Issue Date:
발행 일자
**วันที่จัดทำคู่มือ**
Tanggal Terbit
Ngày phát hành
ITarikh Keluaran

2024-12-09

3149895-8B

Model **IQ BT (HEM-7194T1-FL)**

OMRON

## Automatic Blood Pressure Monitor

오므론 자동전자혈압계
**เครื่องวัดความดันโลหิตอัตโนมัติ**
Monitor Tekanan Darah Otomatis
Máy đo huyết áp tự động
Pemantau Tekanan Darah Automatik

# Instruction Manual 1: Safety and Other Information

사용설명서 1: 안전 및 기타 정보
**คู่มือแนะนำการใช้งาน 1: ข้อมูลด้านความปลอดภัยและข้อมูลอื่น ๆ**
Buku Petunjuk 1: Keselamatan dan Informasi Lainnya
Hướng dẫn sử dụng 1: An toàn và thông tin khác
Manual Arahan 1: Keselamatan dan Maklumat Lain

**EN**
**KO**
**TH**
**ID**
**VI**
**MS**
**Symbols**
기호 / **สัญลักษณ์** / Simbol / Biểu tượng / Simbol

Intelli sense AFib™

CE 0197

# Overview

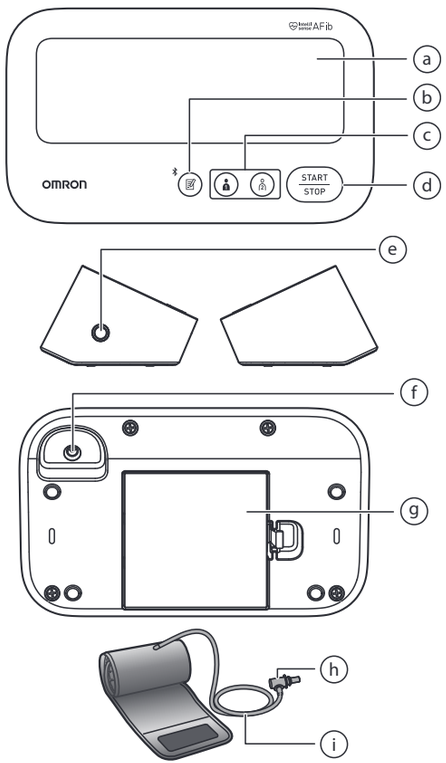
**KO** 개요

**TH** ภาพรวม

**ID** Gambaran Umum

**VI** Tổng quan

**MS** Gambaran Keseluruhan




| | | | |
|---|---|---|---|
| a | **Display** | Layar | |
| | 디스플레이 | Màn hình | |
| | **หน้าจอ** | Paparan | |
| b | **[Memory] (Connection) button** | | |
| | [메모리] (연결) 버튼 | | |
| | **ปุ่ม ［หน่วยความจำ］(การเชื่อมต่อ)** | | |
| | Tombol (Koneksi) [Memori] | | |
| | Nút [Bộ nhớ] (Kết nối) | | |
| | Butang [Memori] (Sambungan) | | |
| c | **[User ID 1]/[User ID 2] buttons** | | |
| | [사용자 ID 1]/[사용자 ID 2] 버튼 | | |
| | **[ID ผู้ใช้ 1]/[ID ผู้ใช้ 2] ปุ่ม** | | |
| | Tombol [ID Pengguna 1]/[ID Pengguna 2] | | |
| | Nút [ID Người dùng 1]/[ID Người dùng 2] | | |
| | Butang [ID Pengguna 1]/[ID Pengguna 2] | | |
| d | **[START/STOP] button** | | |
| | [START/STOP] (시작 / 정지) 버튼 | | |
| | **ปุ่ม [START/STOP] (เริ่ม/หยุด)** | | |
| | Tombol [START/STOP] (mulai/berhenti) | | |
| | nút [START/STOP] (Khởi động/dừng lại) | | |
| | Butang [START/STOP] (MULA / BERHENTI) | | |
| e | **Air jack** | **ช่องต่อท่อลม** | Ổ cắm ống khí |
| | 에어 잭 | Jack udara | Jack udara |

| | | | |
|---|---|---|---|
| ⓕ | **AC adapter jack**<br>AC 어댑터 잭<br>**หัวเสียบหม้อแปลงไฟฟ้า AC Adapter**<br>Jack adaptor AC<br>Giắc cắm bộ chuyển đổi AC<br>Soket penyesuai AC | | |
| ⓖ | **Battery compartment**<br>건전지 삽입<br>**ช่องใส่แบตเตอรี่**<br>Ruang baterai | Khoang chứa pin<br>Peti bateri | |
| ⓗ | **Air plug**<br>에어 플러그 | **ปลั๊กสายอากาศ**<br>Sumbat udara | Phích cắm ống khí<br>Palam udara |
| ⓘ | **Air tube**<br>에어 튜브<br>**ท่อลม** | Selang udara<br>Ống khí<br>Tiub udara | |

