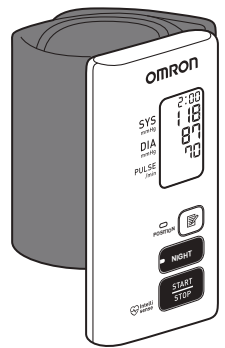


OMRON

Automatic Wrist Blood Pressure Monitor

NightView (HEM-9601T-E3) Instruction Manual



Intelli
sense
IM-HEM-9601T-E3-01-12/2019
3288985-3A

All for Healthcare

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Introduction

Thank you for purchasing the NightView. This blood pressure monitor is to be worn on your wrist.

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 NightView. To ensure the safe and proper use of this monitor, READ and UNDERSTAND all of these instructions. If you do not understand these instructions or have any questions, contact 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

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 13.5 cm to 21.5 cm. The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings. Upon user's discretion the "nocturnal measurement" mode can be activated to automatically take 3 measurements during nighttime. The device will obtain the nocturnal blood pressure regardless whether the user is asleep or awake at the time of the measurements*. It is mainly designed for general household use.

*Asayama K, Fujiwara T, Hoshida S, et al. Nocturnal blood pressure measured by home devices: evidence and perspective for clinical application. J Hypertens. 2019;37(5):905-916.

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

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

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

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

- 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 a 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 applying SpO2 sensor or IBP catheter, arterio-venous (A-V) shunt.
- 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 with hyperbaric oxygen chambers, or in oxygen rich environments or near flammable gas.
- Consult with a 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 and children.
- If this product produces smoke, strange odors, or strange sounds, stop using immediately and contact your OMRON retail outlet or distributor. This may cause a fire or explosion.
- DO NOT use this monitor with magnetic resonance imaging (MRI). It may cause the topically fever or burn.
- DO NOT place this monitor in the following environment.
 - In locations with vibration such as in ambulance or helicopter ambulance.
 - In locations with gas or fire.
 - In location with water splash or vapor.
 - Storage of chemical agents.
- If error appears or having doubt of the measurement result, check the patient's vital signs with auscultation or palpation.
- The management responsibility rests a hospital or a medical clinic. Regularly inspect and maintenance this product.

- Regularly check the circulatory status of the patient when taking measurement frequently and long time. Apply the cuff with patient's wrist correctly consulting with this manual.

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 and children.

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

- 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 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 a physician before using this monitor in following cases;
 - Peripheral circulatory failure or particularly low blood pressure or temperature
 - Using a artificial heart lung
 - Arteriovenous fistula
 - Pseudohypertension
 - Convulsion or venous pulse, body movement such as during cardiac massage or rheumatism
- Consult with a 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 section 8.
- During measurement, observe the wrist to ensure that the monitor is not causing prolonged impairment to blood circulation.
- DO NOT use this monitor in high-use environments such as medical clinics or physician offices.
- DO NOT use this monitor with other medical electrical (ME) equipment simultaneously. This may result in incorrect operation of the monitor and/or cause an inaccurate reading.
- Avoid bathing, drinking alcohol or caffeine, smoking, exercising and eating for at least 30 minutes before taking a measurement.
- Rest for at least 5 minutes before taking a measurement.
- Remove tight-fitting or thick clothing and any accessories from patient's 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 section 8.
- DO NOT crease the wrist cuff excessively.
- DO NOT use this monitor after the durable period has ended. Refer to section 8.
- This product should only be used on minors under the direct supervision of a physician.
- Before using this product, visually inspect the product to ensure that it is not dirty, wet, or deformed due to being dropped or damaged.
- If this product has not been used for a long period, be sure to test the device to confirm that it functions normally and safely before using it.
- Clean this product regularly.
- DO NOT use alcohol, thinners or benzine to clean this monitor.
- DO NOT clean this product using an autoclave, or gas sterilization (EOG, formaldehyde gas, highly concentrated ozone, etc.).
- Before and during measurement, be sure to check that the following conditions do not apply.
 - The monitor is not at the same level as patient's heart.
 - The patient is moving his/her body while taking the measurement.
- Read and follow the "Correct Disposal of This Product" in section 10 when disposing of the device.
- DO NOT place this monitor in the following environment;
 - In locations direct sunlight, dust or corrosive vapors such as bleach.
 - In locations exposed to vibrations or shocks.
 - In locations near the heater.

