

OMRON®

INSTRUCTION MANUAL

7 Series Wrist Blood Pressure Monitor

Model BP6350



All for Healthcare

ENGLISH

Table of Contents

| | |
|--|----|
| Introduction | 3 |
| Important Safety Information | 5 |
| 1. Know Your Monitor | 9 |
| 2. Preparation | 15 |
| 3. Using Your Monitor without a Smart Device | 21 |
| 4. Using Your Monitor with a Smart Device | 24 |
| 5. Using Memory Function | 27 |
| 6. Other Settings | 29 |
| 7. Error Messages and Troubleshooting | 31 |
| 8. Maintenance | 35 |
| 9. Specifications | 36 |
| 10. FCC Statement | 39 |
| 11. Limited Warranty | 40 |
| 12. Guidance and Manufacturer's Declaration | 42 |

Introduction

Thank you for purchasing the OMRON BP6350 Wrist Blood Pressure Monitor. This blood pressure monitor is to be worn on your wrist. This monitor can be used by multiple users.

This new blood pressure monitor uses the oscillometric method of blood pressure measurement. When the cuff inflates, this monitor senses the pressure pulsations of the artery underneath the cuff. The pulses are called oscillometric pulses. The electronic pressure sensor displays a digital reading of blood pressure.

Safety Instructions

This instruction manual provides you with important information about the OMRON BP6350 Wrist Blood Pressure Monitor. To ensure the safe and proper use of this 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 this monitor. For specific information about your own blood pressure, consult with 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 5.3 inches to 8.5 inches (13.5 cm to 21.5 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

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

Important Safety Information

Please read the Important Safety Information in this instruction manual before using this monitor.

Please follow this instruction manual thoroughly for your safety.

Please 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 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** apply the wrist cuff 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; pre-eclampsia or renal disease. **NOTE** that any of these conditions in addition to patient motion, trembling, or shivering may affect the measurement reading.
- **NEVER** diagnose or treat yourself based on your readings. **ALWAYS** consult with your physician.
- 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 and remove batteries when in RF restricted areas. For further information on potential restrictions refer to documentation on the Bluetooth usage by the FCC/IC.

Battery Handling and Usage

- Keep batteries out of the reach of infants, toddlers or children.
-

 **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.
- 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 measurements more often than necessary because bruising, due to blood flow interference, may occur.
- **ONLY** inflate the wrist cuff when it is applied on your wrist.
- Remove the wrist cuff if it does not start deflating during a measurement.
- **DO NOT** use this monitor for any purpose other than measuring blood pressure.
- 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.

- **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 chapter 9.
- During measurement, observe the arm to ensure that the monitor is not causing prolonged impairment to blood circulation.
- **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 measurement.
- Rest for at least 5 minutes before taking a measurement.
- Remove tight-fitting, thick clothing and any accessories from your wrist while taking a measurement.
- Remain still and **DO NOT** talk while taking a 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 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 chapter 9.
- **DO NOT** crease the wrist cuff excessively.
- **DO NOT** use this monitor after the durable period has ended. Refer to chapter 9.

Data Transmission

- **DO NOT** replace batteries while your reading is being transferred to your smart device. This may result in the incorrect operation of this monitor and failure to transfer your blood pressure data.

