

10 Series Upper Arm Blood Pressure Monitor Model BP7465 Instruction Manual

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Introduction

Thank you for purchasing the OMRON BP7465 Upper Arm Blood Pressure Monitor. This monitor can be used by multiple users. This blood pressure monitor uses the oscillometric method of blood pressure measurement. This means this monitor detects your blood movement through your brachial artery and converts the movements into a digital reading.

Safety Instructions

This instruction manual provides you with important information about the OMRON BP7465 Upper Arm Blood Pressure Monitor. To ensure the safe and proper use of this monitor, READ and UNDERSTAND all of these 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. The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.

The device includes the Atrial Fibrillation Detection Feature. The feature analyzes pulse pressure wave data captured during the user's blood pressure measurement to identify episodes of atrial fibrillation (AFib) and provides a notification on the display screen to the user. This feature is intended to be used for home screening for the possibility of AFib.

The Atrial Fibrillation Detection Feature is not intended to provide a notification on every episode of AFib and the absence of detection is not intended to indicate the absence of atrial fibrillation. The feature is not intended to replace traditional methods of diagnosis or treatment or to be used in the management of patients with AFib.

The device is intended for over-the-counter (OTC) use in the home environment. The device is intended for use in adults (22 years or older); it has not been tested for and is not intended for use in pregnant women or people with implanted pacemakers or defibrillators.

Receiving and Inspection

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

Symbols Glossary

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

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.

Usage on Individuals

- **NOT intended for use** if you have an implanted defibrillator or pacemaker.
- **NOT intended for use** if you are pregnant.
- **NOT intended for use** if you are under 22 years of age.
- **NEVER** diagnose or treat yourself based on your readings. **ALWAYS consult with your physician.**
- **DO NOT** use this monitor on infants, toddlers, children or persons who cannot express themselves.
- **DO NOT** use this monitor on an injured arm or an arm under medical treatment.
- **DO NOT** apply the arm cuff on your arm while on an intravenous drip or blood transfusion.
- **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 or renal disease. **NOTE** that any of these conditions in addition to patient motion, trembling, or shivering may affect the measurement reading.
- This product contains small parts that may cause a choking hazard if swallowed by infants, toddlers and children.
- To help avoid strangulation, keep the air tube and AC adapter cable away from infants, toddlers and children.

Use Environment

- This monitor is **not intended for use** in ambulatory environment.
- **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.

Device Output

- **DO NOT adjust medication** (including altering your use of any drug or treatment) 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 and heart related conditions.
- If you are experiencing any symptoms or concerns, **consult with your physician.**
- **DO NOT** postpone/stop regular checkups or physician visits based on the results that you are getting from this monitor.

- The possible AFib detection feature evaluates for a possibility of AFib ONLY. It will **NOT** detect other potentially life-threatening arrhythmias or diseases, such as a possibility of other cardiac arrhythmias or heart attack.
- This monitor is **not intended for the diagnosis, treatment, or management of AFib.**

Data Transmission

- After the pairing process is completed, this product always 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. Disable the **Bluetooth®** feature in this monitor, or remove the batteries and unplug the AC adapter when in RF restricted areas. For further information on potential restrictions refer to documentation on the Bluetooth usage by the FCC.

AC Adapter Handling and Usage

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

Battery Handling and Usage

- Keep the batteries out of the reach of infants, toddlers and 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.

Usage on Individuals

- Safety and effectiveness in patients with peripheral arterial disease (PAD) have not been established.
- 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 an arm 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 or lymph node clearance.
- 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.
- Avoid bathing, drinking alcohol or caffeine, smoking, exercising and eating for at least 30 minutes before taking a measurement.

Important Safety Information

- Rest for at least 5 minutes before taking a measurement.
- Remove tight-fitting or thick clothing from your arm while taking a measurement.
- Remain still and **DO NOT** talk while taking a measurement.
- **ONLY** use the arm cuff on persons whose arm circumference is within the specified range of the cuff.

Use Environment

- 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** 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 or on an aircraft.
- **DO NOT** use this monitor in places with high or low humidity or high or low temperatures. Refer to section 14.
- **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 devices and/or cause an inaccurate reading.
- 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. It is recommended that you wait 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 on operating and storage/transport temperature, refer to section 14.

General Device Usage

- **ONLY** inflate the arm cuff when it is applied on your upper arm.
- Remove the arm cuff if it does not start deflating during a measurement.
- **DO NOT** use this monitor for any purpose other than measuring blood pressure and/or detecting a possibility of AFib.
- **DO NOT** disassemble or attempt to repair this monitor or other components. This may cause an inaccurate reading.
- **DO NOT** drop or subject this monitor to strong shocks or vibrations.
- During measurement, observe the arm to ensure that the monitor is not causing prolonged impairment to blood circulation.
- **DO NOT** use this monitor after the durable period has ended. Refer to section 14.
- **DO NOT** crease the arm cuff or the air tube excessively.
- **DO NOT** fold or kink the air tube while taking a measurement. This may cause an injury by interrupting blood flow.
- **DO NOT** use if the monitor or any components are damaged.
- To unplug the air plug, pull on the plastic air plug at the base of the tube, not the tube itself.

- **ONLY** use the AC adapter, arm cuff, batteries and accessories specified for this monitor. Use of unsupported AC adapters, arm cuffs and batteries may damage and/or may be hazardous to this monitor.
- **ONLY** use the approved arm cuff for this monitor. Use of other arm cuffs may result in incorrect readings.
- Inflating to a higher pressure than necessary may result in bruising of the arm where the cuff is applied. **NOTE:** refer to “If your systolic pressure is more than 210 mmHg” at the end of section 3 of this instruction manual for additional information.

Data Transmission

- **DO NOT** replace the batteries or unplug the AC adapter while your readings are being transferred to your smart device. This may result in incorrect operation of this monitor and failure to transfer your blood pressure data.

AC Adapter Handling and Usage

- 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 AC adapter cable.
- When handling the AC adapter 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 wiping this monitor.

Battery Handling and Usage

- **DO NOT** insert batteries with their polarities incorrectly aligned.
 - **ONLY** use 4 “AA” alkaline or manganese 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 the 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 the batteries to ensure they are in good working condition.
-

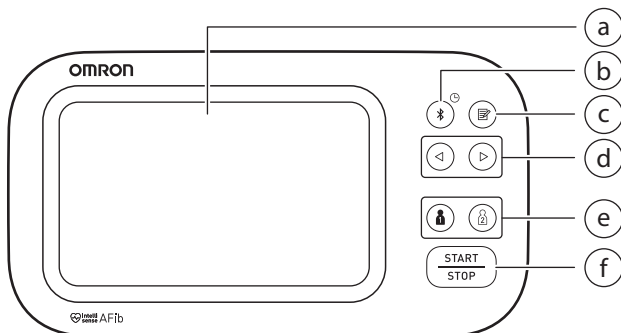
1. Know Your Monitor

1.1 Contents/Product Includes

Monitor, Easy-Wrap ComFit Cuff, AC adapter (HEM-ADPTW5), 4 "AA" batteries, instruction manual, quick start guide

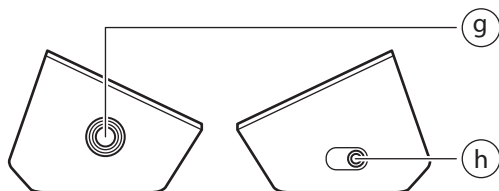
1.2 Monitor and Arm Cuff

Front of the monitor



- (a) Display
- (b) [Connection] button
(Date/Time)
- (c) [Memory] button
- (d) [Forward]/[Backward] buttons
- (e) [User ID 1]/[User ID 2] buttons
- (f) [START/STOP] button

