①EN ②ES ③FR

OMRON

INSTRUCTION MANUAL

Wrist Blood Pressure Monitor

Model BP654

3200764-8A

INTRODUCTION

Thank you for purchasing the OMRON BP654 Wrist Blood Pressure Monitor.

Fill in for future reference.

DATE PURCHASED: _____

SERIAL NUMBER: _____

- *Staple your purchase receipt here*
- *Register your product on-line at www.register-omron.com*

The monitor is compact and easy-to-use at home, at work, and portable for travel. Perfect for people who frequently monitor their own blood pressure.
Your new digital blood pressure monitor uses the oscillometric method of blood pressure measurement. This means the monitor detects your blood's movement through your brachial artery and converts the movements into a digital reading. An oscillometric monitor does not need a stethoscope so the monitor is simple to use. Clinical research has proven a direct relationship between blood pressure in the wrist and blood pressure in the arm. Changes in wrist blood pressure reflect changes in arm blood pressure because the arteries in the wrist and the arm are close to each other. Frequently measuring the blood pressure in your wrist will provide your physician with an accurate indication of changes in your blood pressure.
The BP654 comes with the following components:
• Monitor • Storage Case • 2 "AAA" Alkaline Batteries
• Instruction Manual • Quick Start Guide

Please read this instruction manual thoroughly before using the unit. Please keep for future reference. For specific information about your own blood pressure, CONSULT YOUR DOCTOR.

SAVE THESE INSTRUCTIONS

SAFETY INFORMATION

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 1/4 inches to 8 1/2 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.

To assure the correct use of the product, basic safety measures should always be followed including the warnings and cautions listed in this instruction manual.

SAFETY SYMBOLS USED IN THIS INSTRUCTION MANUAL	
⚠ WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
⚠ CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property.

GENERAL USAGE
⚠ Contact your physician for specific information about your blood pressure. Self-diagnosis and treatment using readings may be dangerous. Follow the instructions of your physician or licensed healthcare provider.
⚠ 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.
⚠ The monitor is not intended to be a diagnostic device.
⚠ Consult your physician before using the device for any of the following conditions: common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, arterial sclerosis, poor perfusion, diabetes, age, pregnancy, pre-eclampsia, renal diseases. Note that PATIENT motion, trembling, shivering may affect the reading.
⚠ Do not use the device on the injured wrist or the wrist under medical treatment.
⚠ Do not apply the wrist cuff on the arm while being on an intravenous drip or blood transfusion.
⚠ Contains small parts that may cause a choking hazard if swallowed by infants.
⚠ Consult your physician before using the device on the wrist with an arterio-venous (A-V) shunt.
⚠ Do not use the device with other medical electrical (ME) equipment simultaneously.
⚠ Do not use the device in the area the high frequency (HF) surgical equipment, magnetic resonance imaging (MRI), or computerized tomography (CT) scanner exists, or in the oxygen rich environment.

BATTERY USAGE
⚠ Keep the batteries out of the reach of young children.

DATA TRANSMISSION
⚠ Do not use this product on aircraft or in hospitals. Please remove the battery from the unit. This product emits radio frequencies (RF) in the 2.4 GHz band, use of this product in locations where RF is restricted is not recommended.
The use of RF in this product is licensed for use by the FCC/IC, for further information on any potential restrictions refer to documentation on *Bluetooth*® usage by the FCC/IC.

GENERAL USAGE
⚠ Consult your physician before using the device for any of the following conditions:
• If you have had a mastectomy.
• If you have a condition that may compromise circulation, you may get an inaccurate reading with this device.
• People with severe blood flow problems or blood disorders as cuff inflation can cause bruising.
⚠ Do not take measurements more than necessary. It may cause bruising due to blood flow interference.
⚠ Read all of the information in the instruction manual and any other literature in the box before operating the unit.
⚠ Do not use this device on infants or persons who cannot express their intentions.
⚠ Operate the device only as intended. Do not use the device for any other purpose.
⚠ Do not use a mobile phone or other devices that emit electromagnetic fields near the device except when in use for wireless communications. This may result in incorrect operation of the device.
⚠ Do not use the device in a moving vehicle (car, airplane).
⚠ Use only Omron authorized parts and accessories. Parts and accessories not approved for use with the device may damage the unit.
⚠ Although this device is waterproof (IP22), please be careful about the operating environment.

