# OMRON

### **Wrist Blood Pressure Monitor**

Model BP4350 Instruction Manual



All for Healthcare

2829250-8A

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Thank you for purchasing the OMRON BP4350 Wrist Blood Pressure Monitor. This blood pressure monitor is to be worn on your

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 BP4350 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-

### 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.



Indicates a potentially hazardous situation AWarning 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 or in

oxygen rich environments. This may result in incorrect operation of the monitor and/or cause an inaccurate reading. 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

### Indicates a potentially hazardous situation which, if not avoided, may result in minor or **∴**Caution 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 arteriovenous (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 emit 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

• 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

• Ensure this monitor is not impairing blood circulation by observing the wrist while measurement is occurring. • DO NOT use this monitor in high-use environments such as

medical clinics or physician offices. • DO NOT use this monitor with other medical electrical (ME) equipment simultaneously. This may result in incorrect

operation of the monitor and/or cause an inaccurate reading. · Avoid bathing, drinking alcohol or caffeine, smoking, exercising and eating for at least 30 minutes before taking a 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 the monitor has acclimated to room temperature before taking a measurement. Taking a measurement after an

extreme temperature change could lead to an inaccurate

reading. • DO NOT crease the wrist cuff excessively.

## **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 • Remove batteries if this monitor will not be used for a long

· If battery fluid should get in your eyes, immediately rinse with plenty of clean water. Consult with your physician

• 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.

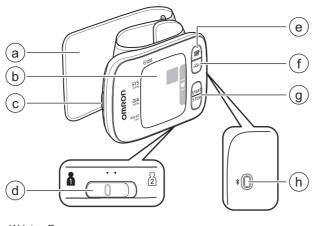
• ONLY use batteries specified for this monitor. Use of s may damage and/or may be ha to this monitor.

### 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))

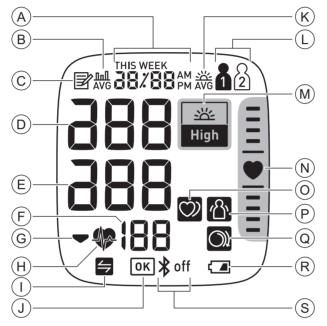
b. Display

c. Battery compartment d. [User ID selection] switch

e. [Memory] button [Morning average] button

g. [START/STOP] button . [Connection] button

### 1.3 Display



### 1.4 Display Symbols

	, -,		
Α	Date and time display		
В	ДлД AVG	Average value symbol Appears when viewing the average readings of the latest 2 or 3 readings taken within 10 minutes span.	
С	<b></b>	Memory symbol Appears when viewing readings stored in the memory.	

# D Systolic blood pressure reading

E Diastolic blood pressure reading

### Pulse display / Memory number

Pulse rate appears after the measurement. When pressing the B button, the memory number appears for approximately one second before the pulse rate appears on the display.

G	-	<b>Deflation symbol</b> Flashes during cuff deflation.
н	*	Heartbeat symbol Flashes while taking a measurement.
ı	<b>5</b>	Sync symbol Flashes 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 your monitor deletes the oldest readings. Up to 100 readings can be stored in the internal memory per user.
J	ОК	OK symbol Flashes when your monitor is connected to the smart device or readings are transferred successfully.

Appears when viewing the weekly average readings

Weekly averages for the measurement taken in the

morning within 4 weeks appear on the display.

The user ID number appears when selecting the user

The " High " symbol appears if your systolic blood

pressure is 135 mmHg or above and/or the diastolic

The "High" " symbol appears when the morning weekly

blood pressure is 85 mmHg or above.

Morning hypertension symbol

average is 135/85 mmHg or above.

Morning average symbol

with [User ID selection] switch.

Hypertension symbol

taken in the morning.

User ID symbol

### 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. Irregular heartbeat symbol Normal Heartbeat Appears along with Pulse \_\_\_\_\_ readings when an irregular rhythm is Blood pressure detected 2 or more times during a Irregular Heartbeat measurement. An irregular heartbeat Pulse \_\_\_\_\_ hythm is defined as a Blood pressure rhythm that is 25% less or 25% more than the average rhythm detected while your monitor is measuring the systolic and diastolic blood pressure. If it continues to appear, we recommend you to consult with and follow the directions of your physician. Movement error symbol 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. Cuff wrap guide symbol Appears if the wrist cuff is not wrapped around the wrist correctly while taking a measurement. It also appears

Heart zone indicator

### Appears when Bluetooth is enabled. **Bluetooth OFF symbol** Appears when Bluetooth is disabled

when viewing past readings.