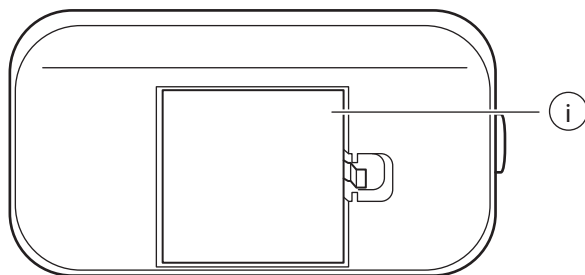
Left and right side of the monitor



g Air jack

h AC adapter jack

Bottom of the monitor



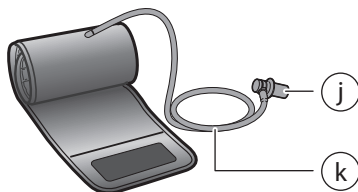
i Battery compartment

Arm cuff

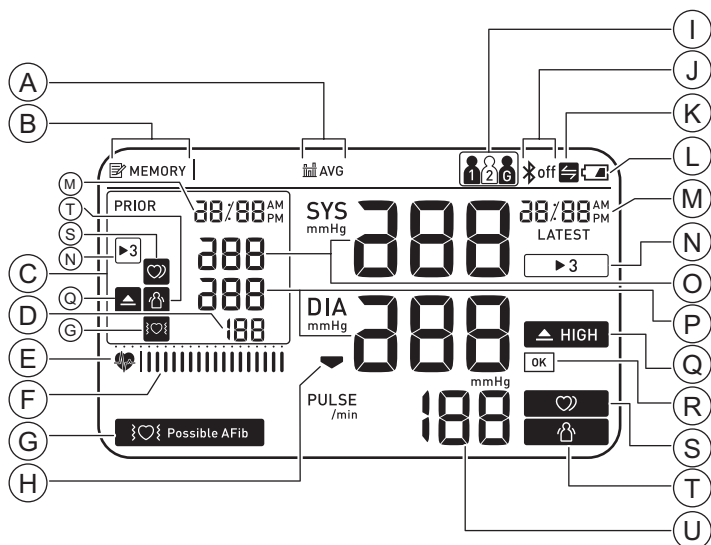
(Upper arm circumference: 9" - 17" (22 - 42 cm))

j Air plug












k Air tube










1.3 Display and Symbols











- (A) Average value symbol
- (B) Memory symbol
- (C) Comparison display
- (D) Pulse display / Memory number
- (E) Heartbeat symbol
- (F) Pulse level
- (G) Possible AFib detector symbol
- (H) Deflation symbol
- (I) User ID (1/2/Guest) symbol
- (J) Bluetooth ON / OFF symbol
- (K) Sync symbol
- (L) Low battery symbol / Depleted battery symbol
- (M) Date / Time display / Consecutive measurement number for TruRead
- (N) TruRead symbol
- (O) Systolic blood pressure reading
- (P) Diastolic blood pressure reading / AF
- (Q) High symbol
- (R) OK symbol
- (S) Irregular heartbeat symbol
- (T) Movement error symbol
- (U) Pulse display / Interval counter for TruRead

| | | |
|-----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (A) |  AVG | Average value symbol Flashes when viewing the average of the latest 2 or 3 readings taken within the most recent 10 minute timeframe. |
| (B) |  MEMORY | Memory symbol Appears when viewing readings stored in the memory. |
| (C) | Comparison display Displays past readings. Refer to section 5 for more information. | |
| (D) | Pulse display / Memory number <ul style="list-style-type: none"> • Pulse rate from the past reading appears. • When pressing the  button, the memory number appears for approximately 2 seconds before the pulse rate appears on the display. | |
| (E) |  | Heartbeat symbol Flashes while taking a measurement. |
| (F) |  | Pulse level Moves along with the pulse strength detected while deflating. |
| (G) |  Possible AFib  flashes with the display as below  | Possible AFib detector symbol Flashes when a possibility of AFib is detected. <i>Generally, blood pressure and pulse rate measured during AFib cannot be reliable.</i> Therefore, the readings are not displayed when a possibility of AFib is detected. Consult with your physician if your results include the “ /  Possible AFib ” symbol. For more information regarding AFib, refer to section 12. |
| (H) |  | Deflation symbol Appears during cuff deflation. |

1. Know Your Monitor

| | | |
|---|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ① |  | User ID (1 or 2) symbol The user ID number appears when selecting the user with the [User ID 1] or [User ID 2] button. |
| |  | User ID Guest symbol The user ID “G” appears when your monitor is in the guest mode. Refer to sub-section 3.3 for details. |
| ② |  | Bluetooth ON symbol Appears when your readings are being transferred. |
| |  | Bluetooth OFF symbol Appears when Bluetooth is disabled. |
| ③ |  | Sync symbol <ul style="list-style-type: none"> • Flashes when the stored memory is almost full, or the date and time are not set. • Appears when the stored memory is completely full. Once you pair your monitor with your smart device, transfer your readings immediately before the monitor deletes the oldest reading. Up to 100 readings can be stored in the internal memory of your monitor per user. |
| ④ |  | Low battery symbol Flashes when batteries are low. |
| |  | Depleted battery symbol Appears when batteries are depleted. |
| ⑤ | Date / Time display / Consecutive measurement number for TruRead | |

| | | |
|-----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (N) |   | <p>TruRead symbol</p> <p>Appears when a measurement is taken if the TruRead mode is enabled.</p> <p>The TruRead mode automatically takes 3 consecutive readings at intervals you can customize and displays the average.</p> <p>To set the interval of the TruRead mode, refer to sub-section 2.4.</p> <p>To use the TruRead mode, refer to sub-section 3.2.</p> <p>To view your readings in TruRead measurement, refer to sub-section 5.1.</p> |
| (O) | Systolic blood pressure reading | |
| (P) | Diastolic blood pressure reading / AF | |
| (Q) |   | <p>High symbol</p> <p>Appears if your systolic blood pressure is ≥ 130 mmHg or the diastolic blood pressure is ≥ 80 mmHg. Refer to sub-section 1.4 for more information.</p> |
| (R) |  | <p>OK symbol</p> <p>Flashes when your monitor is connected to your smart device or readings are transferred successfully.</p> |

| | | |
|------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>(S)</p> |  | <p>Irregular heartbeat symbol</p> <ul style="list-style-type: none"> • Appears when irregular rhythm is detected 2 or more times during a measurement. • This symbol will not appear when viewing the average readings (except for the TruRead mode). • This symbol may be displayed when the monitor detects arm movements while taking a measurement. Refer to section 7 for more information. <p>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.</p>  <p>If it continues to appear, it is recommended that you consult with, and follow the directions of your physician.</p> |
| <p>(T)</p> |  | <p>Movement error symbol</p> <p>Appears with your reading when your body is moving during a measurement. If it appears, remove the arm cuff and wait for about 1 minute. Then, reapply the cuff, remain still and take another measurement.</p> <p>(This function is disabled when a possibility of AFib or irregular heartbeat is detected during a measurement.)</p> |
| <p>(U)</p> | <p>Pulse display / Interval counter for TruRead</p> <ul style="list-style-type: none"> • Pulse rate appears after the measurement. • Counts the seconds for next TruRead during TruRead measurement. | |

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

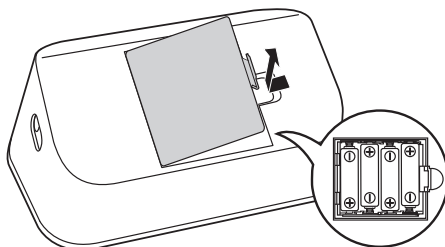
⚠ Warning

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

2. Preparation

2.1 Installing Batteries

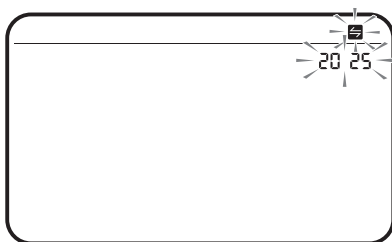
1. **Remove the battery cover.**
2. **Insert 4 “AA” batteries as indicated in the battery compartment.**




3. **Close the battery cover.**

As soon as the batteries are correctly installed, the year flashes on the display.