BATTERY USAGE
⚠ Use only 1.5V Alkaline batteries with this device. Do not use other types of batteries. This may damage the device.
⚠ Do not replace the batteries while the data is transferred.

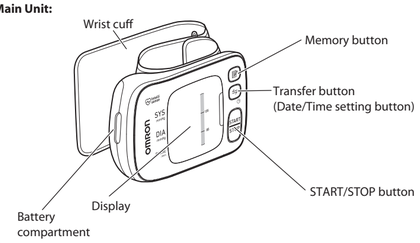
GENERAL PRECAUTIONS
⚠ Do not subject the monitor to strong shocks, such as dropping the unit on the floor.
⚠ Do not submerge the device or any of the components in water.
⚠ Store the device and the components in a clean, safe location.
⚠ Changes or modification not approved by the manufacturer will void the user warranty. Do not disassemble or attempt to repair the unit or components. This may cause an inaccurate reading as well.
⚠ Do not use the device outside the specified environment. It may cause an inaccurate reading.
⚠ Dispose of the device, components and optional accessories according to applicable local regulations. Unlawful disposal may cause environmental pollution.

BEFORE TAKING A MEASUREMENT

To ensure a reliable reading, follow these recommendations:
1. Avoid eating, drinking alcohol, smoking, exercising, and bathing for 30 minutes before taking a measurement. Rest for at least 5 minutes before taking the measurement.
2. Stress raises blood pressure. Avoid taking measurements during stressful times.
3. The cuff can be applied to your left or right wrist.
4. Measurements should be taken in a quiet place.
5. Position the unit at heart level throughout the measurement.
6. Remain still and do not talk during the measurement.
7. Keep 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. Try to measure your blood pressure at the same time each day for consistency.

KNOW YOUR UNIT

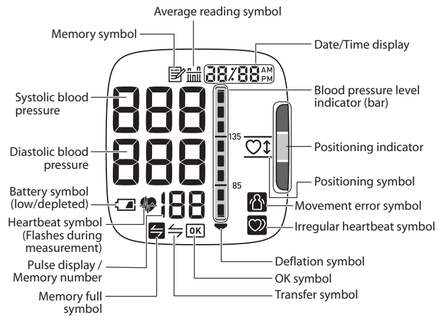
Main Unit:



Components:

2 "AAA" Alkaline Batteries | **Storage Case** | **Instruction Manual** | **Quick Start Guide**

UNIT DISPLAY

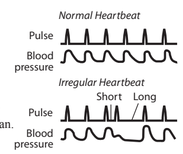


DISPLAY SYMBOLS

HEARTBEAT SYMBOL ( )
The Heartbeat symbol flashes on the display at every heartbeat during the measurement.

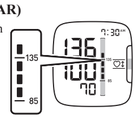
AVERAGE READING SYMBOL ( )
The Average Reading Symbol is displayed when you press and hold the button for more than 2 seconds. The most recent average reading appears on the display screen.

IRREGULAR HEARTBEAT SYMBOL ( )
When the monitor detects an irregular rhythm two or more times during the measurement, the Irregular Heartbeat Symbol will appear on the display with the readings.
An irregular heartbeat rhythm is defined as a rhythm that varies by 25% less or 25% more than the average rhythm detected while the monitor is measuring the systolic and diastolic blood pressure.
If the irregular heartbeat symbol displays with your readings, we recommend you consult your physician. Follow the directions of your physician.



MOVEMENT ERROR SYMBOL ( )
The Movement Error Symbol ( ) is displayed if you move your body during the measurement. Please remove the wrist cuff, and wait 2-3 minutes. Reapply the wrist cuff and take another measurement.

BLOOD PRESSURE LEVEL INDICATOR (BAR)
Blood pressure level indicator (bar) will light up between the systolic blood pressure and the diastolic blood pressure.



