

Automatic Wrist Blood Pressure Monitor



RS3 Intelli IT (HEM-6161T-E) Instruction Manual

IM-HEM-6161T-E-EN-01-09/2018
4602352-2A

All for Healthcare

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Introduction

Thank you for purchasing the RS3 Intelli IT Automatic Wrist Blood Pressure Monitor. This blood pressure monitor is to be worn on your wrist.

This blood pressure monitor uses the oscillometric method of blood pressure measurement. When the 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 RS3 Intelli IT Automatic 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 your OMRON retail outlet or distributor before attempting to use this monitor. For specific information about your own blood pressure, consult with your physician.

Intended Use

This device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 13.5 cm to 21.5 cm. This monitor detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings. It is mainly designed for general household use.

Receiving and Inspection

Remove this monitor from the packaging and inspect for damage. If this monitor is damaged, DO NOT USE and consult with your OMRON retail outlet or distributor.

Important Safety Information

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

Please follow this instruction manual thoroughly for your safety. Please keep for future reference. For specific information about your own blood pressure, CONSULT WITH YOUR PHYSICIAN.

Warning Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

- DO NOT use this monitor on infants, toddlers, children or persons who cannot express themselves.
- DO NOT adjust medication based on readings from this blood pressure monitor. Take medication as prescribed by your physician. ONLY a physician is qualified to diagnose and treat high blood pressure.
- DO NOT use this monitor on an injured wrist or a wrist under medical treatment.
- DO NOT apply the wrist cuff on your wrist while on an intravenous drip or blood transfusion.
- DO NOT use this monitor in areas containing high frequency (HF) surgical equipment, magnetic resonance imaging (MRI) equipment, computerized tomography (CT) scanners. This may result in incorrect operation of the monitor and/or cause an inaccurate reading.
- DO NOT use this monitor in oxygen rich environments or near flammable gas.
- Consult with your physician before using this monitor if you have common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation; arterial sclerosis; poor perfusion; diabetes; pregnancy; pre-eclampsia or renal disease. NOTE that any of these conditions in addition to patient motion, trembling, or shivering may affect the measurement reading.
- NEVER diagnose or treat yourself based on your readings. ALWAYS consult with your physician.
- This product contains small parts that may cause a choking hazard if swallowed by infants, toddlers or children.

Data Transmission

This product emits radio frequencies (RF) in the 2.4 GHz band. DO NOT use this product in locations where RF is restricted, such as on an aircraft or in hospitals. Turn off the Bluetooth feature in this monitor and remove batteries when in RF restricted areas.

Battery Handling and Usage

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

Caution Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient, or cause damage to the equipment or other property.

- Stop using this monitor and consult with your physician if you experience skin irritation or discomfort.

- Consult with your physician before using this monitor on a wrist where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present because of temporary interference to blood flow which could result in injury.
- Consult with your physician before using this monitor if you have had a mastectomy.
- Consult with your physician before using this monitor if you have severe blood flow problems or blood disorders as cuff inflation can cause bruising.
- DO NOT take measurements more often than necessary because bruising, due to blood flow interference, may occur.
- ONLY inflate the wrist cuff when it is applied on your wrist.
- Remove the wrist cuff if it does not start deflating during a measurement.
- DO NOT use this monitor for any purpose other than measuring blood pressure.
- During measurement, make sure that no mobile device or any other electrical device that emits electromagnetic fields is within 30 cm of this monitor. This may result in incorrect operation of the monitor and/or cause an inaccurate reading.
- DO NOT disassemble or attempt to repair this monitor or other components. This may cause an inaccurate reading.
- DO NOT use in a location where there is moisture or a risk of water splashing this monitor. This may damage this monitor.
- DO NOT use this monitor in a moving vehicle such as in a car.
- DO NOT drop or subject this monitor to strong shocks or vibrations.
- DO NOT use this monitor in places with high or low humidity or high or low temperatures. Refer to chapter 7.
- 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 this monitor has acclimated to room temperature before taking a measurement. Taking a measurement after an extreme temperature change could lead to an inaccurate reading. OMRON recommends waiting for approximately 2 hours for the monitor to warm up or cool down when the monitor is used in an environment within the temperature specified as operating conditions after it is stored either at the maximum or at the minimum storage temperature. For additional information of operating and storage/transport temperature, refer to chapter 7.
- DO NOT crease the wrist cuff excessively.
- Read and follow the "Correct Disposal of This Product" in chapter 9 when disposing of the device and any used accessories or optional parts.
- DO NOT use this monitor after the durable period has ended. Refer to chapter 7.