Battery Handling and Usage

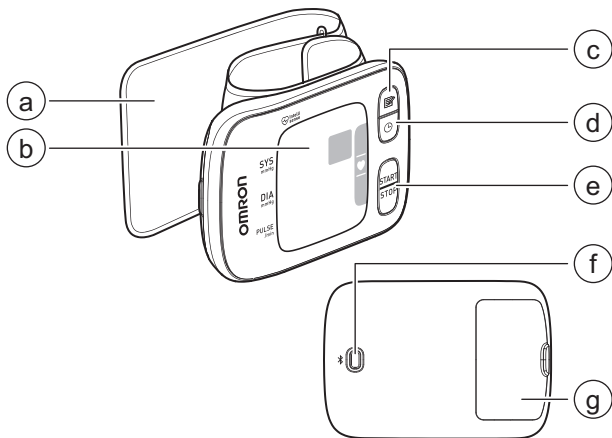
- **DO NOT** insert batteries with their polarities incorrectly aligned.
 - **ONLY** use 2 “AAA” alkaline batteries with this monitor. **DO NOT** use other types of batteries. **DO NOT** use new and used batteries together. **DO NOT** use different brands of batteries together.
 - Remove batteries if this monitor will not be used for a long period of time.
 - If battery fluid should get in your eyes, immediately rinse with plenty of clean water. Consult with your physician immediately.
 - If battery fluid should get on your skin, wash your skin immediately with plenty of clean, lukewarm water. If irritation, injury or pain persists, consult with your physician.
 - **DO NOT** use batteries after their expiration date.
 - Periodically check batteries to ensure they are in good working condition.
 - **ONLY** use batteries specified for this monitor. Use of unsupported batteries may damage and/or may be hazardous to this monitor.
-

1. Know Your Monitor

1.1 Contents

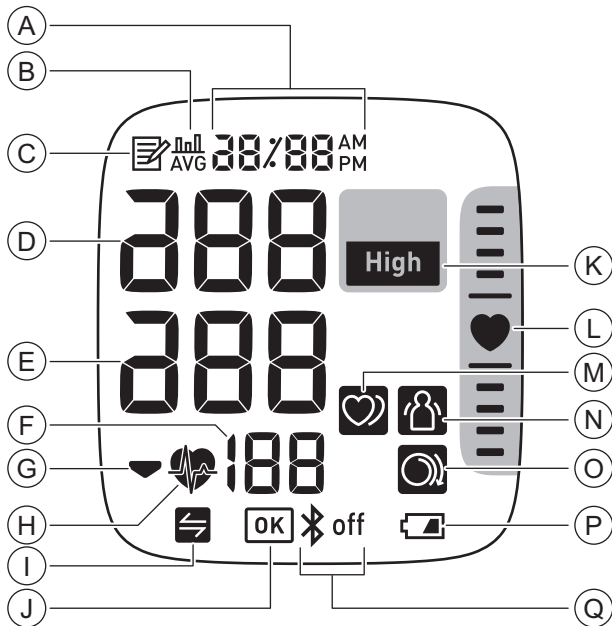
Monitor, 2 “AAA” alkaline batteries, storage case, instruction manual, quick start guide








1.2 Monitor





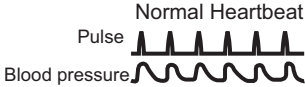
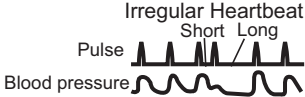








- a. Wrist cuff
(Wrist circumference 5.3" to 8.5" (13.5 cm to 21.5 cm))
- b. Display
- c. [Memory] button
- d. [Date/Time setting] button
- e. [START/STOP] button
- f. [Connection] button
- g. Battery compartment

1.3 Display and Symbols



| | | |
|----------|---|--|
| A | Date and time display | |
| B |  | Average value symbol Appears when viewing the average readings of the latest 2 or 3 readings taken within 10 minutes span. |
| C |  | Memory symbol Appears when viewing readings stored in the memory. |
| D | Systolic blood pressure reading | |
| E | Diastolic blood pressure reading | |
| F | Pulse display / Memory number Pulse rate appears after the measurement. When pressing the  button, the memory number appears for approximately one second before the pulse rate appears on the display. | |
| G |  | Deflation symbol Appears during cuff deflation. |
| H |  | Heartbeat symbol Flashes while taking a measurement. |
| I |  | Sync symbol Flashes/appears when your data needs to be transferred because the stored memory is either almost, or completely full. Once you pair your monitor with a smart device, transfer your readings immediately before the monitor deletes the oldest readings. Up to 90 readings can be stored in the internal memory per user. |
| J |  | OK symbol Flashes when your monitor is connected to the smart device or readings are transferred successfully. |