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# 1 Introduction

Thank you for purchasing the OMRON Automatic Blood Pressure Monitor. This blood pressure monitor uses the oscillometric method of blood pressure measurement. This means this monitor detects your blood movement through your brachial artery and converts the movements into a digital reading.

## 1.1 Safety Instructions

This instruction manual provides you with important information about the OMRON Automatic Blood Pressure Monitor. To ensure the safe and proper use of this monitor, READ and UNDERSTAND all of these instructions. **If you do not understand these instructions or have any questions, contact your local OMRON representative before attempting to use this monitor. For specific information about your own blood pressure, consult with your physician.**

## 1.2 Intended Use

### Intended Purpose

This device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population. The device can detect an irregular pulse suggestive of Atrial Fibrillation (AFib). Please note that the device is not intended to diagnose AFib.

***Note:** A diagnosis of AFib can only be confirmed by a physician with an Electrocardiogram (ECG). If the AFib symbol appears, consult with your physician.

### Intended Patients

Adult patient population

### Intended Users

Adult population (may include patients themselves) who can understand this instruction manual.

### Clinical Benefit

Patient's blood pressure can be measured non-invasively and simply in the home environment, and the possibility of AFib is detected from the pulse wave obtained from the blood pressure measurement and provided to the user.

### Type of Use

This monitor is intended to be multiple patient multiple use.

### Limitation

Patient's arm circumference must be 22 - 42 cm.

### Indication

This device is used by healthy individuals, patients with hypertension, patients with health-conscious individuals, in a general household situation for the following purpose.

- measure blood pressure and pulse rate
- detect the possibility of AFib

## 1.3 Receiving and Inspection

Remove this monitor and other components from the packaging and inspect for damage. If this monitor or any other components is damaged, DO NOT USE and consult with your local OMRON representative.

# 2 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.**

## 2.1 Contraindications

- DO NOT use this monitor on an injured arm or an arm under medical treatment.
- DO NOT apply the arm cuff on your arm while on an intravenous drip or blood transfusion.
- DO NOT use this monitor on infants, toddlers, children or persons who cannot express themselves.

## 2.2 Side Effects

- Taking measurements more often than necessary may cause bruising due to blood flow interference.
- Inflating to a higher pressure than necessary may result in bruising of the arm where the cuff is applied. NOTE: refer to "If your systolic pressure is more than 210 mmHg" in the end of instruction manual 2 for additional information.
- Stop using this monitor and consult with your physician if you experience skin irritation or discomfort.

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## 2.3 Warning

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

- DO NOT adjust medication (including altering your use of any drug or treatment) based on readings from this blood pressure monitor. Take medication as prescribed by your physician. ONLY a physician is qualified to diagnose and treat high blood pressure and heart related conditions.
- NEVER diagnose or treat yourself based on your readings. ALWAYS consult with your physician.
- The possible AFib detection feature detects for a possibility of AFib ONLY. It will NOT detect other potentially life-threatening arrhythmias or diseases, such as a possibility of other cardiac arrhythmias or heart attack.
- If you are experiencing any symptoms or concerns, consult with your physician.
- DO NOT postpone/stop regular checkups or physician visits based on the results that you are getting from this monitor.
- The possible AFib detection feature is not intended to be used for the users who have already been diagnosed with AFib.

- This monitor may not detect a possibility of AFib in people with pacemakers or defibrillators. People with pacemakers or defibrillators should therefore not use this monitor to detect a possibility of AFib.
- 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.
- To help avoid strangulation, keep the air tube and AC adapter cable away from infants, toddlers and children.
- This product contains small parts that may cause a choking hazard if swallowed by infants, toddlers and children.