Data Transmission

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

Battery Handling and Usage

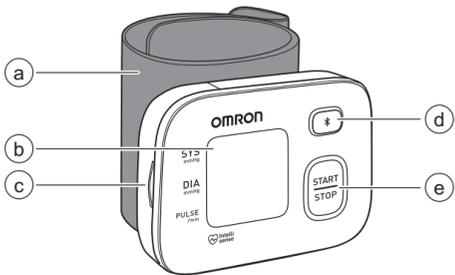
- DO NOT insert batteries with their polarities incorrectly aligned.
- ONLY use 2 "AAA" alkaline batteries with this monitor. DO NOT use other types of batteries. DO NOT use new and used batteries together. DO NOT use different brands of batteries together.
- Remove batteries if this monitor will not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

1. Know Your Monitor

1.1 Contents

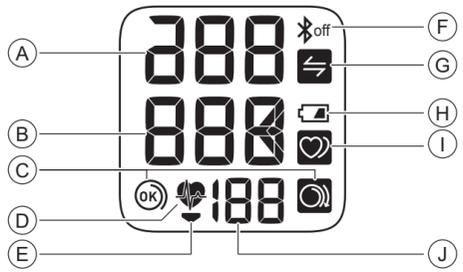
Monitor, 2 "AAA" alkaline batteries, storage case, instruction manual, setup instructions

1.2 Monitor



- a. Wrist cuff (Wrist circumference 13.5 cm to 21.5 cm)
- b. Display
- c. Battery compartment
- d. [Connection] button
- e. [START/STOP] button

1.3 Display and Symbols



| | | |
|----------|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| A | Systolic blood pressure reading | |
| B | Diastolic blood pressure reading | |
| C | | Cuff wrap guide symbol (OK) Appears if the wrist cuff is wrapped around the wrist correctly while taking a measurement. It also appears when viewing past readings. |
| C | | Cuff wrap guide symbol (loose) Appears if the wrist cuff is not wrapped around the wrist correctly while taking a measurement. It also appears when viewing past readings. |
| D | | Heartbeat symbol Flashes while taking a measurement. Appears if your systolic blood pressure is 135 mmHg or above and/or the diastolic blood pressure is 85 mmHg or above. |
| E | | Deflation symbol Appears during cuff deflation. |
| F | | Bluetooth ON symbol Appears when Bluetooth is enabled. |
| F | | Bluetooth OFF symbol Appears when Bluetooth is disabled. |
| G | | Sync symbol Flashes/appears when your data needs to be transferred because the stored memory is either almost, or completely full. Once you pair your monitor with a smart device, transfer your readings immediately before the monitor deletes the oldest readings. Up to 30 readings can be stored in the internal memory. |
| H | | Battery symbol (low) Flashes when batteries are low. |
| H | | Battery symbol (depleted) Appears when batteries are depleted. |
| I | | Irregular heartbeat symbol Appears along with readings when an irregular rhythm is detected 2 or more times during a measurement. An irregular heartbeat rhythm is defined as a rhythm that is 25% less or 25% more than the average rhythm detected while your monitor is measuring blood pressure. If it continues to appear, we recommend you to consult with and follow the directions of your physician. |
| J | Pulse display / Memory number Pulse rate appears after the measurement. | |

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 |

These ranges are from statistical values for blood pressure.

* European Society of Hypertension (ESH) and European Society of Cardiology (ESC).

Warning

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

2. Preparation

2.1 Installing Batteries

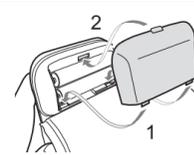
1. Push down the hook of the battery cover and pull downward.



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



3. Close the battery cover.



Note

- When the " " symbol flashes on the display, it is recommended you replace batteries.
- To replace batteries, turn your monitor off and remove all batteries. Then replace with 2 new alkaline batteries at the same time.
- Replacing batteries will not delete previous readings.
- The supplied batteries may have a shorter life than new batteries.
- Disposal of used batteries should be carried out in accordance with local regulations.
- As soon as batteries are correctly installed, "P" flashes on the display to start pairing. To pair your monitor, refer to section 2.2. If your monitor has already been paired with your smart device when batteries are installed, "O" will flash. If it flashes, transfer your readings.