Refer to sub-section 2.3 to set the date and time manually, or refer to sub-section 4.1 to pair your monitor with a smart device to set the date and time automatically.



Note

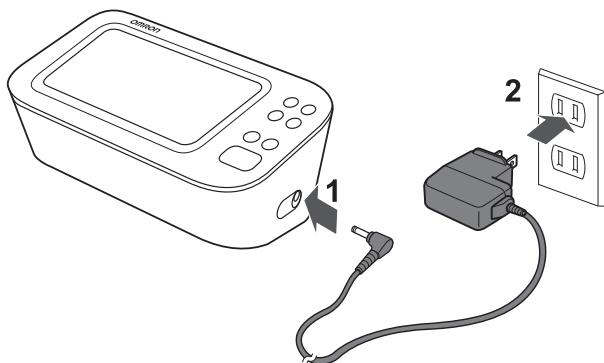
- When the “” symbol flashes on the display, it is recommended that you replace the batteries.
- To replace the batteries, turn your monitor off and remove all batteries. Then replace with 4 new batteries at the same time.
- Replacing the batteries will not delete previous readings.
- The supplied batteries may have a shorter life span than new batteries.
- Disposal of used batteries should be carried out in accordance with local regulations.

2.2 Using the AC Adapter

Note

- Make sure not to place your monitor in a location where it is difficult to plug and unplug the AC adapter.
- It is recommended that you keep the batteries in your monitor at all times, even if you choose to use the AC adapter. If only the AC adapter is used without keeping the batteries in your monitor, you may need to reset the date and time each time you unplug and plug back the AC adapter. The readings will not be deleted.

1. Insert the AC adapter plug into the AC adapter jack on the right side of your monitor.



2. Plug the AC adapter into an electrical outlet.

To unplug the AC adapter, unplug the AC adapter from the electrical outlet and then remove the AC adapter plug from the monitor.

Caution

- ONLY use the AC adapter, arm cuff, batteries and accessories specified for this monitor. Use of unsupported AC adapters, arm cuffs and batteries may damage and/or may be hazardous to this monitor.
-

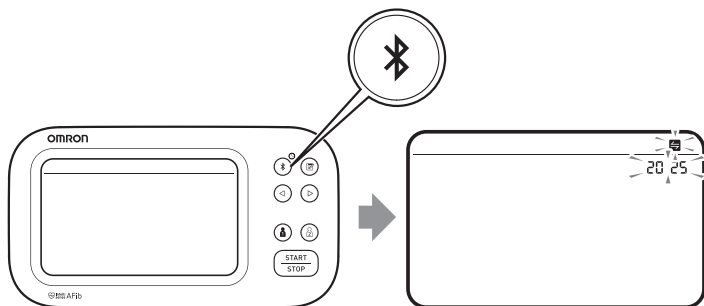
2.3 Setting the Date and Time

Note


- Set your monitor to the correct date and time before taking a measurement for the first time.
- The date and time will automatically be set when the monitor is paired with the compatible OMRON app. Refer to sub-section 4.1.
- As soon as the batteries are correctly installed, the year flashes on the display of your monitor.
- **DO NOT PRESS THE [START/STOP] BUTTON** to set and confirm the date and time.


1. If nothing is displayed, press the button to display the year.

If the year is already displayed, skip this step.

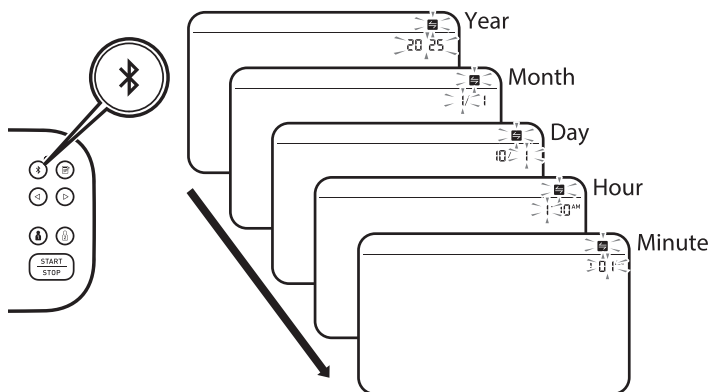


2. Press the or button to adjust the year.

Press and hold the  button to quickly advance the years.

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


3. Press the  button to confirm the year, then the month will flash. Repeat the same steps to adjust the month, day, hour, and minute.



4. Press the  button to store the setting.

TruRead mode setting is displayed 3 seconds after the minutes have been set in this sequence. Refer to sub-section 2.4.

Note

- If you need to reset the date and time, replace the batteries or press the  button, then set the date and time as shown in the above steps.
- If the date and time are not set, " - : - - " flashes during or after measurement.

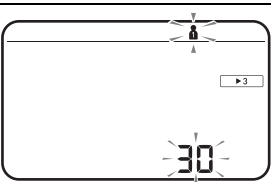
2.4 Setting the Interval of the TruRead Mode

The TruRead mode takes 3 consecutive measurements. The monitor will take a measurement 3 times, separated by a short interval between each measurement.

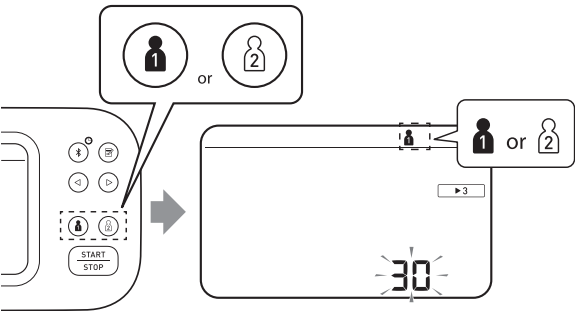
1. Set or bypass the date and time settings.

Follow the steps in sub-section 2.3 and set or bypass the date and time settings.

After it is completed, the "▶3" symbol appears and the "👤" or "2" symbol and the interval setting flash on the display.
The interval setting is 30 seconds as default.

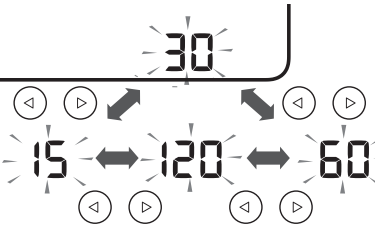


2. Press the 👤 or 2 button to select your user ID.



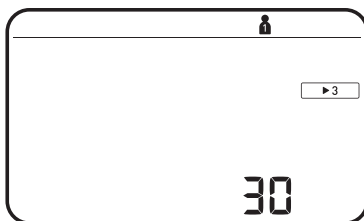
3. Press the ◀ or ▶ button to change the interval.

It can be set 15, 30, 60, or 120 seconds.



4. Press the button to confirm.

Your monitor will automatically turn off in a second.



To take a measurement in TruRead mode, refer to “Using the TruRead Mode” in sub-section 3.2.