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

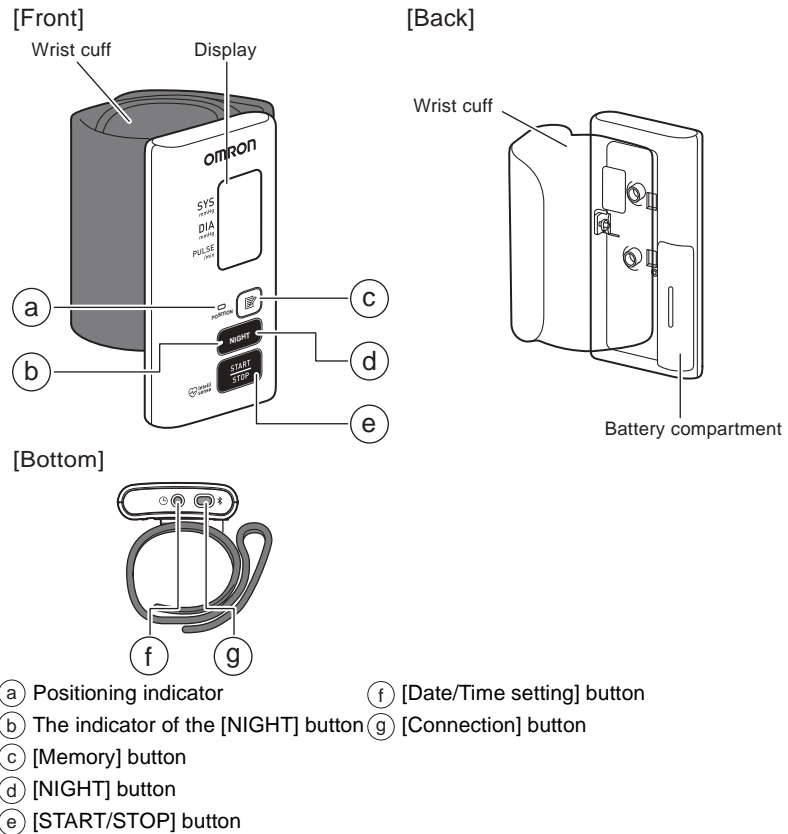
- DO NOT insert batteries with their polarities incorrectly aligned.
- ONLY use 2 "AAA" alkaline batteries with this monitor. DO NOT use other types of batteries. DO NOT use new and used batteries together. DO NOT use different brands of batteries together.
- Remove batteries if this monitor will not 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.
- DO NOT replace the batteries while the power is on.

1. Know Your Monitor

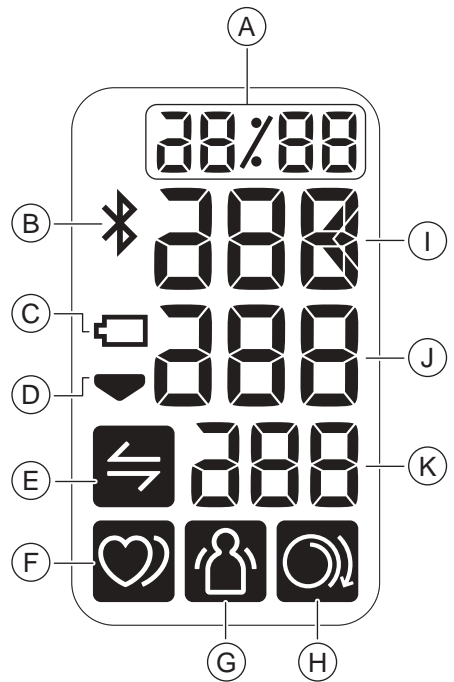
1.1 Contents

Monitor, 2 "AAA" alkaline batteries, storage case, instruction manual, blood pressure pass

1.2 Monitor



1.3 Display and Symbols



| | |
|---|--|
| A | Date and time display |
| B | Bluetooth ON symbol Appears when Bluetooth is enabled. |
| C | Battery symbol Flashes when batteries are low. Appears when batteries are depleted. |
| D | Deflation symbol Appears during cuff deflation. |
| E | 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 350 readings can be stored in the internal memory per user. |
| F | 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. |
| G | 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. |
| H | Cuff wrap guide symbol Appears if the wrist cuff is wrapped around the wrist too loosely while taking a measurement. It also appears on past readings in the memory if the cuff was wrapped too loosely during those readings taken. |
| I | Systolic blood pressure reading |
| J | Diastolic blood pressure reading |
| K | Pulse display / Memory number Pulse rate appears after the measurement. When pressing the [Memory] button, the memory number appears for approximately one second before the pulse rate appears on the display. |