2.2 Pairing Your Monitor with a Smart Device

Review the list of compatible smart devices at www.omronconnect.com/devices/

1. Enable Bluetooth on your smart device.

2. Download and install the free "OMRON connect" app onto your smart device.



If you already have the "OMRON connect" app, open the app and add your new monitor.

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

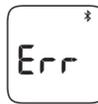
4. Confirm that your monitor is connected successfully.

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



Note

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



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. Please use the Blood Pressure Diary to keep records of several readings over a certain period of time. To download PDF files of the diary, visit www.omron-healthcare.com.

Caution

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

2.4 Applying the Wrist Cuff

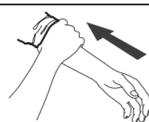
Note

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

Caution

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

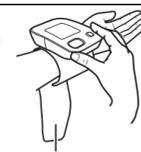
1. Apply the wrist cuff to your left wrist.



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

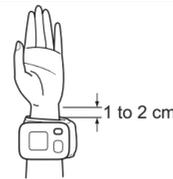
2. Put your wrist through the cuff loop.

Your palm and monitor display should both face upward.



Wrist cuff

3. Position the wrist cuff leaving a clearance of 1 to 2 cm between the cuff and the bottom of your palm.



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



Note

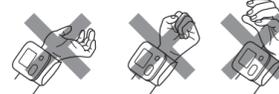
- Make sure the wrist cuff does not cover the protruding part of the wrist bone on the outside of your wrist.

2.5 Sitting Correctly

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

- Sit in a chair with your legs uncrossed and your feet flat on the floor.
- Sit with your back and arm being supported.

- Your monitor must be approximately the same level as your heart. If the monitor is too high above your heart, your blood pressure will be artificially low. If the monitor is too low below your heart, your blood pressure will be artificially high.
- Relax your wrist and hand. Do not bend your wrist back, clench your fist, or bend your wrist forward.



3. Using Your Monitor

3.1 Taking a Measurement

Note

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

Caution

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

1. Press the [START/STOP] button.

All symbols appear on the display before starting the measurement.

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

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

The " " symbol flashes at every heartbeat.

Note

- The " " symbol appears if the wrist cuff is wrapped around the wrist correctly.
- When the " " symbol is displayed, the wrist cuff is not applied correctly. Press the [START/STOP] button to turn your monitor off, then apply the cuff correctly.

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

If either the systolic or the diastolic reading is high (refer to section 1.3), the " " symbol appears.



▲ START ▲ INFLATING ▲ COMPLETED

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

Note

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

3.2 Disabling/Enabling Bluetooth

Disable Bluetooth in your monitor in the following areas where use of wireless equipment is prohibited.

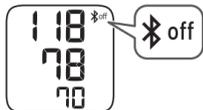
- On aircraft
 - In hospitals
 - While abroad
- Bluetooth is enabled as default.

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

- "OFF" appears on the display.



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



Note

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

Transferring Data Automatically/Manually

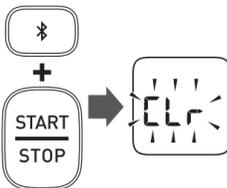
- The readings will be transferred to your smart device within 1 hour after taking a measurement.
- To transfer the readings manually, press the  button.

4. Other Settings

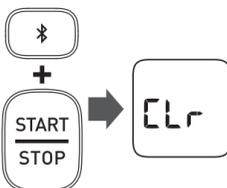
4.1 Restoring Your Monitor to the Default Settings

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

- While holding the  button down, press and hold the [START/STOP] button for more than 2 seconds. The following display flashes.



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



Note

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

5. Error Messages and Troubleshooting

In case of any of the below problems occur during measurement, first check that no other electrical device is within 30cm. If the problem persists, please refer to the table below.