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

2.6 Applying the Arm Cuff

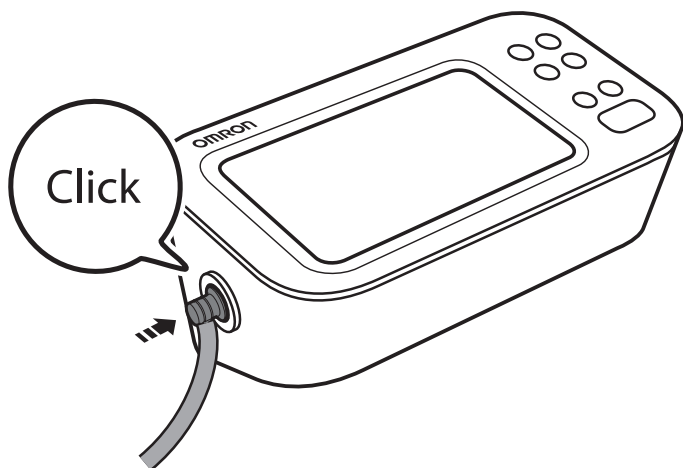
Note

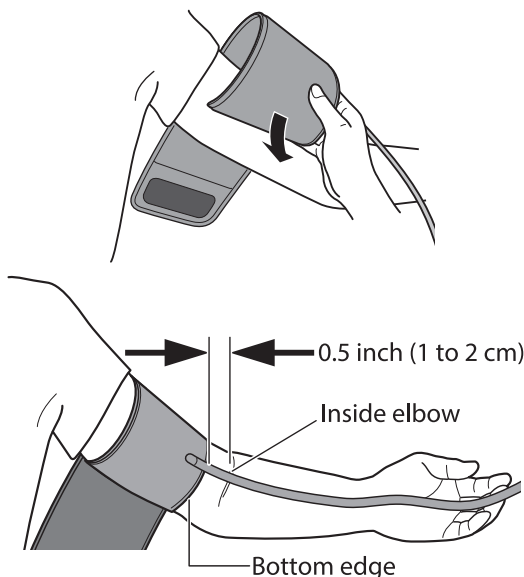
- The following steps are for applying the arm cuff to your left arm.
- To take a measurement on your right arm, follow the cuff and tube placement instructions for use on your right arm mentioned under “To take a measurement on your right arm” located at the end of this sub-section.
- Blood pressure can differ between the right arm and the left arm, and the measured blood pressure readings can be different. It is recommended that you always use the same arm for measurement. If the readings between both arms differ substantially, check with your physician to determine which arm to use for your measurements.

Caution

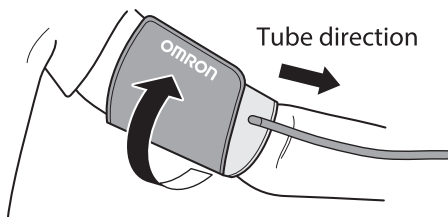
- Remove tight-fitting or thick clothing from your arm while taking a measurement.

- 1. Plug the arm cuff into your monitor by inserting the air plug into the air jack securely until it clicks.**



2. Apply the arm cuff to your left upper arm.**Note**

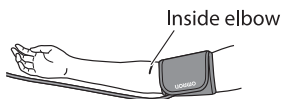
- The bottom edge of the arm cuff should be 0.5 inch (1 to 2 cm) **above** the inside elbow. The air tube is on the inside of your arm (palm facing up) and aligned with your middle finger.
- Arm cuff circumference: 9" - 17" (22 - 42 cm)

3. Make sure that the air tube is positioned on the inside of your arm and wrap the cuff securely, so it cannot move around your arm.

2. Preparation

To take a measurement on your right arm

When you take a measurement on your right arm, the air tube should run along the side of your elbow, along the bottom of your arm. Be careful not to rest your arm on the air tube.



2.7 Sitting Correctly

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

- Sit in a comfortable chair with your back and arm supported.
- Keep your feet flat and your legs uncrossed.
- The arm cuff should be placed on your arm at the same level as your heart, with the arm resting comfortably on a table.



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 sub-section 4.1.

Your monitor is designed to take measurements and store the readings in the memory for 2 people.

Note

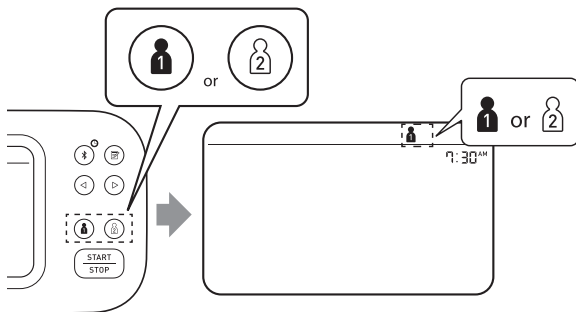
- To stop the measurement, press the [START/STOP] button once to deflate the arm cuff.

⚠ Caution

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

1. Press the or button to select your user ID.

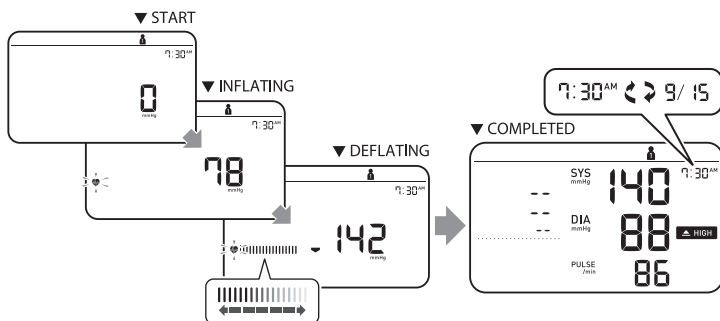
All symbols except the battery symbol appear, then the selected user ID appears on the display.



2. Press the [START/STOP] button.

The arm cuff starts to inflate automatically.

3. Remain still and do not talk until the entire measurement process is complete.



The "❤️" symbol flashes at every heartbeat.

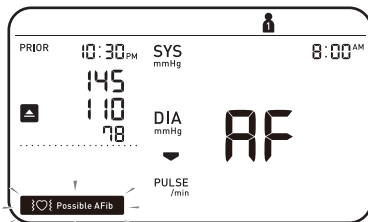
The pulse level moves along with the pulse strength detected while deflating.



When the measurement is complete, your blood pressure and pulse rate are displayed and the time/date appear alternately.

Note

- If either the systolic or the diastolic reading is high (refer to sub-section 1.4), the "▲ HIGH" symbol appears.
- If irregular rhythm is detected 2 or more times during a measurement, the irregular heartbeat symbol "❤️" appears on the display.

If the monitor detects a possibility of AFib...



The “ /  Possible AFib ” symbol flashes on the display.

Generally, blood pressure and pulse rate measured during AFib cannot be reliable. Therefore, the readings are not displayed when a possibility of AFib is detected.

This is not a diagnosis. It is only a potential finding for AFib. You should contact your physician to discuss the findings.

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




Note

- Your monitor automatically turns off after 2 minutes.
- Wait about 1 minute between measurements. The wait time allows the arteries to return to their pre-measurement state. You may need to increase the wait time depending on your individual physiological characteristics.

Warning

- This monitor is **not intended for the diagnosis, treatment, or management of AFib.**
 - **DO NOT adjust medication** (including altering your use of any drug or treatment) 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 and heart related conditions.
 - **NEVER** diagnose or treat yourself based on your readings. **ALWAYS consult with your physician.**
 - If you are experiencing any symptoms or concerns, **consult with your physician.**
 - **DO NOT** postpone/stop regular checkups or physician visits based on the results that you are getting from this monitor.
-

3.2 Using the TruRead Mode

1. Press the  or  button to select your user ID.
2. Press and hold the [START/STOP] button for more than 2 seconds.
3. Release the [START/STOP] button when the " 3" symbol appears on the display.

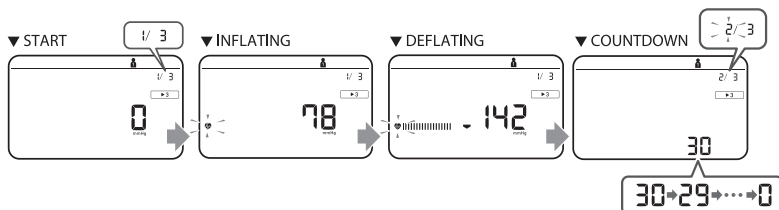
The arm cuff starts to inflate automatically.

After the first measurement is complete, wait for the next measurement to start.

The interval you selected during TruRead settings will appear on the display.

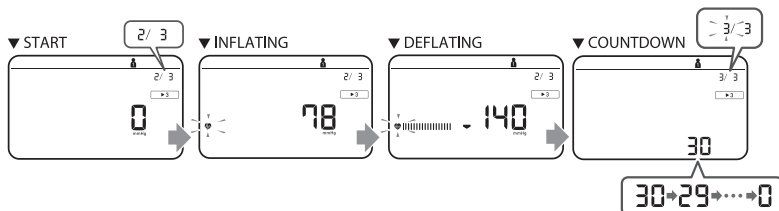
Note

- To change the interval of the measurements, refer to sub-section 2.4.