1.4 Classification of BP (Blood Pressure)

2018 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. While holding the hook of the battery cover, slide and remove it.
 2. Insert 2 "AAA" alkaline batteries as indicated in the battery compartment.
 3. Close the battery cover.
- As soon as batteries are correctly installed, the display flashes as shown in the figure to the right for 2 minutes, then your monitor will automatically turn off.

Note

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

2.2 Pairing Your Monitor with a Smart Device

You can track changes in your blood pressure by transferring your readings from your monitor to your 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 www.omronconnect.com/devices/

1. Enable Bluetooth on your smart device.
2. Download and install the "OMRON connect" app onto your smart device.
3. Open the app on your smart device and press and hold the [Connection] button for more than 2 seconds. Then follow the instructions.
4. Confirm that your monitor is connected successfully.

When your monitor is connected successfully to your smart device, "OK" appears after flashing 3 times.

Note

- 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 Setting Date and Time Manually

If your monitor is paired with your smart device, date and time is set automatically. When you need to set them manually, follow the instructions below.

1. Press and hold the [Date/Time setting] button for more than 2 seconds.
The year flashes.
2. Press the [Memory] button to adjust the year.
Press and hold the [Memory] button to quickly advance the years.
3. Press the [Date/Time setting] button to confirm the year and the month will flash.
Repeat the same steps to adjust the month, day, hour, and minute.
4. Press the [Date/Time setting] button to store the setting.

2.4 Blood Pressure Measurement Tips

To help ensure an accurate reading, follow these directions:

- Stress raises blood pressure. Avoid taking measurements during stressful times.
- Measurements should be taken in a quiet place.
- It is important to take measurements at same times each day. Taking measurements in the morning and in the evening is recommended.
- Remember to have a record of your blood pressure and pulse readings for your physician. A single measurement does not provide an accurate indication of your true blood pressure. You need to take and record several readings over a period of time.

⚠Caution

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

2.5 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 or thick clothing and any accessories from your wrist while taking a measurement.

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 wrist through the cuff loop.
Your palm and monitor display should both face upward.
3. Position the wrist cuff leaving a clearance of 1 to 1.5 cm between your monitor 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.

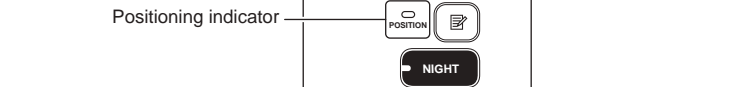
3. Using Your Monitor

⚠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.

3.1 Taking a Measurement in the Morning and Evening

1. Sit with correct posture.
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 high. If the monitor is too low below your heart, your blood pressure will be artificially low.
- The appropriate level can be checked using the positioning indicator after pressing the [START/STOP] button.

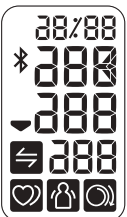


- Relax your wrist and hand. Do not bend your wrist back, clench your fist, or bend your wrist forward.

2. Press the [START/STOP] button.
All symbols (except for the battery symbol) appear on the display before starting the measurement.

Note

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



3. Check the positioning indicator.
Your monitor has a built-in heart zone function 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 indicator will light in blue. When your wrist is higher or lower position relative to your heart, the indicator lights in orange.

Note

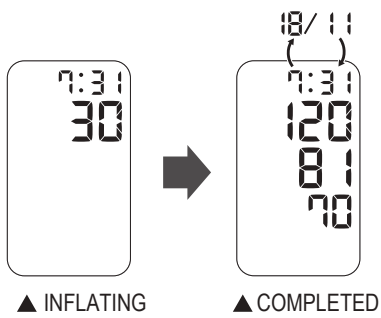
- After 5 seconds from pressing the [START/STOP] button, even if your monitor is not positioned properly, your monitor will start the measurement and the wrist cuff will start to inflate.

4. Remain still and do not move or talk until the entire measurement process is completed.
This monitor detects your blood pressure and pulse rate during inflation.

