your Monitor with a Smart Device

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 "OMRON connect US/CAN" app. If it still appears after checking the app, contact customer service. Refer to section 13.



Note

- "OMRON connect US/CAN" 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 24) to start a measurement.

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

Note

- Make sure your monitor is within 16 ft. (5 m) of your smart device.
 - When the Bluetooth OFF symbol () appears on the display of your monitor, enable Bluetooth. Refer to sub-section 7.2 (page 49).
 - When the sync symbol () appears on the display, the stored memory is almost full. Transfer the data immediately before your readings are deleted.
 - Once you transfer your readings to the app, your readings cannot be sent again to any app or smart device.
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