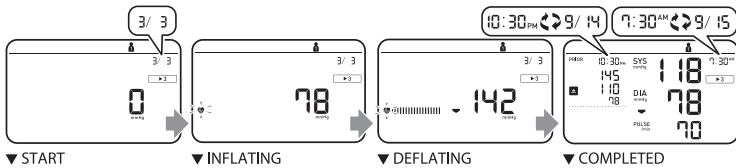
After the second measurement is complete, wait for the next measurement to start.



The interval you selected during TruRead settings will appear on the display.

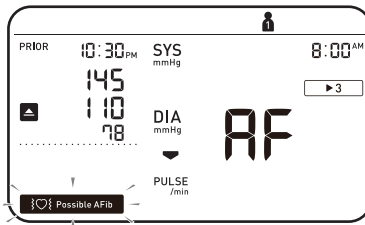




3. Using Your Monitor without a Smart Device

After the third measurement is complete, the average for the 3 measurements appears on the display.



If the monitor detects a possibility of AFib during a measurement in TruRead mode, the “ /  Possible AFib” symbol will flash and blood pressure and pulse rate readings will not be displayed. Generally, blood pressure and pulse rate measured during AFib cannot be reliable.



Consult with your physician if your results include the “ /  Possible AFib” symbol.

For more information regarding AFib, refer to section 12.

To view readings in TruRead measurement, refer to sub-section 5.1.


3.3 Using the Guest Mode

Your monitor stores readings for 2 users in the memory. The guest mode can be used to take a single measurement for another user.

Note

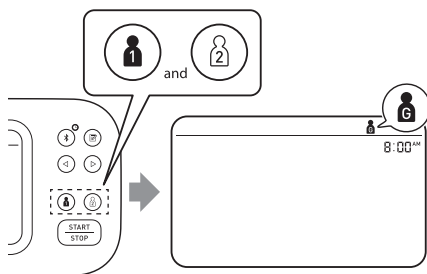
- No readings are stored in the memory, and the TruRead mode is not available when the guest mode is selected.

1. Press the and buttons at the same time.

All symbols except the battery symbol appear, then the user ID “” symbol appears on the display.

Note

- Your monitor automatically turns off after 2 minutes if you do not start taking a measurement. Move to the next step before it happens.



2. Press the [START/STOP] button.

The measurement starts automatically following the same steps as in sub-section 3.1 “Taking a Measurement”.

■ If your systolic pressure is more than 210 mmHg

If your systolic pressure is more than 210 mmHg, take a measurement manually.

After the arm cuff starts to inflate, press and hold the [START/STOP] button until the monitor inflates 30 to 40 mmHg higher than your expected systolic pressure.

Note

- Do not inflate above 299 mmHg.

Caution

-
- Inflating to a higher pressure than necessary may result in bruising of the arm where the cuff is applied.
-

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/connect

1. **Enable Bluetooth on your smart device.**
2. **Scan the code below with your smart device camera or visit OmronHealthcare.com/app to find the OMRON compatible app for this product.**



Please be sure to use apps provided by Google Play or App Store.

3. **Download and install the compatible OMRON app onto your smart device.**

If you already have the compatible OMRON app and have created your account, open the app and add your new monitor.

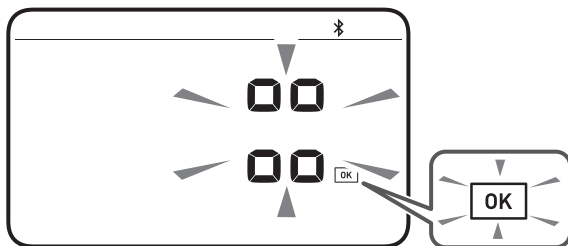
4. **Open the app and follow the pairing instructions shown on your smart device.**

Note

- If your monitor's "⌘" symbol appears even though you cannot connect to your smart device or the smart device of a shared user of your monitor, a cybersecurity event may have occurred. In this case, please refer to sub-section 4.3 to disable the Bluetooth feature and refer to sub-section 6.2 to restore your monitor to the default settings.

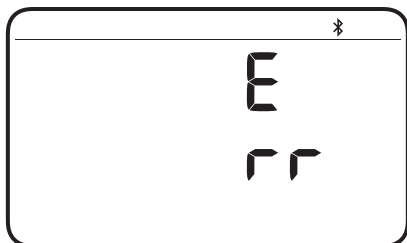
5. Confirm that your monitor is connected successfully.

When your monitor is connected successfully to your smart device, the OK symbol appears.



6. Press the [START/STOP] button to turn your monitor off.**Note**

- If the “Err” appears, follow the instructions in the app.



- Your monitor automatically turns off after 10 seconds.
- Be aware that OMRON will not be responsible for the loss of data and/or information in the app.
- Only compatible OMRON apps should be used with this monitor to help ensure correct data transfer.

4. Using Your Monitor with a Smart Device

4.2 Taking a Measurement

Refer to sub-section 3.1 to start a measurement. Open the app on your smart device and follow the instructions.

Caution

- 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.

Note


- Make sure that your monitor is within 16 ft. (5 m) of your smart device.
- When Bluetooth is enabled, the readings will be transferred to your smart device after taking a measurement.

4.3 Disabling Bluetooth

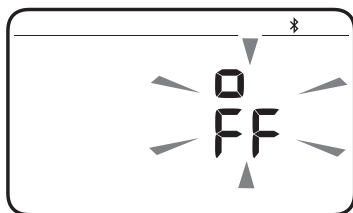
Warning

- After the pairing process is completed, this product always 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. Disable the Bluetooth feature in this monitor, or remove the batteries and unplug the AC adapter when in RF restricted areas. For further information on potential restrictions refer to documentation on the Bluetooth usage by the FCC.

Bluetooth is enabled as default.



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

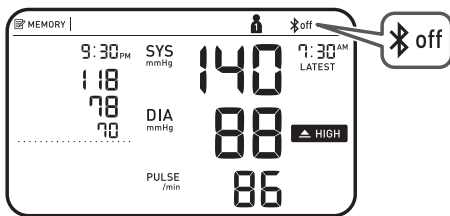
"oFF" flashes 3 times.



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

Note

- To enable Bluetooth, press and hold the  button for more than 2 seconds. "on" appears on the display.
- Your monitor automatically turns off 10 seconds after the completion.
- When Bluetooth is disabled, the " off" symbol appears and your reading will not automatically be transferred to the app.






5. Using Memory Function

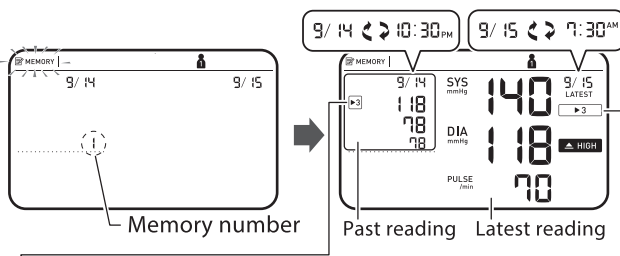
This monitor can store readings for up to 2 users, and automatically stores up to 100 readings per user.

Note

- Make sure you remember which user ID stores your own readings.

5.1 Viewing the Readings Stored in Memory

1. Press the  or  button to select your user ID.
2. Press the  button once.



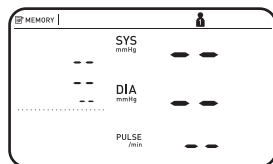
If the past reading was taken in TruRead mode, the "▶3" symbol appears. The reading shown on the left is the average of 3 measurements.

If the latest reading was taken in TruRead mode, the "▶3" symbol appears. The reading shown on the right is the average of 3 measurements.