Note

- The positioning indicator remains on during inflation.
- 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.



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

Note

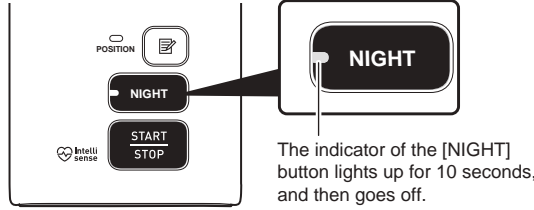
- Your monitor will automatically turn off after 2 minutes.
- Wait 2 - 3 minutes between measurements. The wait time allows the arteries to decompress and return to their pre-measurement form. You may need to increase the wait time depending on your individual physiological characteristics.
- If the battery symbol flashes, the batteries may be depleted during measurement. This may cause an inaccurate reading. Replace the batteries immediately.

Transferring Data Automatically/Manually

- When Bluetooth is enabled, the readings will be transferred to your smart device.
- To transfer the readings manually, open the app, then press the [Connection] button.

3.2 Taking a Measurement automatically while Sleeping (Nocturnal Measurement)

- With the power turned off, press the [NIGHT] button for more than 2 seconds.
Nocturnal measurement mode is set. "ON" appears on the display.

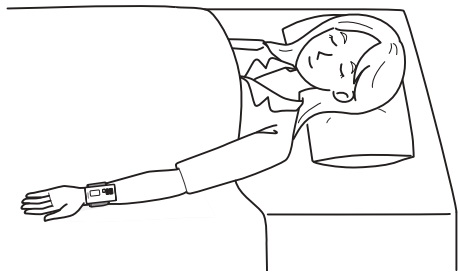


If ":-:" appears on the display, refer to section 6.

- Note**
- If date and time are not set, the year will flash when the [NIGHT] button is pressed for more than 2 seconds. Refer to section 2.3 to set date and time.

- Go to bed.

When you go to sleep try to maintain a position which does not compromise the blood circulation in the arm/wrist of measuring. This will allow your monitor to make the appropriate measurements while you are asleep.
Measurement will automatically start at 2 o'clock, 4 o'clock and 4 hours later after setting nocturnal measurement.



- Note**
- Measurement will not start when the date and time is not set.
 - Once nocturnal mode is set, normal measurement can not be used. For appropriate measurement, check if the wrist cuff is applied correctly and the battery symbol does not flash or appear in advance.
 - Nocturnal measurement mode will be automatically cancelled in the following cases.
 - When "E1" is displayed more than twice in a row when during a measurement. Refer to section 6.
 - When "Er" is displayed. Refer to section 6.
 - If the [NIGHT] button is pressed while nocturnal measurement mode is set, the indicator of the [NIGHT] button will light up for 10 seconds.
 - If the setting time is duplicated, only 1 measurement will be taken at that time.
 - When nocturnal mode is set, the built-in heart zone function does not work.
 - If the measurement is failed during nocturnal measurement because of the error such as "movement error", your monitor will try to take a measurement once more a minute later. (It tries only once.)
 - Nocturnal measurement mode will be cancelled automatically after the measurement is completed at the set time.
 - To manually cancel nocturnal measurement mode, perform the following operation.
 1. With the power turned off, press the [NIGHT] button once.
 2. After checking that the indicator of the [NIGHT] button is lit, hold down the [NIGHT] button for more than 3 seconds. The indicator of the [NIGHT] button will flash 5 times, and nocturnal measurement mode will be cancelled. "OFF" appears on the display.

Transferring Data Automatically/Manually

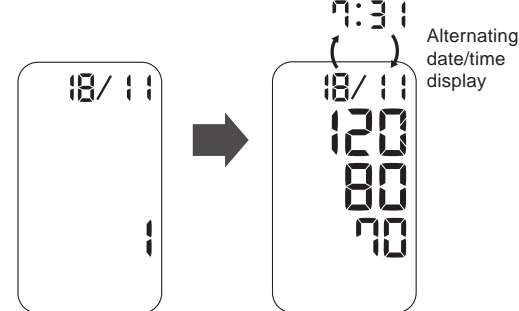
Refer to section 3.1.5.

4. Using Memory Function

Your monitor automatically stores up to 350 readings.

4.1 Viewing the Readings Stored in Memory

- Press the [Memory] button.