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

	Office	Home
Systolic Blood Pressure	≥ 140 mmHg	≥ 135 mmHg
Diastolic Blood Pressure	≥ 90 mmHg	≥ 85 mmHg

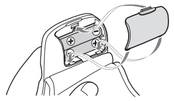
BATTERY INSTALLATION

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

2. Install 2 "AAA" size batteries so the + (positive) and - (negative) polarities match the polarities of the battery compartment as indicated.

3. Replace the battery cover.

NOTE: Make sure that the battery cover is securely in position.



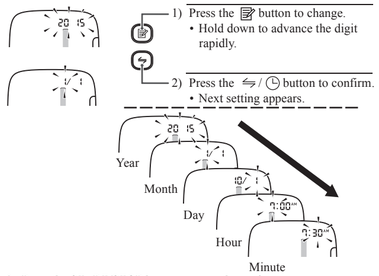
⚠ WARNING
• If battery fluid should get in your eyes, immediately rinse with plenty of clean water. Contact a physician immediately.
• Keep the batteries out of the reach of young children.

NOTES:
• When the depleted battery symbol ( ) appears on the display, turn the monitor off and remove all the batteries. Replace with 2 new batteries at the same time.
• Turn the unit off before replacing the batteries. If the batteries are removed while the unit is still on, the date and time will be reset to that of the previous use. The readings are not deleted.
• When the batteries are replaced, you may need to reset the date and time. Refer to "Setting the Date and Time".
• The batteries included with the device may have a shorter life.

SETTING THE DATE AND TIME

Set the monitor to the correct date and time before taking a measurement for the first time.

1. When the unit is off, press the / button repeatedly until the year flashes on the display.
2. Set the monitor to the correct date and time .



3. Press the START/STOP button to store the setting.

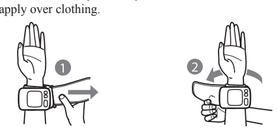
NOTES:
• If the batteries have been removed, the date and time setting will need to be reset.
• The date and time can be automatically set when you transfer your readings to the Omron Wellness App. However, the date/time will only be set for future measurements taken after the reading that was transferred, it will not be saved to the reading that was just transferred.
• If the date and time are not set, "-:--" appears during or after measurement.

APPLYING THE WRIST CUFF

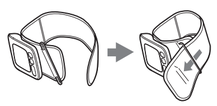
APPLYING THE CUFF ON THE LEFT WRIST
1. Roll up sleeve. Make sure your sleeve is not rolled up too tightly on your arm. This may constrict the flow of blood in your arm.

2. Put your arm through the cuff loop. Your palm should face upward.

3. Position the cuff leaving a clearance of approximately 1/2 inch (1 cm to 2 cm) between the cuff and the bottom of your palm.
4. Wrap the wrist cuff firmly around your wrist. Do not apply over clothing.



NOTES:
• Make sure the wrist cuff does not cover the protruding part of the wrist bone on the outside of the wrist.
• If the wrist cuff comes off, re-assemble as shown in the figure.



APPLYING THE CUFF ON THE RIGHT WRIST
When taking a measurement using the right wrist position the cuff as shown in the illustration.

TAKING A MEASUREMENT

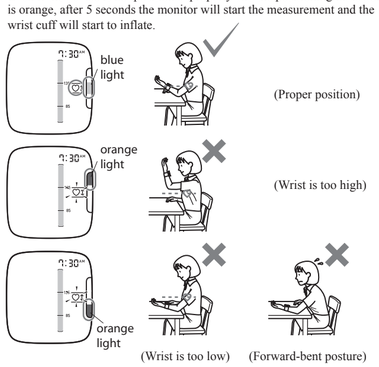
1. Sit comfortably on a chair with your feet flat on the floor. Keep your back straight. Place your elbow on a table and and elevate cuff wrist to heart level.

NOTES:
• The distance from the top of your seat measuring to the top of the table you are sitting at, should be 12 ± 2 inches (30 ± 5 cm). If the distance measured between the top of your seat and table do not fall within this parameter, please correct your seat or table height. If you are unable to make any seat or table adjustments, please turn off the position indicator and position your wrist at heart-level by yourself.
• The cuff must be approximately the same height as your heart. If the cuff is too high above your heart, your blood pressure will read artificially low. If the cuff 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.

2. Press the START/STOP button to start the measurement.

All symbols appear on the display before starting the measurement.