| Display/ Problem | Possible Cause | Solution |
|--------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  appears or the wrist cuff does not inflate. | The wrist cuff is not applied correctly. | Apply the wrist cuff correctly, then take another measurement. Refer to section 2.3. |
| | Air is leaking from the wrist cuff. | Contact your OMRON retail outlet or distributor. |
|  appears | The wrist cuff is overinflated exceeding 300 mmHg. | Do not touch the wrist cuff while taking a measurement. |
|  appears | You move or talk during a measurement. Vibrations disrupt a measurement. | Remain still and do not talk during a measurement. |
|  appears | | Apply the wrist cuff correctly, then take another measurement. Refer to section 2.3. |
|  appears | The pulse rate is not detected correctly. | Remain still and sit correctly during a measurement. |
|  appears | | If the "  " symbol continues to appear, we recommend you to consult with your physician. |

| Display/ Problem | Possible Cause | Solution |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  appears | The monitor is malfunctioned. | Press the [START/STOP] button again. If "Er" still appears, contact your OMRON retail outlet or distributor. |
|  appears | The monitor cannot connect to a smart device or transmit data correctly. | Follow the instructions shown in the "OMRON connect" app. If the "Err" symbol still appears after checking the app, contact your OMRON retail outlet or distributor. |
|  flashes | The  button is pressed and held to pair with a smart device. | Flashes when pairing to the smart device. Visit the "Help" section in the "OMRON connect" app for pairing. |
|  flashes | The  button is pressed to transfer your readings. | Flashes when transferring your readings to the "OMRON connect" app. |
|  flashes | More than 24 readings are not transferred. | Pair or transfer your readings to the "OMRON connect" app so you can keep them in memory in the app, and this error symbol disappears. |
| | Your monitor is not paired or not connected with your smart device. | |
|  appears | 30 readings are not transferred. | |
|  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 appears on the display of the monitor. | Batteries are completely depleted. | Check the battery installation for proper placement. Refer to section 2.1. |
| | Battery polarities are not properly aligned. | |
| Readings appear too high or too low. | Blood pressure varies constantly. Many factors including stress, time of day, and/or how you apply the wrist cuff, may affect your blood pressure. Review sections 2.3 - 2.5 and chapter 3. | |
| Any other problems occur. | Press the [START/STOP] button to turn the monitor off, then press it again to take a measurement. If the problem continues, remove all batteries and wait for 30 seconds. Then re-install batteries. If the problem still persists, contact your OMRON retail outlet or distributor. | |

6. Maintenance

6.1 Maintenance

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

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

Caution

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

6.2 Storage

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

- Store your monitor in a clean, safe location.
- Do not store your monitor:
 - If your monitor is wet.
 - In locations exposed to extreme temperatures, humidity, direct sunlight, dust or corrosive vapors such as bleach.
 - In locations exposed to vibrations or shocks.

6.3 Cleaning

- Do not use any abrasive or volatile cleaners.
- Use a soft dry cloth or a soft cloth moistened with neutral soap to clean your monitor and wrist cuff, and then wipe them with a dry cloth.
- Do not wash or immerse your monitor and wrist cuff in water.
- Do not use gasoline, thinners or similar solvents to clean your monitor and wrist cuff.

6.4 Calibration and Service

- The accuracy of this blood pressure monitor has been carefully tested and is designed for a long service life.
- It is generally recommended to have the unit inspected every two years to ensure correct functioning and accuracy. Please consult your authorised OMRON dealer or the OMRON Customer Service at the address given on the packaging or attached literature.

7. Specifications

| | |
|-----------------------------------------|--------------------------------------------------------------------------------------------------------|
| Product category | Electronic Sphygmomanometers |
| Product description | Automatic Wrist Blood Pressure Monitor |
| Model (Code) | RS3 Intelli IT (HEM-6161T-E) |
| 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 rapid deflation |
| Measurement method | Oscillometric method |
| Transmission method | Bluetooth® low energy technology |
| Wireless communication | Frequency range: 2.4 GHz (2400 - 2483.5 MHz) Modulation: GFSK Effective radiated power: < 20 dBm |
| Operation mode | Continuous operation |
| IP classification | IP 22 |
| Rating | DC3 V 3.0 W |
| Power source | 2 "AAA" alkaline batteries 1.5V |
| Battery life | Approximately 300 measurements (using new alkaline batteries) |
| Durable period (Service life) | 5 years |
| Operating conditions | +10°C to +40°C / 15 to 90% RH (non-condensing) / 800 to 1060 hPa |
| Storage / Transport conditions | -20°C to +60°C / 10 to 90% RH (non-condensing) |
| Weight | Approximately 85 g not including batteries |
| Dimensions | Approximately 84 mm (w) × 62 mm (h) × 21 mm (l) (not including the wrist cuff) |
| Measurable wrist circumference | 13.5 to 21.5 cm |
| Memory | Stores up to 30 readings |
| Contents | Monitor, 2 "AAA" alkaline batteries, storage case, instruction manual, setup instructions |
| Protection against electric shock | Internally powered ME equipment |
| Applied part | Type BF (wrist cuff) |
| Maximum temperature of the applied part | Lower than +48°C |

Note

- 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.
- This monitor is clinically investigated according to the requirements of EN ISO 81060-2:2014.
- 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 issues during a normal operation.
- This device has not been validated for use on pregnant patients.