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

- Note**
- If there are no readings stored in the memory, the screen to the right is displayed.
 - If the memory is full, the monitor will delete the oldest readings.
 - When "E1", "E2", "E3", or "Er" were displayed during a measurement, they also appear while the measurement record is being displayed.
 - The result of built-in heart zone function is also stored in memory. The positioning indicator lights in blue or orange while measurement record is being displayed.
 - When the nocturnal measurement record is displayed, the [NIGHT] button lights up.
 - An error message (e.g. "E1") that is displayed during measurement is also stored in memory. Refer to section 6 about error messages.



- Press the [Memory] button repeatedly to scroll through the previous readings stored in the memory.

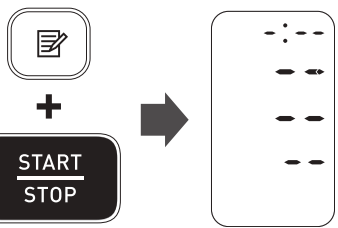
- Press the [START/STOP] button to turn off your monitor.

- Note**
- Your monitor will automatically turn off after 2 minutes.

5. Other Settings

5.1 Deleting All Readings Stored in Memory

- Press the [Memory] button, then the latest reading will appear.
- While holding the [Memory] button down, press and hold the [START/STOP] button for more than 2 seconds.



- Note**
- All readings will be deleted. You cannot partially delete the readings stored in the memory.
 - This action will delete pairing information with your smart device.

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

- Note**
- Your monitor will automatically turn off after 2 minutes.

5.2 Disabling/Enabling Bluetooth

Warning

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

Bluetooth is enabled as default.

- When your monitor is off, press and hold the [Connection] button for more than 10 seconds.
"oFF" appears on the display.



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

- Note**
- Your monitor will automatically turn off after 2 minutes.
 - To enable the Bluetooth, press and hold the [Connection] button for more than 2 seconds. "on" appears on the display.
 - If the Bluetooth is disabled, the following display is shown when pressing the [Connection] button with the power turned off.



Your monitor will automatically turn off after "oFF" flashes 3 times.

5.3 Disabling/Enabling Positioning Indicator

The positioning indicator is enabled as default.

- When your monitor is off, press and hold the [Date/Time setting] button for more than 5 seconds while holding the [Memory] button down.
"oFF" appears on the display and the positioning indicator flashes 5 times.



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

- Note**
- Your monitor will automatically turn off after 2 minutes.
 - To enable the positioning indicator, repeat the steps above. "on" appears on the display and the positioning indicator flashes 5 times.

6. Error Messages and Troubleshooting

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

| Display/Problem | Possible Cause | Solution |
|--|--|---|
| E1 appears or the wrist cuff does not inflate. | The wrist cuff is not applied correctly. Air is leaking from the wrist cuff. | Apply the wrist cuff correctly, then take another measurement. Refer to section 2.5. Contact your OMRON retail outlet or distributor. |
| E3 appears | The wrist cuff is overinflated exceeding 300 mmHg. | Do not touch the wrist cuff while taking a measurement. |
| E4 appears | You move or talk during a measurement. Vibrations disrupt a measurement. | Remain still and do not talk during a measurement. |
| E5 appears | | Apply the wrist cuff correctly, then take another measurement. Refer to section 2.5. |
| appears | The pulse rate is not detected correctly. | Remain still and sit correctly during a measurement. If the " " symbol continues to appear, we recommend you to consult with your physician. |
| appears | | |
| Er appears | Your wrist is moved up and down during a measurement. | Do not move your wrist, then take another measurement. Refer to section 3. |
| Er appears | The monitor is malfunctioned. | Press the [START/STOP] button again. If "Er" still appears, contact your OMRON retail outlet or distributor. |
| Er appears | The monitor cannot connect to a smart device or transmit data correctly. | Follow the instructions shown in the "OMRON connect" app. If the "Er" symbol still appears after checking the app, contact your OMRON retail outlet or distributor. |
| :-:- appears | Date and time is not set. | Pair your monitor with a smart device or set date and time manually. Refer to section 2. |
| P flashes | The [Connection] 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 [Connection] button is pressed to transfer your readings. | Flashes when transferring your readings to the "OMRON connect" app. |
| flashes | Many readings are not transferred. The stored memory is almost full. | 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. |
| appears | 350 readings are not transferred. | |
| flashes or appears | Batteries are low or depleted. Batteries are completely depleted. Battery polarities are not properly aligned. | Replace all batteries with 2 new alkaline batteries. Refer to section 2.1. Check the battery installation for proper placement. Refer to section 2.1. |
| No power. Nothing appears on the display of the monitor. | Batteries are completely depleted. Battery polarities are not properly aligned. | |
| 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 2.4 - 2.5 and section 3. | |
| Any other communication issue occurs. | Follow the instructions shown in the smart device, or visit the "Help" section in the "OMRON connect" app for further help. If the problem still persists, contact your OMRON retail outlet or distributor. | |
| 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. | |