| | | |
|---|---|---|
| K |  | <p>High symbol</p> <p>Appears if your systolic blood pressure is 130 mmHg or above and/or the diastolic blood pressure is 80 mmHg or above. Refer to section 1.4 for more information.</p> |
| L |  | <p>Heart zone indicator</p> <p>Your monitor has a built-in heart zone indicator that is used as an aid in determining if the monitor is at the correct height.</p> <p>The “” symbol lights in blue when your monitor is at the correct position relative to your heart during a measurement. When your monitor is higher or lower position relative to your heart, the heart position locator bar will appear up above, or below the heart symbol to guide correct wrist positioning.</p> |
| M |  | <p>Irregular heartbeat symbol</p> <p>Appears along with readings when an irregular rhythm is detected 2 or more times during a 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 blood pressure. If it continues to appear, we recommend you to consult with and follow the directions of your physician.</p> <div style="display: flex; justify-content: space-around; align-items: flex-start;"> <div style="text-align: center;"> <p>Normal Heartbeat</p>  </div> <div style="text-align: center;"> <p>Irregular Heartbeat</p>  </div> </div> |
| N |  | <p>Movement error symbol</p> <p>Appears along with readings when your body is moving during a measurement. If it appears, remove the wrist cuff, and wait for 2 to 3 minutes. Then, remain still and take another measurement.</p> |
| O |  | <p>Cuff wrap guide symbol</p> <p>Appears if the wrist cuff is wrapped around the wrist too loosely while taking a measurement. It also appears when viewing past readings.</p> |

| | | |
|---|---|--|
| P |  | Battery symbol (low) Flashes when batteries are low. |
| |  | Battery symbol (depleted) Appears when batteries are depleted. |
| Q |  | Bluetooth ON symbol Appears when Bluetooth is enabled. |
| |  | Bluetooth OFF symbol Appears when Bluetooth is disabled. |

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 |

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

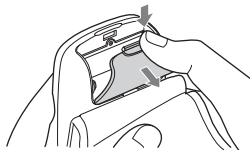
⚠ Warning

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

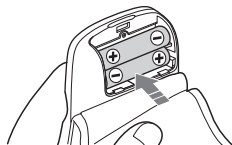
2. Preparation

2.1 Installing Batteries

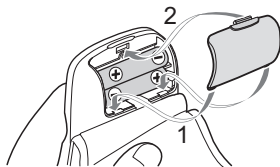
1. Push down the hook of the battery cover and pull downward.




2. Insert 2 “AAA” alkaline batteries as indicated in the battery compartment.



3. Close the battery cover.





Note


- When the “” symbol flashes on the display, it is recommended you replace batteries.
- To replace batteries, turn your monitor off and remove all batteries. Then replace with 2 new alkaline batteries at the same time.
- As soon as batteries are correctly installed, the year flashes on the date and time display to set the date and time.
- Replacing batteries will not delete previous readings.
- The supplied batteries may have a shorter life than new batteries.
- Disposal of used batteries should be carried out in accordance with local regulations.

2.2 Setting the Date and Time

Note

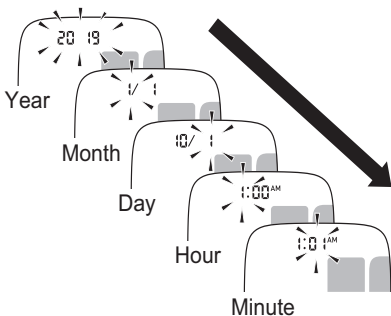
- Set your monitor to the correct date and time before taking a measurement for the first time.
 - As soon as batteries are correctly installed, the year flashes on the display of your monitor.
 - The date and time will automatically be set when the monitor is paired with “OMRON connect US/CAN” app. Refer to section 4.1.
-

1. Press the  or  button once to adjust the year.

Press and hold the  button to quickly advance the years.


Press and hold the  button to quickly go backwards through the years.

2. Press the [START/STOP] button to confirm the year and the month will flash. Repeat the same steps to adjust the month, day, hour, and minute.