The memory number appears for 2 seconds before the pulse rate is displayed. The most recent reading stored in the memory will be numbered as "1". After the memory number appears, the latest reading will appear with a past reading. A past reading will appear in the comparison display on the left.

Note

- If the reading was high (refer to sub-section 1.4), the "▲ / ▲ HIGH" symbol appears.
- If a possibility of AFib was detected during a measurement, the "❤️ / {❤️} Possible AFib" symbol flashes on the display. *Generally, blood pressure and pulse rate measured during AFib cannot be reliable.* Therefore, the readings are not displayed when a possibility of AFib is detected.
- If irregular rhythm was detected 2 or more times during a measurement, the irregular heartbeat symbol "❤️ / ❤️" will be displayed with your reading.
- If there are no readings stored in the memory, the screen to the right is displayed.
- If the memory is full, new readings will replace the old readings, starting with the oldest reading.



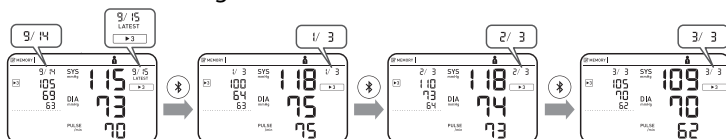
3. Press the ◀ or ▶ button repeatedly to scroll through the previous readings stored in the memory.

◀ : To view the older readings



▶ : To view the more recent readings

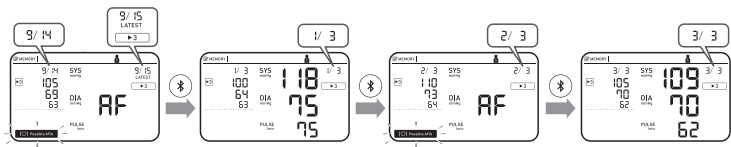
To view individual readings in TruRead measurement

The readings with the TruRead symbol (▶3 / ▶3) are the averages for the consecutive 3 measurements. To view the individual readings, press the ⌘ button while the TruRead average is displayed. When TruRead readings are the past and the latest readings, the individual TruRead readings are displayed on both the left and right sides.



5. Using Memory Function

If a possibility of AFib was detected during a measurement in TruRead mode, the “ /  Possible AFib ” symbol flashes on the average reading display. *Generally, blood pressure and pulse rate measured during AFib cannot be reliable.* Therefore, the readings are not displayed when a possibility of AFib is detected. It is recommended that you consult with, and follow the directions of your physician.







5.2 Viewing the Average Reading

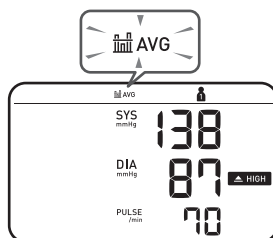
Your monitor can calculate an average reading based on the latest 2 or 3 readings taken within the most recent 10 minute timeframe.

Note



- Set your monitor to the correct date and time before taking a measurement to view the average readings.

1. Press the  or  button to select your user ID.
2. Press and hold the  button for more than 3 seconds.

The “ AVG” symbol flashes, then the average reading appears.



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 sub-section 1.4), the “ HIGH” symbol appears.
- The calculation of the average reading does not include readings when a possibility of AFib was detected. However, if a possibility of AFib is detected in all the target readings, the “ Possible AFib” symbol will flash on the display. *Generally, blood pressure and pulse rate measured during AFib cannot be reliable.* Therefore, the readings are not displayed when a possibility of AFib was detected. It is recommended that you consult with, and follow the directions of your physician.

6. Other Settings

6.1 Deleting All Readings Stored in Memory

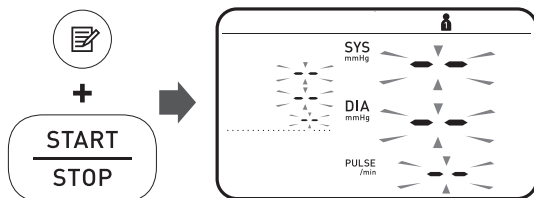
1. Press the  or  button to select your user ID.

2. Press the  button.

After a memory number appears, the latest reading will appear.

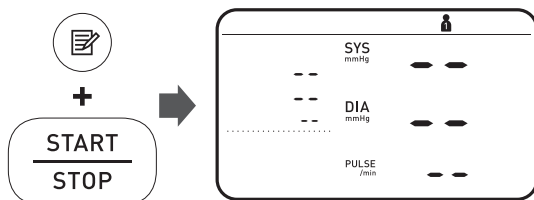
3. While holding the  button down, press and hold the [START/STOP] button for more than 3 seconds.

The display as below flashes.



4. While holding the  button down again, press and hold the [START/STOP] button for more than 3 seconds.

The display stops flashing, then all readings are deleted.



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

Note

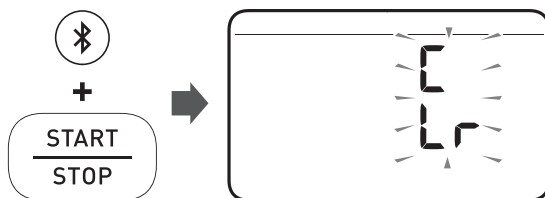
- All readings will be deleted. You cannot partially delete the readings stored in the memory.
- Your monitor automatically turns off after 10 seconds.

6.2 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.

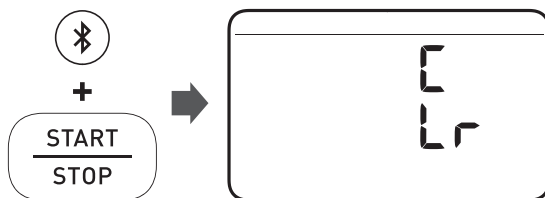
1. **While holding the  button down, press and hold the [START/STOP] button for more than 3 seconds.**

The display as below flashes.



2. **While holding the  button down again, press and hold the [START/STOP] button for more than 3 seconds.**

The display stops flashing, then your monitor is restored to the default settings.



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






Note

- After the completion, the year flashes on the display. Refer to sub-section 2.3 to set the date and time manually, or refer to sub-section 4.1 to pair your monitor with a smart device to set the date and time automatically.
- Reverting to the default setting of your monitor does not delete the information in the app.











7. Error Messages and Troubleshooting





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

| Display/ Problem | Possible Cause | Solution |
|----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| E1 appears or the arm cuff does not inflate. | The [START/STOP] button was pressed while the arm cuff is not applied. | Press the [START/STOP] button again to turn the monitor off. |
| | Air plug is not completely plugged into the monitor. | Insert the air plug securely. |
| | The arm cuff is not applied correctly. | Apply the arm cuff correctly, then take another measurement. Refer to sub-section 2.6. |
| | Air is leaking from the arm cuff. | Replace the arm cuff with a new one. Refer to section 13. |
| E2 appears or a measurement cannot be completed after the arm cuff inflates. | Moving or talking during a measurement causes the arm cuff to not inflate sufficiently. | Remain still and do not talk during a measurement. If "E2" appears repeatedly, inflate the arm cuff manually until the systolic pressure is 30 to 40 mmHg above your previous readings. Refer to the end of section 3. |
| | The systolic pressure is above 210 mmHg and a measurement cannot be taken. | |
| E3 appears | The arm cuff is inflated exceeding the maximum allowable pressure. | Do not touch the arm cuff and/or bend the air tube while taking a measurement. If inflating the arm cuff manually, refer to the end of section 3. |

| Display/ Problem | Possible Cause | Solution |
|------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|
|  appears | Moving or talking during a measurement results in vibrations that disrupt the measurement. | Remain still and do not talk during a measurement. |
|  appears | The pulse rate is not detected correctly. | Apply the arm cuff correctly, then take another measurement. Refer to sub-section 2.6. Remain still and sit correctly during a measurement. |
|  appears | The monitor has malfunctioned. | Press the [START/STOP] button again. If "Er" still appears, contact customer service. Refer to section 10. |
|  appears | The monitor cannot connect to a smart device or transmit data correctly. | Follow the instructions shown in the app. If the "Err" still appears after checking the app, contact customer service. Refer to section 10. |
|  flashes | The monitor is waiting for pairing with the smart device. | Refer to sub-section 4.1 for pairing your monitor with your smart device, or press the [START/STOP] button to cancel pairing and turn your monitor off. |