Appears when batteries are low

Battery symbol (depleted)

Appears when batteries are depleted

Battery symbol (low)

Bluetooth ON symbol

2013 ESH/ESC\* Guidelines for the management of arterial hypertension Definitions of hypertension by office and home blood pressure levels

ommons of hyportons	sion by office and floring	blood pressure levels
	Office	Home
Systolic Blood Pressure	≥ 140 mmHg	≥ 135 mmHg
Diastolic Blood Pressure	≥ 90 mmHg	≥ 85 mmHg

These are from statistical values for blood pressure. \* European Society of Hypertension (ESH) and European Society of Cardiology (ESC).

# **A** Warning

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

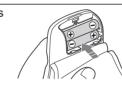
# 2. Preparation

# 2.1 Installing Batteries

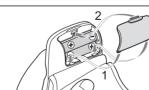
1. Push down the hook of the battery cover and pull downward.



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



Close the battery cover.



• When the " [ " symbol appears on the display, it is recommended you replace batteries.

Replacing batteries will not delete previous readings

• 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.

 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.

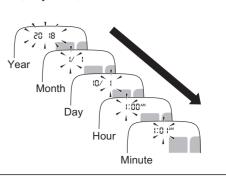
The supplied batteries may have a shorter life than new batteries.

· 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 down the ( ) button to quickly advance the Press and hold down 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.

• If you need to reset the date and time, replace batteries or press 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.

 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

• Following steps are for applying the wrist cuff to your left wrist. When you take a measurement on the right wrist, apply the wrist cuff using the same steps as on the 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

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.

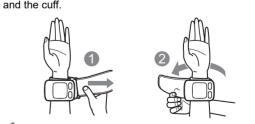
2. Put your wrist through the cuff loop. Your palm and monitor display should both face upward.



**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 Check to make sure that there is no gap between your wrist



✓ Note · Make sure your 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.



• Sit with your back and arm

2.5 Sitting Correctly

To take a measurement, you need

being supported. The distance from the top of your seat measuring to the top of the table you are sitting at,

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

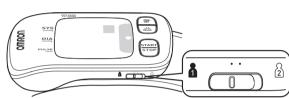
blood pressure will be artificially high. • Relax your wrist and hand. Do not bend your wrist back, clench your fist, or bend your wrist forward.





Your monitor is designed to take measurements and store the readings in the memory for 2 people using the [user ID selection]

1. Select your user ID (1 or 2).



### 3. Using Your Monitor without a Smart Device

You can use your monitor without pairing to a smart device. To pair

### 3.1 Taking a Measurement

• To stop the measurement, press the [START/STOP] button once

your monitor with a smart device, refer to section 4.1.

### 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.

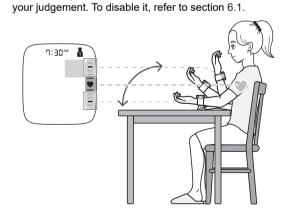
• Remain still and DO NOT talk while taking a measurement

### 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



	Monitor height	Heart Zone Indicator
	Wrist is too high	Any locator bar (-) above the " $ \overline{ igotimes } $ " symbol appears.
<u>=</u>	Proper position	The " $\stackrel{\frown}{ullet}$ " symbol lights in blue.
=	Wrist is too low	Any locator bar (-) below the " $\stackrel{\frown}{\underline{\bullet}}$ " symbol appears.

 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







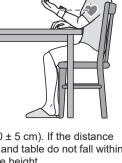








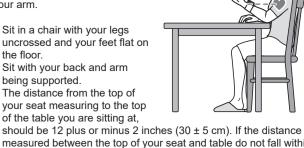


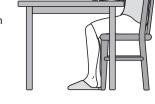












**3.** Remain still and do not move or talk until the entire measurement process is completed.

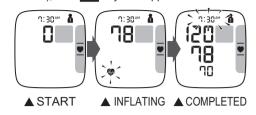
As the cuff inflates, your monitor automatically determines your ideal inflation level. This monitor detects your blood pressure and pulse rate during inflation.

The " \* symbol flashes at every heartbeat.

• 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 1.4), the " High " symbol appears.



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

 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 premeasurement 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





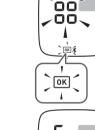
If you already have the "OMRON connect US/CAN" app and have created your account, open the app and add your new

**3.** Open the app on your smart device. Press the [ \* ] button (found on the back of your monitor) for more than 2 seconds to start pairing. Then follow the instructions.