-
- 3.** Press the [START/STOP] button to store the setting.
It automatically turns off after 3 seconds.

Note

- If you need to reset the date and time, replace batteries or press and hold the  button until the year flashes, and set the date and time as above steps.

2.3 Blood Pressure Measurement Tips

To help ensure an accurate reading, follow these directions:

- 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 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 measurement.
 - Rest for at least 5 minutes before taking a measurement.
-

2.4 Applying the Wrist Cuff

Note

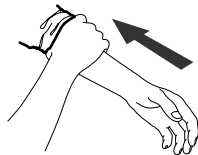
- Following steps are for applying the wrist cuff to your left wrist. When you take a measurement on your right wrist, apply the wrist cuff using the same steps as on your left wrist.
- The blood pressure can differ between the right wrist and the left wrist, and the measured blood pressure values can be different. OMRON recommends to always use the same wrist for measurement. If the values between both wrists differ substantially, please check with your physician as to which wrist to use for your measurements.

⚠ Caution

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

1. Apply the wrist cuff to your left wrist.

Roll up sleeve. Make sure your sleeve is not rolled up too tightly on your arm. This may constrict the flow of blood in your arm.



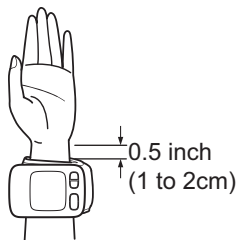
2. Put your wrist through the cuff loop.

Your palm and monitor display should both face upward.

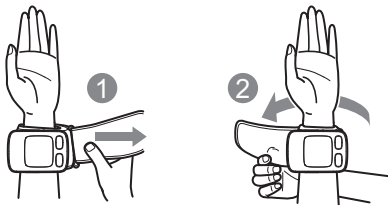


Wrist cuff

-
3. Position the wrist cuff leaving a clearance of 0.5 inch (1 to 2 cm) between the cuff and the bottom of your palm.

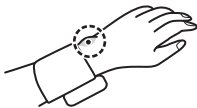


-
4. Wrap the wrist cuff firmly around your wrist. Do not apply over clothing.
Check to make sure that there is no gap between your wrist and the cuff.

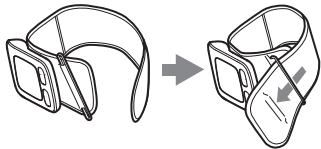


Note

- Make sure the wrist cuff does not cover the protruding part of the wrist bone on the outside of your wrist.



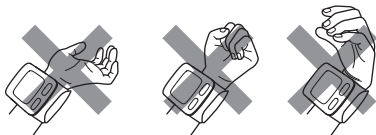
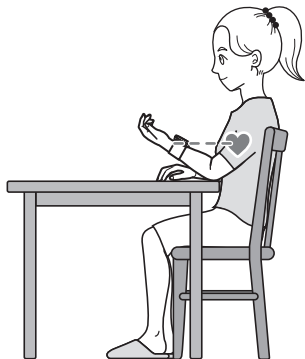
- If the wrist cuff comes out of the metal ring, slide it back through as shown in the figure to the right.



2.5 Sitting Correctly

To take a measurement, you need to be relaxed and comfortably seated in a room with a comfortable temperature. Place your elbow on the table to support your arm.

- Sit in a chair with your legs uncrossed and your feet flat on the floor.
- Sit with your back and arm being supported.
- The distance from the top of your seat measuring to the top of the table you are sitting at, should be 12 plus or minus 2 inches (30 ± 5 cm). If the distance measured between the top of your seat and table do not fall within this parameter, correct your seat or table height. If you are unable to make any seat or table adjustments, please turn off the heart zone indicator and position your wrist at heart level by yourself. Refer to section 6.1.
- Your monitor must be approximately the same level as your heart. 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.
- Relax your wrist and hand. Do not bend your wrist back, clench your fist, or bend your wrist forward.



3. Using Your Monitor without a Smart Device

3.1 Taking a Measurement

You can use your monitor without pairing to a smart device. To pair your monitor with a smart device, refer to section 4.1.