7. Error Messages and Troubleshooting

| Display/ Problem | Possible Cause | Solution |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|   Irregular heartbeat symbol appears | The pulse rate is not detected correctly. | Apply the arm cuff correctly, then take another measurement. Refer to sub-section 2.6. Remain still and sit correctly during a measurement. If the irregular heartbeat symbol “  /  ” continues to appear, it is recommended that you consult with your physician. |
|   Movement error symbol appears | | |
|  does not flash during a measurement | | |
|   flashes with the display as below  | A possibility of AFib is detected during a measurement. | <i>Generally, blood pressure and pulse rate measured during AFib cannot be reliable. Therefore, the readings are not displayed when a possibility of AFib is detected. It is recommended that you consult with, and follow the directions of your physician.</i> |

| Display/ Problem | Possible Cause | Solution |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|
|  flashes | There are more than 80 readings in memory to be transferred. | Pair or transfer your readings to the app so you can keep them in memory in the app, and this symbol disappears. |
| | The date and time are not set. | |
|  appears | There are 100 readings in memory to be transferred. | |
|  flashes | Batteries are low. | Replacing all 4 batteries with new ones is recommended. Refer to sub-section 2.1. |
| A I and  appears, or the monitor is turned off unexpectedly during a measurement. | Batteries are depleted. | Immediately replace all 4 batteries with new ones. Refer to sub-section 2.1. |
| | Batteries are depleted. | |
| Nothing appears on the display of the monitor. | Battery polarities are not properly aligned. | Check the battery installation for proper placement. Refer to sub-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 arm cuff, may affect your blood pressure. Review sub-sections 2.5 - 2.7 and section 3. | |

7. Error Messages and Troubleshooting

| Display/ Problem | Possible Cause | Solution |
|---------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| Any other communication issue occurs. | Follow the instructions shown in the smart device, or visit the "Help" section in the app for further help. If the problem still persists, contact customer service. Refer to section 10. | |
| 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 the batteries. If the problem still persists, contact customer service. Refer to section 10. | |

8. Maintenance

8.1 Maintenance

To protect your monitor from damage, 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

Store your monitor and other components in a clean, safe and dry location.

When storing for a long period of time, remove the battery.

Note

- Do not bend or crease the air tube excessively.

Do not store your monitor and other components:

- If your monitor and other components are 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 Wiping the Monitor

- Do not use any abrasive or volatile cleaners.
- Use a soft dry cloth or a soft cloth moistened with mild (neutral) detergent to wipe your monitor and arm cuff and then wipe them with a dry cloth.
- Do not wash or immerse your monitor and arm cuff or other components in water.
- Do not use gasoline, thinners or similar solvents to wipe your monitor and arm cuff or other components.

8.4 Disposal

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

9. 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 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).

10. Limited Warranty

Your BP7465 Blood Pressure Monitor, excluding the arm cuff, AC adapter and 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 arm cuff and AC adapter are warranted to be free from defects in materials and workmanship appearing within 1 year from the date of purchase when the monitor is used in accordance with the instructions provided with the monitor. The above warranty extends only to the original retail purchaser, and only to products purchased from an Omron authorized seller who is subject to and follows Omron's quality control standards, unless otherwise prohibited by law.

We will, at our option, replace without charge any monitor, arm cuff or AC adapter 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 that may apply.

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, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT. 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.

SOME STATES DO NOT ALLOW THE EXCLUSION OR LIMITATION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES, SO THE ABOVE LIMITATION OR EXCLUSION MAY NOT APPLY TO YOU.

10. Limited Warranty

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 |

11. Guidance and Manufacturer's Declaration

OMRON Battery-operated / AC Adapter-operated Blood Pressure Monitor
Information for Accompanying Documents in the Scope of
IEC 60601-1:2005+A1:2012+A2:2020, IEC 60601-1-2:2014+A1:2020 and
IEC 60601-1-11:2015+A1:2020

Important information regarding Electromagnetic Compatibility (EMC)

BP7465 conforms to IEC 60601-1:2005+A1:2012+A2:2020, IEC 60601-1-2:2014+A1:2020 and IEC 60601-1-11:2015+A1:2020 Electromagnetic Compatibility (EMC) standard.
Further documentation in accordance with this EMC standard is available at <https://healthcare.omron.com/electro-magnetic-compatibility>. Refer to the EMC information for BP7465 on the website.

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External References:

Moody GB, Mark RG. The impact of the MIT-BIH Arrhythmia Database. IEEE Eng in Med and Biol 20(3):45-50 (May-June 2001). (PMID: 11446209)

Contains information from "MIT-BIH Arrhythmia Database" which is made available under the ODC Attribution License.
<https://www.physionet.org/content/mitdb/1.0.0/>
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Moody GB, Mark RG. A new method for detecting atrial fibrillation using R-R intervals. Computers in Cardiology. 10:227-230 (1983).

Contains information from "MIT-BIH Atrial Fibrillation Database" which is made available under the ODC Attribution License.
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Clifford GD, Liu C, Moody B, Li-wei HL, Silva I, Li Q, Johnson AE, Mark RG. AF classification from a short single lead ECG recording: The PhysioNet/computing in cardiology challenge 2017.

In 2017 Computing in Cardiology (CinC) 2017 Sep 24 (pp. 1-4). IEEE.
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Contains information from "AF Classification from a Short Single Lead ECG Recording: The PhysioNet/Computing in Cardiology Challenge 2017" which is made available under the ODC Attribution License.
<https://physionet.org/content/challenge-2017/1.0.0/training/#files-panel>
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12. What is Possible AFib?

What is Blood Pressure?

Blood pressure is a measure of the force of blood flowing against the walls of the arteries. Arterial blood pressure is constantly changing during the course of the heart's cycle.

The highest pressure in the cycle is called the Systolic Blood Pressure; the lowest is the Diastolic Blood Pressure. Both pressures, the Systolic and Diastolic, are necessary to enable a physician to evaluate the status of a patient's blood pressure.

What is Arrhythmia?

Arrhythmia is a condition where the heartbeat rhythm is abnormal due to flaws in the bio-electrical system that drives the heartbeat. Typical symptoms are skipped heartbeats, premature contraction, an abnormally rapid (tachycardia) or slow (bradycardia) pulse.

What is AFib?

Atrial fibrillation (AFib) is a serious heart condition that causes an irregular and often rapid heartbeat. It's a type of arrhythmia, or abnormal heartbeat, that occurs when the upper chambers of the heart, or atria, beat irregularly and sometimes much faster than normal. This irregular beating prevents the heart's upper and lower chambers from working together properly, which can cause blood to pool in the atria and potentially clot. AFib can lead to serious complications, including: Blood clots, Stroke, Heart failure.



Some people with atrial fibrillation (AFib) don't experience any symptoms, a condition called asymptomatic or "silent" AFib. This means that people with silent AFib may not have any warning signs of the condition.

Possible AFib Detection



The monitor will notify you of a possibility of AFib if your monitor determines an irregularity from pulse to pulse intervals during a measurement.

The possible AFib detection feature ONLY evaluates for a possibility of AFib after taking a measurement. It does NOT continuously monitor your heart and therefore cannot alert you if AFib happens at any other time. This monitor cannot detect all forms of AFib. If the irregularity of the heart rhythm is too small, it may not be detected. For example, if there is an abnormality in the conduction between the atria and the ventricle, the heart rhythm may be in sinus rhythm, in which case a possibility of AFib cannot be detected by this monitor.