• Make sure that your monitor is turned off. If it is on, press the [START/STOP] button to clear the LCD screen.

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

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

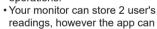


 $\Gamma\Gamma$ 

# ✓ Note

• If the "Err" symbol appears, follow the message of the app. Your monitor automatically turns off

after 10 seconds without any operations.



readings, however the app can only store 1 user's readings. Each user will need his/her own OMRON connect account to transfer their readings. · 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

• Read the utilization method and usage instruction within the app for details.

### 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

### **A** Warning

 This product emits radio frequencies (RF) in the 2.4 GHz band. DO NOT use this product in locations where RF is restricted, such as on an aircraft or in hospitals. Turn off the Bluetooth feature in 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 onto 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 on the [\*] button for more than 2 seconds. "on" appears on the display.

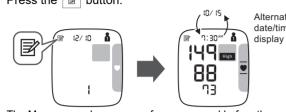
 Your monitor will automatically turn off within 3 seconds after the completion.

### 5. Using Memory Function

Your monitor automatically stores up to 100 readings per user

### 5.1 Viewing the Readings Stored in Memory

1. Select your User ID.



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

• If the heart zone indicator is enabled before the measurement, the heart zone indicator is displayed with the readings

• If the reading is high (refer to section 1.4), 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

------

AVG A

149 High

73

**3.** Press the (**□**) button repeatedly to scroll through the previous readings stored in the memory.

### 5.2 Viewing the Average Reading

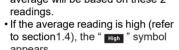
delete the oldest readings

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

1. Select your User ID.

**2.** 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

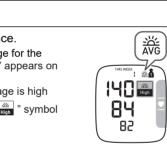


# 5.3 Viewing Morning Weekly Averages

Your monitor calculates and displays weekly averages for the measurements taken in the morning for 4 weeks per user.

1. Select your User ID.

2. Press the (🛎) button once. The morning weekly average for the current week "THIS WEEK" appears on the display If the morning weekly average is high (refer to section 1.4), the " symbol

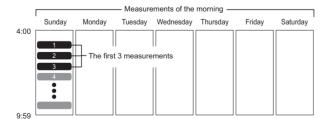


**3.** Continue to press the (عد) button to display the average for the previous weeks Your monitor displays "-1 WEEK" for the previous week's average, to "-3 WEEK" for the oldest set of averages.

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

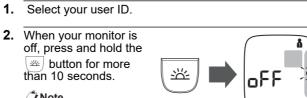
### Morning Weekly Average Calculation

This is the average for the measurements taken during the morning measurements taken in the morning between 4:00am - 9:59am will be used to calculate the morning average for each day.



### 6. Other Settings

### 6.1 Disabling/Enabling Heart Zone Indicator The heart zone indicator is enabled as default.



Your monitor will



automatically turn off

after 3 seconds from the completion • To enable the heart zone indicator, follow the same steps as

### 6.2 Deleting All Readings Stored in Memory

**1.** Select your user ID.

**2.** Press the button, then the " r symbol appears.

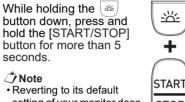
3. While holding the button down, press and hold the [START/ + STOP] button for more than 2 seconds. ∠ Note START All readings will be deleted. ST0P You cannot partially delete

### 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 (44) button down, press and hold the [START/STOP]

the readings stored in the

memory.



setting of your monitor does STOP not delete the information in

the app. Your monitor will

transferred to your app.

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

# 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	The wrist cuff is not applied correctly.	Apply the wrist cuff correctly, then take another measurement. Refer to section 2.4.
wrist cuff does not inflate.	Air is leaking from the wrist cuff.	Contact customer service. Refer to chapter 11.
E B appears	The wrist cuff is overinflated exceeding 300 mmHg.	Do not touch the wrist cuff while taking a measurement.
<b>E 4</b> appears	You move or talk during a measurement. Vibrations disrupt a measurement.	Remain still and do not talk during a measurement. Refer to chapter 3.
appears  Appears	The pulse rate is not detected correctly.	Apply the wrist cuff correctly, then take another measurement. Refer to section 2.4. Remain still and sit correctly during a measurement. Refer to section 2.5.
appears		If the " " symbol continues to appear, we recommend you to consult with your physician.
<b>E n</b> appears	Your wrist is moved up and down during a measurement.	Do not move your wrist, then take another measurement. Refer to chapter 3.
<b>E</b> rappears	The monitor is malfunctioned.	Press the [START/ STOP] button again. If "Er" still appears, contact customer service. Refer to chapter 11.
E	The monior cannot connect to a smart device or transmit data	Follow the instructions shown in the "OMRON connect US/CAN" app. If the "Err" symbol still appears after checking

correctly.