Note

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


Caution

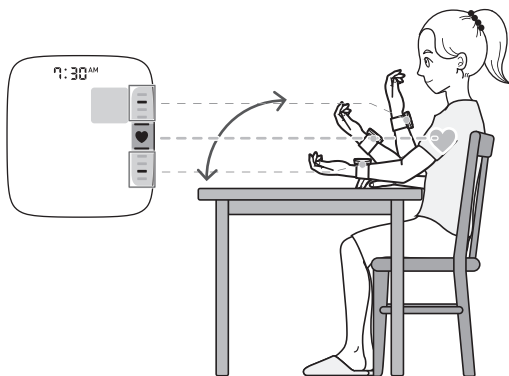
- DO NOT use this monitor with other medical electrical (ME) equipment simultaneously. This may result in incorrect operation of the monitor and/or cause an inaccurate reading.
- Remain still and DO NOT talk while taking a measurement.





1. Press the [START/STOP] button.

All symbols appear on the display before starting the measurement.

2. Check the heart zone indicator.

Your monitor has a built-in heart zone indicator that is used as an aid in determining if the 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, the “” symbol will light in blue. When your wrist is higher or lower position relative to your heart, a locator bar will appear according to the wrist position. Due to difference in individual size and physique, this feature may not be helpful in all cases and you may wish to disable this feature. If you feel the position of the wrist according to heart zone indicator's guidance does NOT match your heart level, disable this feature and follow your judgement. To disable it, refer to section 6.1.




| | Monitor height | Heart Zone Indicator |
|--|-------------------|---|
|  | Wrist is too high | Any locator bar (-) above the “  ” symbol appears. |
| | Proper position | The “  ” symbol lights in blue. |
| | Wrist is too low | Any locator bar (-) below the “  ” symbol appears. |

Note


- After 5 seconds from pressing the [START/STOP] button, even if your monitor is not positioned properly, your monitor will start the measurement and the wrist cuff will start to inflate.


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

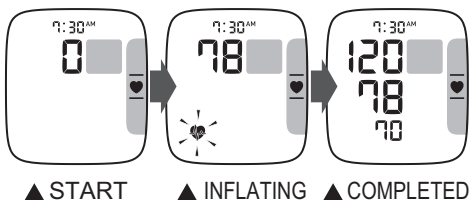
As the cuff inflates, your monitor automatically determines your ideal inflation level. This monitor detects your blood pressure and pulse rate during inflation.

The “” symbol flashes at every heartbeat.

Note

- When the “” symbol is displayed, the wrist cuff is not applied correctly. Press the [START/STOP] button to turn your monitor off, then apply the cuff correctly.

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 1.3), the “” symbol appears.



4. Press the [START/STOP] button to turn your monitor off.

Note

- Your monitor will automatically turn off after 2 minutes.
- Wait 2 - 3 minutes between measurements. The wait time allows the arteries to decompress and return to their pre-measurement form. You may need to increase the wait time depending on your individual physiological characteristics.

4. Using Your Monitor with a Smart Device

4.1 Pairing Your Monitor with a Smart Device

The date and time on your monitor will automatically be set when you pair your monitor with your smart device.

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

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

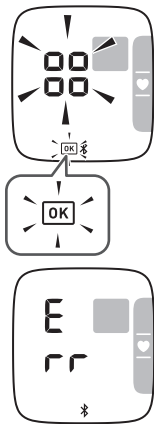


If you already have the “OMRON connect US/CAN” app and have created your account, open the app and add your new monitor.

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

4. Confirm that your monitor is connected successfully.

When your monitor is connected successfully to your smart device, the “OK” symbol flashes.



Note

- If the “Err” symbol appears, follow the instructions in the “OMRON connect US/CAN” app
- Your monitor automatically turns off after 10 seconds without any operations.
- Any readings currently saved in the memory of your monitor are automatically transferred to the app after successful completion of the pairing process.
- Please be aware that OMRON will not be responsible for the loss of data and/or information in the app.
- “OMRON connect US/CAN” is the only app that we recommend to use with your monitor to transfer data correctly.