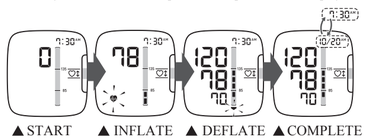
Positioning Indicator - The monitor has a built-in positioning indicator that is used as an aid in determining if the monitor is at the correct height. It has been designed to work with most people so that when your wrist is at the correct position relative to your heart, the positioning indicator will be blue. If the positioning indicator changes to orange, the device may not be at the correct height relative to your heart. Due to difference in individual size and physique, this feature may not helpful in all cases and you may wish to turn off this feature. If you feel the position of the wrist according to positioning indicator's guidance does NOT match your heart level, please turn off this feature and follow your judgement. It can be disabled, see "Turn OFF (ON) the Positioning Indicator".
NOTE: Even if the device is not positioned properly and the positioning indicator is orange, after 5 seconds the monitor will start the measurement and the wrist cuff will start to inflate.



As the cuff inflates, the monitor automatically determines your ideal inflation level. This monitor detects your blood pressure and pulse rate during inflation. The Heartbeat Symbol ( ) flashes at every heartbeat.

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

After the monitor has detected your blood pressure and pulse rate, the cuff automatically deflates. Your blood pressure and pulse rate are displayed.



NOTE: To stop the inflation or measurement, push the START/STOP button. The monitor will stop inflating, start deflating, and will turn off.

3. Press the START/STOP button to turn the monitor off.

NOTES:
• The monitor will automatically turn off after 2 minutes.
• Wait 2-3 minutes between measurements. The wait time allows the arteries to return to the condition prior to taking the blood pressure measurement. You may need to increase the wait time depending on your individual physiological characteristics.

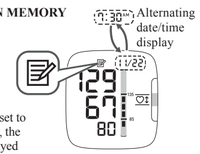
TURN OFF (ON) THE POSITIONING INDICATOR
The positioning indicator is set "on" as default.
1. When the unit is off, press and hold the / and button for more than 5 seconds to set the positioning indicator.

2. Press the START/STOP button to store the positioning indicator setting.

USING THE MEMORY FUNCTION

The monitor automatically stores up to 100 readings.
It can also calculate an average reading based on the last 3 readings taken within 10 minutes.

TO VIEW THE READINGS STORED IN MEMORY
1. Press the button.

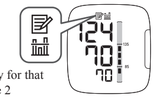


The Memory number appears for a second before the pulse rate is displayed. The most recent reading set is numbered "1".

NOTES:
• If the positioning indicator is set to "on" before the measurement, the positioning indicator is displayed with the readings.
• When viewing the readings taken without setting the date and time, "-:--" is displayed instead of the date and time.
• If there are no readings stored in the memory, the screen to the right is displayed.

2. Press the button repeatedly to view the readings stored in the memory.

TO VIEW THE AVERAGE READING
When the unit is off, press and hold the button for more than 2 seconds.



NOTES:
• If the previous measurement was taken without setting the date and time, the average reading is not calculated.
• If there are only 2 readings in the memory for that period, the average will be based on these 2 readings.
• If there is 1 reading in the memory for that period, this is displayed as the average.

TO PAIR THIS DEVICE WITH A SMARTPHONE
To begin using the OMRON Wellness software for the first time, please visit www.omronwellness.com for the initial set-up instructions.
1. Download and install onto your smartphone, the free "Omron Wellness" App.

Download on the App Store | ANDROID APP ON Google play

2. Open the App on your smartphone and follow set-up and pairing instructions.

NOTE: Please make sure that you do not currently have an active reading screen on. If there is a reading on the screen, press the START/STOP button to clear the screen to allow you to begin to transfer your readings.

3. Press and hold the / button for more than 2 seconds.

The transfer symbol ( ) will appear on the display.

4. Open the App on your smartphone and follow the device pairing instructions shown on your smartphone, while the transfer symbol is flashing on the display.

5. The OK symbol and will flash when pairing is completed.

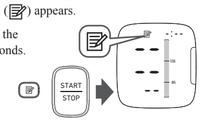
Any readings currently saved in the blood pressure monitor's memory will automatically be transferred to the App after successful completion of the pairing process.