appears

the app, contact

to chapter 11.

customer service. Refer

Display/ Problem	Possible Cause	Solution	
flashes	The [*] button is pressed and held to pair with a smart device.	Appears when pairing to the smart device.	
flashes	The [\$] button is pressed to transfer your readings.	Flashes when transferring your readings to the "OMRON connect US/ CAN" app.	
	More than 80 readings are not transferred.	Pair or transfer your	
flashes	This monitor is ready for pairing or transferring your readings.	readings to the "OMRON connect US/ CAN" app so you can keep them in memory in	
appears	100 readings are not transferred.	the app, and this error symbol disappears.	
heart symbol The heart symbol in the heart zone indicator does not light and a locator bar does not appear.	The "heart zone indicator" is disabled.	Enable the "heart zone indicator". Refer to section 6.1.	
flashes	Batteries are low.	Replacing all batteries with 2 new alkaline batteries is recommended. Refer to section 2.1.	
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	Batteries are completely depleted.		
appears on the display of the monitor.	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 co including stress, time of c apply the wrist cuff, may a pressure. Review section 3.	day, and/or how you affect your blood	
Any other communication	Follow the instructions shown in the smart device If the problem still persists, contact customer		

# 8. Maintenance

### 8.1 Maintenance

issue occurs.

Any other

problems

occurs.

To protect your monitor from damage, please follow the directions

service. Refer to chapter 11.

service. Refer to chapter 11.

install batteries

Press the [START/STOP] button to turn the

measurement. If the problem continues, remove

all batteries and wait for 30 seconds. Then re-

If the problem still persists, contact customer

monitor off, then press it again to take a

• 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 and other components in the storage case when not in use.

 Store your monitor and other components in a clean, safe location. Do not store your monitor and other components: If your monitor and other components are wet

In locations exposed to vibrations or shocks.

• In locations exposed to extreme temperatures, humidity, direct sunlight, dust or corrosive vapors such as bleach.

### 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

• Do not wash or immerse your monitor and wrist cuff or other

components in water.

• Do not use gasoline, thinners or similar solvents to clean your monitor and wrist cuff or other components.

### 8.4 Disposal

9. Specifications

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

Model	BP4350 REF HEM-6232T-Z
Display	LCD digital display
Cuff pressure range	0 to 299 mmHg
Blood pressure	SYS: 60 to 260 mmHg
measurement range	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 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
IP classification	IP 22
Rating	DC3 V 3.0 W
Power source	2 "AAA" alkaline batteries 1.5V
Battery life	Approximately 300 measurements (usin new alkaline batteries)
Durable period (Service life)	5 years
Operating conditions	+50°F to +104°F (+10°C to +40°C) / 15 90% RH (non-condensing) / 800 to 106 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. (90 g) not including batteries
Dimensions	Approximately 3.6" (w) $\times$ 2.5" (h) $\times$ 0.5" (91.0 mm $\times$ 63.4 mm $\times$ 13.4 mm) (not including the wrist cuff)
Measurable wrist circumference	5.3" to 8.5" (13.5 to 21.5 cm)
Memory	Stores up to 100 readings per user
Contents	Monitor, storage case, 2 "AAA" alkaline batteries, instruction manual, quick sta guide
Protection against electric shock	Internally powered ME equipment
Applied part	Type BF (wrist cuff)

• These specifications are subject to change without notice.

• In the clinical validation study, K5 was used on 85 subjects for

determination of diastolic blood pressure

issues during a normal operation.

• This monitor is clinically investigated according to the requirements of ISO 81060-2:2013. • IP classification is degrees of protection provided by enclosures in accordance with IEC 60529. This monitor is protected against

solid foreign objects of 12.5 mm diameter and greater such as a

finger, and against oblique falling water drops which may cause

### 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.

f 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/IC 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/IC radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) Exposure Guidelines and RSS 102 of the IC radio frequency (RF) Exposure rules. This equipment has very low levels of RF energy that are deemed to comply without testing of specific absorption ratio (SAR).

# 11. Limited Warranty

return receipt requested.

Your BP4350 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

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### FOR CUSTOMER SERVICE

Visit our web site at

Call toll free

For USA - OmronHealthcare.com For Canada - OmronHealthcare.ca

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)

BP4350 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 BP4350 on the

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