4.2 Taking a Measurement

Refer to section 3.1 to start a measurement. The readings will be transferred to your smart device.

4.3 Disabling/Enabling Bluetooth

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 this monitor and remove batteries when in RF restricted areas. For further information on potential restrictions refer to documentation on the Bluetooth usage by the FCC/IC.

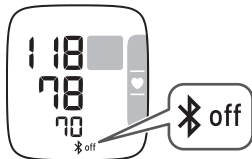
Bluetooth is enabled as default.

1. When your monitor is off, press and hold the [⌘] button for more than 10 seconds.

- “oFF” appears on the display.



- When the Bluetooth is disabled, the following symbol appears.



Note

- To enable the Bluetooth, press and hold the [⌘] button for more than 2 seconds. “on” appears on the display.
- Your monitor will automatically turn off within 3 seconds after the completion.


5. Using Memory Function

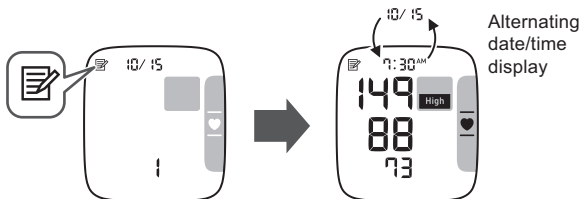
Your monitor automatically stores up to 90 readings.

Note

- This monitor can be used by multiple users. When you use memory function with other users, track (or manage) your own readings appropriately.

5.1 Viewing the Readings Stored in Memory

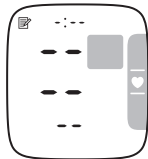
1. Press the  button.




The Memory number appears for one second before the pulse rate is displayed. The most recent reading set is numbered “1”.

Note


- If the heart zone indicator is enabled, the heart zone indicator is displayed with the readings.
- If the reading is high (refer to section 1.3), the “High” symbol appears.
- If there are no readings stored in the memory, the screen to the right is displayed.
- If the memory is full, the monitor will delete the oldest readings.




2. Press the  button repeatedly to scroll through the previous readings stored in the memory.

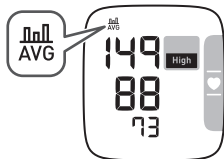
5.2 Viewing the Average Reading

Your monitor can calculate an average reading based on the latest 2 or 3 readings taken within 10 minutes span.

1. When your monitor is off, press and hold the  button for more than 2 seconds.

Note


- If there are only 2 readings in the memory for that period, the average will be based on these 2 readings.
- If the average reading is high (refer to section 1.3), the “” symbol appears.

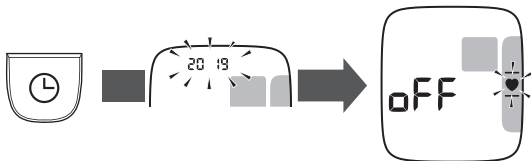


6. Other Settings

6.1 Disabling/Enabling Heart Zone Indicator

The heart zone indicator is enabled as default.




1. When your monitor is off, press and hold the  button for more than 10 seconds.



Note

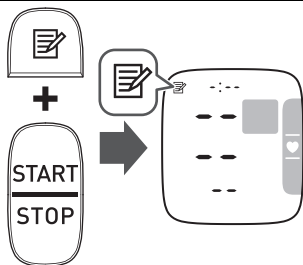
- Your monitor will automatically turn off after 3 seconds from the completion.
- To enable the heart zone indicator, follow the same steps as above.

6.2 Deleting All Readings Stored in Memory

1. Press the  button, then the “” symbol appears.
2. While holding the  button down, press and hold the [START/STOP] button for more than 2 seconds.


Note

- All readings will be deleted. You cannot partially delete the readings stored in the memory.