7. Maintenance

7.1 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.

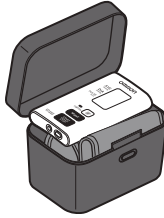
Caution

- DO NOT disassemble or attempt to repair this monitor or other components. This may cause an inaccurate reading.
- Before using this product, visually inspect the product to ensure that it is not dirty, wet, or deformed due to being dropped or damaged.

7.2 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.
 - If sweat or cosmetics are adhering to your monitor.
- In locations exposed to extreme temperatures, humidity, direct sunlight, dust or corrosive vapors such as bleach.
- In locations exposed to vibrations or shocks.



7.3 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.

7.4 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.

8. Specifications

| | |
|---|--|
| Product category | Electronic Sphygmomanometers |
| Product description | Automatic Wrist Blood Pressure Monitor |
| Model (code) | NightView (HEM-9601T-E3) |
| 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 |
| Wireless communication | Frequency range: 2.4 GHz (2400 - 2483.5 MHz) Modulation: GFSK Effective radiated power: < 20 dBm |
| Operation mode | Continuous operation |
| IP classification | IP 22 |
| Rating | DC3 V 3.0 W |
| Power source | 2 "AAA" alkaline batteries 1.5 V |
| Battery life | Approximately 150 measurements (using new alkaline batteries) |
| Durable period (Service life) | 3 years |
| Operating conditions | +10 to +40°C / 15 to 90% RH (non-condensing) / 800 to 1060 hPa |
| Storage / Transport conditions | -20 to +60°C / 10 to 90% RH (non-condensing) |
| Weight | Approximately 110 g not including batteries |
| Dimensions | Approximately 55 (w) × 101 (h) × 17 (l) mm (not including the wrist cuff) |
| Measurable wrist circumference | 135 to 215 mm |
| Memory | Stores up to 350 readings |
| Contents | Monitor, storage case, 2 "AAA" alkaline batteries, instruction manual, blood pressure pass |
| Protection against electric shock | Internally powered ME equipment |
| Applied part | Type BF (wrist cuff) |
| Maximum temperature of the applied part | Lower than +43°C |

Note

- These specifications are subject to change without notice.
- This monitor is clinically investigated according to the requirements of ISO 81060-2:2013. In the clinical validation study, K5 was used on 85 subjects for determination of diastolic blood pressure.
- This monitor has not been validated for use on pregnant patients.
- IP classification is degrees of protection provided by enclosures in accordance with IEC 60529. This monitor is protected against solid foreign objects of 12.5 mm diameter and greater such as a finger, and against oblique falling water drops which may cause issues during a normal operation.
- Operating mode is classification in accordance with IEC 60601-1.

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. Wireless communication has risks that any third party may intercept the radio waves willfully or accidentally, for any unexpected purpose.

9. 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.

10. Guidance and Manufacturer's Declaration

CE0197

- 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-9601T-E3 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.
- Please report to the manufacturer and the competent authority of the Member State in which you are established about any serious incident that has occurred in relation to this device.

| 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 |
| LOT | LOT number |
| MD | Medical Device |
| | Temperature limitation |
| | Humidity limitation |
| | Atmospheric pressure limitation |
| | OMRON's trademarked technology for blood pressure measurement |
| | Need for the user to consult this instruction manual. |
| == | Direct current |
| | 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. |
| | Date of manufacture |
| | Indicates the correct positioning for the monitor on the wrist Measurable wrist circumference |

Important information regarding Electromagnetic Compatibility (EMC)

HEM-9601T-E3 conforms to EN60601-1-2:2015 Electromagnetic 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-9601T-E3 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.