About a wireless communication interference

This product operates in an unlicensed ISM band at 2.4 GHz. In the event this Product is used near other wireless devices such as microwave and wireless LAN, which operate on the same frequency band as this Product, there is a possibility that interference may occur.

If interference occurs, stop the operation of the other devices or relocate this Product away from other wireless devices before attempting to use it.

8. Limited Warranty

Thank you for buying an OMRON product. This product is constructed of high quality materials and great care has been taken in its manufacturing. It is designed to give you every satisfaction, provided that it is properly operated and maintained as described in the instruction manual.

This product is warranted by OMRON for a period of 3 years after the date of purchase. The proper construction, workmanship and materials of this product is warranted by OMRON. During this period of warranty OMRON will, without charge for labour or parts, repair or replace the defect product or any defective parts.

The warranty does not cover any of the following:

- Transport costs and risks of transport.
- Costs for repairs and / or defects resulting from repairs done by unauthorised persons.
- Periodic check-ups and maintenance.
- Failure or wear of optional parts or other attachments other than the main device itself, unless explicitly warranted above.
- Costs arising due to non-acceptance of a claim (those will be charged for).
- Damages of any kind including personal caused accidentally or from misuse.
- Calibration service is not included within the warranty.

Should warranty service be required please apply to the dealer whom the product was purchased from or an authorised OMRON distributor. For the address refer to the product packaging / literature or to your specialised retailer. If you have difficulties in finding OMRON customer services, contact us for information. www.omron-healthcare.com

Repair or replacement under the warranty does not give rise to any extension or renewal of the warranty period. The warranty will be granted only if the complete product is returned together with the original invoice / cash ticket issued to the consumer by the retailer.

9. Guidance and Manufacturer's Declaration

CE 0197

- This device fulfils the provisions of EC directive 93/42/EEC (Medical Device Directive).
- This blood pressure monitor is designed according to the European Standard EN1060, Non-invasive sphygmomanometers Part 1: General Requirements and Part 3: Supplementary requirements for electromechanical blood pressure measuring systems.
- Hereby, OMRON HEALTHCARE Co., Ltd., declares that the radio equipment type HEM-6161T-E is in compliance with Directive 2014/53/EU.
- The full text of the EU declaration of conformity is available at the following internet address: www.omron-healthcare.com
- This OMRON product is produced under the strict quality system of OMRON HEALTHCARE Co., Ltd., Japan. The Core component for OMRON blood pressure monitors, which is the Pressure Sensor, is produced in Japan.

| Symbols description | |
|---------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | Applied part - Type BF Degree of protection against electric shock (leakage current) |
| IP XX | Ingress protection degree provided by IEC 60529 |
| CE | CE Marking |
| SN | Serial number |
|  | Temperature limitation |
|  | Humidity limitation |
|  | Atmospheric pressure limitation |
|  | To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment. |
|  | Need for the user to consult this instruction manual. |
|  | Indicates the correct positioning for the monitor on the wrist Measurable wrist circumference |
|  | Battery |
|  | Direct current |

Important information regarding Electro Magnetic Compatibility (EMC)

HEM-6161T-E manufactured by OMRON HEALTHCARE Co., Ltd. conforms to EN60601-1-2:2015 Electro Magnetic Compatibility (EMC) standard. Further documentation in accordance with this EMC standard is available at www.omron-healthcare.com. Refer to the EMC information for HEM-6161T-E on the website.

Correct Disposal of This Product (Waste Electrical & Electronic Equipment)

This marking shown on the product or its literature, indicates that it should not be disposed of, with other household wastes at the end of its working life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate this product from other types of wastes and recycle it responsibly to promote the sustainable reuse of material resources.



Household users should contact either the retailer where they purchased this product, or their local government office, for details of where and how they can return this item for environmentally safe recycling. Business users should contact their supplier and check the terms and conditions of the purchase contract. This product should not be mixed with other commercial waste for disposal.



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