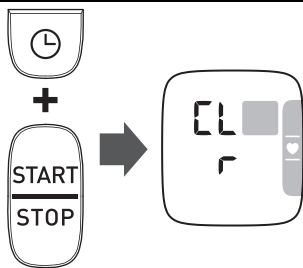
6.3 Restoring Your Monitor to the Default Settings

To delete all the information stored in your monitor, follow the instructions below. Make sure that your monitor is turned off.

1. While holding the  button down, press the [START/STOP] button within 2 seconds. Hold both buttons for more than 5 seconds.








Note






- Reverting to its default setting of your monitor does not delete the information in the app.
- Your monitor will automatically turn off after 3 seconds.
- You will need to re-pair your monitor when using the monitor again. Without re-pairing, your readings will not be transferred to your app.



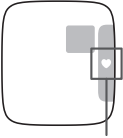




7. Error Messages and Troubleshooting

In case of 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.

| Display/Problem | Possible Cause | Solution |
|--|--|---|
|  appears or the wrist cuff does not inflate. | The wrist cuff is not applied correctly. | Apply the wrist cuff correctly, then take another measurement. Refer to section 2.4. |
| | Air is leaking from the wrist cuff. | Contact customer service. Refer to chapter 11. |
|  appears | The wrist cuff is overinflated exceeding 300 mmHg. | Do not touch the wrist cuff while taking a measurement. |
|  appears | You move or talk during a measurement. Vibrations disrupt a measurement. | Remain still and do not talk during a measurement. |
|  appears | The pulse rate is not detected correctly. | Apply the wrist cuff correctly, then take another measurement. Refer to section 2.4. |
|  appears | | Remain still and sit correctly during a measurement. |
|  appears | | If the “  ” symbol continues to appear, we recommend you to consult with your physician. |

| Display/Problem | Possible Cause | Solution |
|--|--|---|
|  appears | Your wrist is moved up and down during a measurement. | Do not move your wrist, then take another measurement. Refer to chapter 3. |
|  appears | The monitor is malfunctioned. | Press the [START/STOP] button again. If “Er” still appears, contact customer service. Refer to chapter 11. |
|  appears | The monitor cannot connect to a smart device or transmit data correctly. | Follow the instructions shown in the “OMRON connect US/CAN” app. If the “Err” symbol still appears after checking the app, contact customer service. Refer to chapter 11. |
|  flashes | The [⌘] button is pressed and held to pair with a smart device. | Flashes when pairing to the smart device. Visit the “Help” section in the “OMRON connect US/CAN” app for pairing. |
|  flashes | The [⌘] button is pressed to transfer your readings. | Flashes when transferring your readings to the “OMRON connect US/CAN” app. |

| Display/Problem | Possible Cause | Solution |
|--|---|---|
|  <p>flashes</p> | <p>More than 70 readings are not transferred.</p> | <p>Pair or transfer your readings to the “OMRON connect US/ CAN” app so you can keep them in memory in the app, and this error symbol disappears.</p> |
|  <p>appears</p> | <p>This monitor is ready for pairing or transferring your readings.</p> | |
|  <p>heart symbol</p> <p>The heart symbol in the heart zone indicator does not light and a locator bar does not appear.</p> | <p>The heart zone indicator is disabled.</p> | <p>Enable the heart zone indicator. Refer to section 6.1.</p> |
|  <p>flashes</p> | <p>Batteries are low.</p> | <p>Replacing all batteries with 2 new alkaline batteries is recommended. Refer to section 2.1.</p> |

| Display/Problem | Possible Cause | Solution |
|---|---|--|
|  appears or the monitor is turned off unexpectedly during a measurement | Batteries are depleted. | Immediately replace all batteries with 2 new alkaline batteries. Refer to section 2.1. |
| No power. Nothing appears on the display of the monitor. | Batteries are completely depleted. | |
| | Battery polarities are not properly aligned. | Check the battery installation for proper placement. Refer to section 2.1. |
| Readings appear too high or too low. | Blood pressure varies constantly. Many factors including stress, time of day, and/or how you apply the wrist cuff, may affect your blood pressure. Review sections 2.3 - 2.5 and chapter 3. | |
| Any other communication issue occurs. | Follow the instructions shown in the smart device, or visit the “Help” section in the “OMRON connect US/CAN” app for further help. If the problem still persists, contact customer service. Refer to chapter 11. | |
| Any other problems occur. | Press the [START/STOP] button to turn the monitor off, then press it again to take a measurement. If the problem continues, remove all batteries and wait for 30 seconds. Then re-install batteries. If the problem still persists, contact customer service. Refer to chapter 11. | |