NOTES:
• If the pairing has failed, the screen to the right is displayed.
• The monitor will automatically turn off after 10 seconds without any operations.

TO TRANSFER THE DATA
1. Open the App on your smartphone and log in.
2. Tap "Transfer Readings" on the App and follow the instructions.

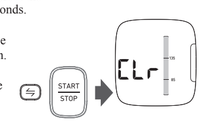
NOTE: When the Memory full symbol ( ) blinks or is lit on the display, transfer the data before the readings are deleted.
Blinking: 80 readings have been stored.
Lit: 100 readings have been stored.
If the memory is full, the monitor will delete the oldest reading. Please transfer your readings to the Omron Wellness App to help ensure your data is saved before old readings are deleted from the memory.

TO DELETE ALL THE READINGS STORED IN MEMORY
1. Press the button, the memory symbol ( ) appears.
2. While holding the button down, press the START/STOP button for more than 2 seconds.



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

TO DELETE ALL READINGS AND SETTINGS
You can delete all readings and settings when you want to dispose of the device or present it to others.
1. While holding the / button down, press the START/STOP button for more than 5 seconds.
2. When the CLr symbol appears, release the / button and START/STOP button.
3. Press the START/STOP button to turn the monitor off.



NOTES:
• Unpairing your device will not delete the information in the mobile App.
• The monitor will automatically turn off after 2 minutes.
• If you re-pair your smartphone to your blood pressure monitor, all prior reading history stored on the mobile App will be retained.

CARE AND MAINTENANCE

To keep your digital blood pressure monitor in the best condition and protect the unit from damage, follow the directions listed below:

⚠ **CAUTION**
- Do not forcefully bend the cuff. Do not fold tightly.
- Clean the monitor with a soft and dry cloth.
- Do not use any abrasive or volatile cleaners.
- Wipe clean on the surface of the cuff with a soft, moistened cloth with a dilution of neutral detergent.
- Do not allow any liquids inside the cuff. If a liquid gets in the cuff, dry the inside well.

⚠ **CAUTION**
Do not wash the device and any components or immerse them in water. Do not subject the monitor to extreme hot or cold temperatures, humidity or direct sunlight.

⚠ **CAUTION**
Store the device and the components in a clean, safe location.

⚠ **CAUTION**
Do not subject the monitor to strong shocks, such as dropping the unit on the floor.

⚠ **CAUTION**
Remove the batteries if the unit will not be used for three months or longer. Always replace all the batteries with new ones at the same time.

⚠ **CAUTION**
Use only OMRON authorized parts and accessories. Parts and accessories not approved for use with the device may damage the unit.

⚠ **CAUTION**
Changes or modification not approved by the manufacturer will void the user warranty. Do not disassemble or attempt to repair the unit or components.

⚠ **CAUTION**
Do not store the device in the following situations:
- If the device is wet.
- Locations exposed to extreme temperatures, humidity, direct sunlight, dust or corrosive vapors such as bleach.
- Locations exposed to vibrations, shocks or where it will be at an angle.

ERROR MESSAGES

SYMBOL	CAUSE	CORRECTION
	Irregular heartbeats are detected.	Please remove the wrist cuff, and wait 2-3 minutes. Reapply the wrist cuff and take another measurement. Repeat the steps in section "Taking a Measurement". If this error continues to appear, contact your physician.
	Movement during measurement.	Carefully read and repeat the steps in section "Taking a Measurement".
E1	Wrist cuff not applied correctly.	Apply the wrist cuff correctly. Refer to "Applying the Wrist Cuff".
E3	Movement during measurement.	Do not hold the wrist cuff. Remain still and do not talk during measurement. Refer to "Taking a Measurement".
E4		
E5	Wrist cuff not applied correctly or movement during measurement.	Apply the wrist cuff correctly. Refer to "Applying the Wrist Cuff". Remain still and do not talk during measurement. Refer to "Taking a Measurement".
E7	Arm position changed during measurement.	Remain still until the measurement is complete. Refer to "Taking a Measurement".
Er	Device error.	Contact Customer Service.
	Batteries are low.	Recommend to replace the batteries with new ones ahead of time. Refer to "Battery Installation".
	Batteries are depleted.	Replace the two batteries. Refer to "Battery Installation".