The state in which the “ /  “ symbol is displayed can influence your blood pressure measurements and make it difficult to get an accurate reading. If this occurs, it is recommended that you consult with your physician. The AFib detection algorithm was validated through a multi-center clinical study comparing against EKG recording between AFib cohort and non-AFib cohort. Racial representation was designed in the study, with 7.1 % minority in the AFib cohort. Representation of certain races and ethnicities were limited in the clinical evaluation and the sensitivity of the “Possible AFib” results cannot be confirmed as they could not be adequately studied.

Race and Ethnicity ratio in the AFib cohort

| | | | | | |
|------|---------------------------------------------------|--------|-----------|-----------------------------|--------|
| Race | White | 92.9 % | Ethnicity | Non-Hispanic and non-Latino | 97.4 % |
| | African American | 5.2 % | | | |
| | Others (Asian, Pacific Islander, American Indian) | 1.9 % | | Hispanic or Latino | 2.6 % |

Clinical study outcome of AFib detection performance



| Subgroup | | Sensitivity (%) | Specificity (%) |
|--------------------|-----------------------|-----------------|-----------------|
| Age | 22 - 64 years (N=176) | 90.3 | 98.6 |
| | Over 65 years (N=383) | 95.7 | 98.7 |
| Gender | Female (N=282) | 97.7 | 99.5 |
| | Male (N=277) | 93.9 | 96.9 |
| Race/ Ethnicity | Non-Caucasian (N=135) | 96.3 | 99.1 |
| | Caucasian (N=424) | 95.0 | 98.4 |

12. What is Possible AFib?

What is the difference between the possible AFib detection feature and EKG?

The possible AFib detection feature uses pulse wave detection to detect a possibility of AFib. EKG measures the electrical activity of the heart and can be used by a physician to diagnose AFib.

If the “ / Possible AFib” symbol does not flash, does it mean there is no possibility of AFib?

Even if the “ /  Possible AFib” symbol does not flash, there might be still a possibility of AFib.



If taking a measurement at a time when AFib does not occur, possible AFib might not be detectable. This monitor cannot detect all forms of AFib.

⚠ Warning

- The possible AFib detection feature evaluates for a possibility of AFib ONLY. It will **NOT** detect other potentially life-threatening arrhythmias or diseases, such as a possibility of other cardiac arrhythmias or heart attack.

Should I consult with my physician if the “ / Possible AFib” symbol flashes?



It is recommended that you consult with your physician if the

“ /  Possible AFib” symbol flashes. This symbol may flash for other reasons, such as other heart arrhythmias.





What should I do if the “ / Possible AFib” symbol sometimes flashes?

AFib does not always have symptoms. It is recommended that you consult with, and follow the directions of your physician.

I have been diagnosed with AFib by my physician, but the

“ /  Possible AFib” symbol does not flash.

AFib may not occur at the time of specific blood pressure measurements. It is recommended that you consult with your physician regularly.

Is the blood pressure reading reliable when the “ /  Possible AFib ” symbol flashes or the irregular heartbeat symbol “ /  ” appears?

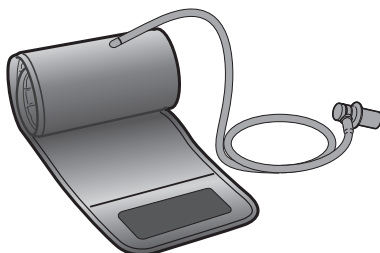
AFib or an irregular heartbeat can influence your blood pressure measurements and make it difficult to get an accurate reading. Therefore, the readings are not displayed when a possibility of AFib is detected. The readings will be displayed if irregular heartbeats are detected, but repeated measurements may be required to overcome fluctuations.* The monitor will indicate an error message (E5) if the influence of the irregular heartbeat is too severe to give a measurement result. If this occurs repeatedly, it is recommended that you consult with your physician.

* O'Brien E, et al.; J Hypertens. 2003; 21: 821-848.

13. Optional Accessories

Easy-Wrap ComFit Cuff

Arm circumference
9" - 17" (22 - 42 cm)

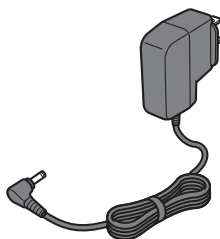


Model: HEM-FL31-B REF HEM-FL31-BZ

Note

- Do not throw the air plug away. The air plug can be applicable to the optional cuff.

AC Adapter



Model: HEM-ADPTW5

For further information, visit our website at OmronHealthcare.com



14. Specifications

| | |
|----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| Model | BP7465 <small>REF</small> HEM-7381T1-AZ |
| 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: ± 5 % of display reading |
| Inflation | Automatic by electric pump |
| Deflation | Automatic pressure release valve |
| Measurement method | Oscillometric method |
| Transmission method | Bluetooth® Low Energy |
| 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: IP21 AC adapter: IP21 |
| Rating | DC6 V 4.0 W |
| Power source | 4 "AA" batteries 1.5 V or AC adapter (INPUT AC100 - 240 V 50 - 60 Hz 0.12 - 0.065 A) |
| Battery life | Approximately 500 measurements (using new alkaline batteries) |
| Durable period (Service life) | Monitor: 5 years or the time when reaching 30000 times of use. Arm cuff: 5 years or the time when reaching 10000 times of use. AC adapter: 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) |

14. Specifications

| | |
|----------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Weight | Monitor: Approximately 15.9 oz. (450 g) not including batteries Arm cuff: Approximately 5.8 oz. (163 g) |
| Dimensions | Monitor: Approximately 7.5" (w) × 3.3" (h) × 4.6" (l) (191 mm × 85 mm × 117 mm) Arm cuff: Approximately 5.7" × 20.9" (air tube: 29.5") (145 mm × 532 mm (air tube: 750 mm)) |
| Cuff circumference applicable to the monitor | 9" to 17" (22 to 42 cm) |
| Memory | Stores up to 100 readings per user |
| Contents | Monitor, Easy-Wrap ComFit Cuff, AC adapter (HEM-ADPTW5), 4 "AA" batteries, instruction manual, quick start guide |
| Protection against electric shock | Internally powered ME equipment (when using only batteries) Class II ME equipment (when using AC adapter) |
| Applied part | Type BF (arm cuff) |



Note

- These specifications are subject to change without notice.
- This monitor is clinically investigated according to the requirements of ISO 81060-2:2013 and complies with ISO 81060-2:2013 and ISO 81060-2:2018+A1:2020. In the clinical validation study, K5 was used on 85 subjects in general population for determination of diastolic blood pressure. This has not been validated for the patients with AFib. If a possibility of AFib was detected during a measurement, the " /  Possible AFib" symbol flashes on the display. *Generally, blood pressure and pulse rate measured during AFib cannot be reliable.* Therefore, the readings are not displayed when a possibility of AFib is detected.
- 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 and AC adapter are protected against solid foreign objects of 0.5 inch (12.5 mm) diameter and greater such as a finger, and are protected against vertically falling water drops which may cause issues during a normal operation.
- Operation mode classification complies with IEC 60601-1.
- Please report to the manufacturer and the regulatory authority in which you are established about any serious incident that has occurred in relation to this device.
- This monitor does not support software updates by the customer. If a cybersecurity event may have occurred, refer to sub-section 4.3 and sub-section 6.2. If the problem persists, refer to section 10 to contact customer service.

About a wireless communication interference

The Bluetooth option in the product is used to connect to dedicated apps on mobile devices to synchronize date/time data from mobile device to the product, and to synchronize measurement data from the product to mobile device. Further handling of the data on the mobile device is up to the user's discretion. This product operates in an unlicensed ISM band at 2.4 GHz where any third party can intercept the radio waves, willfully or accidentally, for any unknown purpose. 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

| | |
|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
|  | Types of marks used to indicate the correct positioning of the artery for the upper arm |
|  | Identifies the type of cuff that is compatible with the blood pressure monitor |



OMRON HEALTHCARE Co., Ltd.
53, Kunotsubo, Terado-cho, Muko, Kyoto, 617-0002 JAPAN

Distributed by:
OMRON HEALTHCARE, INC.
2895 Greenspoint Pkwy. Hoffman Estates, IL 60169 USA

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