8. Maintenance

8.1 Maintenance

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

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

Caution

- DO NOT disassemble or attempt to repair this monitor or other components. This may cause an inaccurate reading.

8.2 Storage

Keep your monitor in the storage case when not in use.

- 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.

8.3 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 wrist cuff, and then wipe them with a dry cloth.
- Do not wash or immerse your monitor and wrist cuff in water.
- Do not use gasoline, thinners or similar solvents to clean your monitor and wrist cuff.

8.4 Disposal

Dispose of your monitor and other components according to applicable local regulations.

Unlawful disposal may cause environmental pollution.

9. Specifications

| | |
|----------------------------------|--|
| Model | BP6350 [REF] HEM-6231T-Z |
| Display | LCD digital display |
| Cuff pressure range | 0 to 299 mmHg |
| Blood pressure measurement range | SYS: 60 to 260 mmHg DIA: 40 to 215 mmHg |
| Pulse measurement range | 40 to 180 beats / min. |
| Accuracy | Pressure: ± 3 mmHg Pulse: $\pm 5\%$ of display reading |
| Inflation | Automatic by electric pump |
| Deflation | Automatic rapid deflation |
| Measurement method | Oscillometric method |
| Transmission method | Bluetooth [®] 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 | IP 22 |
| Rating | DC3 V 3.0 W |
| Power source | 2 "AAA" alkaline batteries 1.5 V |
| Battery life | Approximately 300 measurements (using new alkaline batteries) |
| Durable period (Service life) | 5 years |
| Operating conditions | +50°F to +104°F (+10°C to +40°C) / 15 to 90% RH (non-condensing) / 800 to 1060 hPa |
| Storage / Transport conditions | -4°F to +140°F (-20°C to +60°C) / 10 to 90% RH (non-condensing) |
| Weight | Approximately 3.2 oz. (91 g) not including batteries |

| | |
|---|---|
| Dimensions | Approximately 3.6" (w) × 2.5" (h) × 0.5" (l)* (91 mm × 63 mm × 13 mm) (not including the wrist cuff) |
| Measurable wrist circumference | 5.3" to 8.5" (13.5 to 21.5 cm) |
| Memory | Stores up to 90 readings |
| Contents | Monitor, storage case, 2 "AAA" alkaline batteries, instruction manual, quick start guide |
| Protection against electric shock | Internally powered ME equipment |
| Applied part | Type BF (wrist cuff) |
| Maximum temperature of the applied part | Lower than +118.4°F (+48°C) |

* thinnest part

Note

- These specifications are subject to change without notice.
- This monitor is clinically investigated according to the requirements of ISO 81060-2:2013. In the clinical validation study, K5 was used on 85 subjects for determination of diastolic blood pressure.
- 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 solid foreign objects of 0.5 inches (12.5 mm) diameter and greater such as a finger, and against oblique falling water drops which may cause issues during a normal operation.

Pictogram on the Product



Indicates the correct positioning for the monitor on the wrist.

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.

10. 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 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).

11. Limited Warranty

Your BP6350 Wrist Blood Pressure Monitor, excluding batteries, is warranted to be free from defects in materials and workmanship appearing within 5 years 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 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

12. 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 Electro Magnetic Compatibility (EMC)

BP6350 manufactured by OMRON HEALTHCARE Co., Ltd. conforms to IEC60601-1-2:2014 Electro Magnetic Compatibility (EMC) standard.

Further documentation in accordance with this EMC standard is available at OmronHealthcare.com/emc. Refer to the EMC information for BP6350 on the website.



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