TROUBLESHOOTING TIPS

PROBLEM	CAUSES AND SOLUTIONS
No power. No display appears on the unit.	Replace both batteries with new ones at the same time. Check the battery installation for proper placement of the battery polarities. Review the section "Battery Installation".
Readings appear too high or too low.	Blood pressure varies constantly. Many factors including stress, time of day, how you wrap the cuff, where you position your wrist, may affect your blood pressure. Review the sections "Before Taking a Measurement" and "Taking a Measurement".
Data cannot be sent.	The destination device is too far away from the monitor. After checking that there are no sources of interference nearby, move the device to a distance within 16 ft. (5 m) of the monitor.
	The *Bluetooth* function on the destination device is turned off. Turn on the *Bluetooth* function and try sending the data again.
	The *Bluetooth* function on the monitor is not turned on. Press the ⇋ / ◷ button, turn on the *Bluetooth* function and try sending the data again.
	Pairing (registering) has not been completed. Perform pairing (registration). Refer to "To Pair This Device With a Smartphone".
	The application on the destination device is not ready. Check the application then try sending the data again. Refer to "To Pair This Device With a Smartphone". If the Err symbol still lights after checking the application, contact customer service.

FCC/IC STATEMENT AND TRADEMARKS

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

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).

This device complies with Part 15 of FCC Rules and Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of this device.

This Product operates in the unlicensed ISM band at 2.4GHz. In case this Product is used around the other wireless devices including microwave and wireless LAN, which operate same frequency band of this Product, there is a possibility that interference occurs between this Product and such other devices. If such interference occurs, please stop the operation of other devices or relocate this Product before using this Product or do not use this Product around the other wireless devices.

The *Bluetooth*® *Smart* word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by OMRON HEALTHCARE Co.,Ltd. is under license. Other trademarks and trade names are those of their respective owners.

Apple, the Apple logo, iPad, and iPhone are trademarks of Apple Inc., registered in the U.S. and other countries.
App Store is a service mark of Apple Inc.

Android and Google Play are both trademarks of Google Inc.

Samsung and Galaxy S are both registered trademarks of Samsung Electronics Co., Ltd.

LIMITED WARRANTY

Your BP654 Wrist Blood Pressure Monitor, excluding the 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 Proof of Purchase. Include a letter, with your name, address, phone number, and description of the specific problem. Pack the product carefully to prevent damage in transit. Because of possible loss in transit, we recommend insuring the product with return receipt requested.

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

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

This warranty provides you with specific legal rights, and you may have other rights which vary from state to state. Some states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you. 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.

FOR CUSTOMER SERVICE

Visit our web site at: www.omronhealthcare.com / www.omronhealthcare.ca
Call toll free: 1-800-634-4350

SPECIFICATIONS

Model:	BP654 REF HEM-6320T-Z
Display:	LCD Digital Display
Measurement Range:	Pressure: 0 mmHg to 299 mmHg Pulse: 40 beats/min to 180 beats/min
Accuracy:	Pressure: ±3 mmHg or 2% of reading Pulse: ±5% of reading
Inflation:	Automatic by electric pump
Deflation:	Automatic rapid deflation
Measurement Method:	Oscillometric method
IP Classification :	IP 22
Power Source:	2 "AAA" alkaline batteries 1.5V
Battery Life:	Approximately 300 uses with 2 new alkaline batteries
Operating Temperature /Humidity:	50ºF to 104ºF (10ºC to 40ºC) /15% RH to 90% RH
Storage Temperature /Humidity/Air Pressure:	-4ºF to 140ºF (-20ºC to 60ºC) /10% RH to 95% RH 700 hPa to 1060 hPa
Main Unit Weight:	Approximately 3 1/2 oz. (100 g) not including batteries
Main Unit Dimensions:	Approximately 3 1/2"(w) × 2 3/8"(l) × 1"(d) (89 mm × 61 mm × 25 mm) (not including the wrist cuff)
Measurable Circumference of Wrist:	Approximately 5 1/4" to 8 1/2" (13.5 cm to 21.5 cm)
Memory:	Up to 100 readings
Contents:	Main Unit, Storage Case, 2 "AAA" Alkaline Batteries, Instruction Manual, and Quick Start Guide
Protection against Electric Shock:	Internally powered ME equipment
Applied Part:	= Type BF

NOTES:
- These specifications are subject to change without notice.
- In the clinical validation study, the 5th phase was used on 85 subjects for determination of diastolic blood pressure.
- This device has not been validated for use in pregnancy.
- IP classification is degrees of protection provided by IEC 60529.

GUIDANCE AND MANUFACTURER'S DECLARATION

OMRON Wrist Blood Pressure Monitor (BPM)

Information for accompanying documents in the scope of IEC60601-1-2:2007

Important information regarding Electro Magnetic Compatibility (EMC)

With the increased number of electronic devices such as PC's and mobile (cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and create a potentially unsafe situation. Medical devices should also not interfere with other devices.

In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the IEC60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices.

Medical devices manufactured by OMRON Healthcare conform to this IEC60601-1-2:2007 standard for both immunity and emissions.
Nevertheless, special precautions need to be observed:
- The use of accessories and cables other than those specified by OMRON, with the exception of cables sold by OMRON as replacement parts for internal components, may result in increased emission or decreased immunity of the device.
- The medical devices should not be used adjacent to or stacked with other equipment.
  In case adjacent or stacked use is necessary, the medical device should be observed to verify normal operation in the configuration in which it will be used.
- Refer to further guidance below regarding the EMC environment in which the device should be used.
- The MEDICAL ELECTRICAL EQUIPMENT BPM needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this documentations.
- The Essential Performance of the BPM is to measure a blood pressure and a pulse rate and using the memory function.

The BPM may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSION requirements.

(Table 1)

Guidance and manufacturer's declaration – electromagnetic emissions

OMRON BPM is intended for use in the electromagnetic environment specified below. The customer or the user of this OMRON BPM should assure that it is used in such environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The OMRON BPM uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The OMRON BPM is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable.	
Voltage fluctuations/ flicker emissions IEC61000-3-3	Not Applicable.	

(Table 2)

Guidance and manufacturer's declaration – electromagnetic immunity

OMRON BPM is intended for use in the electromagnetic environment specified below. The customer or the user of this OMRON BPM should assure that it is used in such environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not Applicable.	Not Applicable.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not Applicable.	Not Applicable.
Voltage dips, short interruptions and voltage variations on power supply inputlines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle	Not Applicable.	Not Applicable.
	40 % U_T (60 % dip in U_T) for 5 cycles		
	70 % U_T (30 % dip in U_T) for 25 cycles		
	<5 % U_T (>95 % dip in U_T) for 5 sec.		
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the A.C. mains voltage prior to application of the test level.

(Table 4)

Guidance and manufacturer's declaration – electromagnetic immunity

OMRON BPM is intended for use in the electromagnetic environment specified below. The customer or the user of this OMRON BPM should assure that it is used in such environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the OMRON BPM including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter. **Recommend separation distance**
Conducted RF IEC 61000-4-6	3 V rms 150 kHz to 80 MHz	Not Applicable.	Not Applicable.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

Note1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the OMRON BPM is used exceeds the applicable RF compliance level above, the OMRON BPM should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the OMRON BPM.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

(Table 6)

Recommended separation distance between portable and mobile RF communications equipment and the OMRON BPM

OMRON BPM is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this OMRON BPM can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the OMRON BPM as recommended below, according to the maximum output power of the communications equipment.

Output Power of Transmitter in Watt	Separation distance according to frequency of transmitter in meter		
	150 kHz to 80 MHz Not Applicable.	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5GHz $d = 2.3\sqrt{P}$
0.01	Not Applicable.	0.12	0.23
0.1	Not Applicable.	0.38	0.73
1	Not Applicable.	1.2	2.3
10	Not Applicable.	3.8	7.3
100	Not Applicable.	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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

Distributed by :
OMRON HEALTHCARE, INC.
1925 West Field Court
Lake Forest, IL 60045 U.S.A.

www.omronhealthcare.com
© 2014 OMRON HEALTHCARE, INC.

Made in Vietnam