### Data Transmission

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

### AC Adapter (optional accessory) Handling and Usage

- DO NOT use the AC adapter if this monitor or the AC adapter cable is damaged. If this monitor or the cable is damaged, turn off the power and unplug the AC adapter immediately.
- Plug the AC adapter into the appropriate voltage outlet. DO NOT use in a multi-outlet plug.
- NEVER plug in or unplug the AC adapter from the electric outlet with wet hands.
- DO NOT disassemble or attempt to repair the AC adapter.

### Battery Handling and Usage

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

## 2.4 Precaution

**⚠ 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.**

- Consult with your physician before using this monitor on an arm where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present because of temporary interference to blood flow and could result in injury.
- Consult with your physician before using this monitor if you have had a mastectomy or lymph node clearance.
- Consult with your physician before using this monitor if you have severe blood flow problems or blood disorders as cuff inflation can cause bruising.
- ONLY inflate the arm cuff when it is applied on your upper arm.
- Remove the arm cuff if it does not start deflating during a measurement.
- DO NOT use this monitor for any purpose other than measuring blood pressure and/or detecting a possibility of AFib.
- 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 or on an aircraft.
- 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 5.
- During measurement, observe the arm to ensure that the monitor is not causing prolonged impairment to blood circulation.
- DO NOT use this monitor with other medical electrical (ME) equipment simultaneously. This may result in incorrect operation of the devices and/or cause an inaccurate reading.
- 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 from your arm while taking a measurement.
- Remain still and DO NOT talk while taking a measurement.
- ONLY use the arm cuff on persons whose arm circumference is within the specified range of the cuff.
- Ensure that this monitor has acclimated to room temperature before taking a measurement. Taking a measurement after an extreme temperature change could lead to an inaccurate reading. It is recommended that you wait for approximately 2 hours for the monitor to warm up or cool down when the monitor is used in an environment within the temperature specified as operating conditions after it is stored either at the maximum or at the minimum storage temperature. For additional information on operating and storage / transport temperature, refer to section 5.
- DO NOT use this monitor after the durable period has ended. Refer to section 5.
- DO NOT crease the arm cuff or the air tube excessively.
- DO NOT fold or kink the air tube while taking a measurement. This may cause an injury by interrupting blood flow.
- To unplug the air plug, pull on the plastic air plug at the base of the tube, not the tube itself.
- ONLY use the AC adapter, arm cuff, batteries and accessories specified for this monitor. Use of unsupported AC adapters, arm cuffs and batteries may damage and/or may be hazardous to this monitor.

- ONLY use the approved arm cuff for this monitor. Use of other arm cuffs may result in incorrect readings.
- Read and follow the "Correct Disposal of This Product" in section 6 when disposing of the device and any used accessories or optional parts.

### Data Transmission

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

### AC Adapter (optional accessory) Handling and Usage

- Fully insert the AC adapter into the outlet.
- When unplugging the AC adapter from the outlet, be sure to safely pull from the AC adapter. DO NOT pull from the AC adapter cable.
- When handling the AC adapter cable:
  DO NOT damage it. / DO NOT break it. / DO NOT tamper with it. / DO NOT pinch it. / DO NOT forcibly bend or pull it. / DO NOT twist it. / DO NOT use it if it is gathered in a bundle. / DO NOT place it under heavy objects.
- Wipe any dust off of the AC adapter.
- Unplug the AC adapter when not in use.
- Unplug the AC adapter before wiping this monitor.

### Battery Handling and Usage

- DO NOT insert batteries with their polarities incorrectly aligned.
- ONLY use 4 "AA" alkaline or manganese batteries with this monitor. DO NOT use other types of batteries. DO NOT use new and used batteries together. DO NOT use different brands of batteries together.
- Remove the batteries if this monitor will not be used for a long period of time.
- If battery fluid should get in your eyes, immediately rinse with plenty of clean water. Consult with your physician immediately.
- If battery fluid should get on your skin, wash your skin immediately with plenty of clean, lukewarm water. If irritation, injury or pain persists, consult with your physician.
- DO NOT use batteries after their expiration date.
- Periodically check the batteries to ensure they are in good working condition.

## 2.5 General Notices

- To stop a measurement, press the [START/STOP] button while taking a measurement.
- When you take a measurement on the right arm, the air tube should be at the side of your elbow. Be careful not to rest your arm on the air tube.



- Blood pressure may differ between the right and left arm, and may result in a different measurement value. Always use the same arm for measurements. If the values between both arms differ substantially, check with your physician on which arm to use for your measurements.
- 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.
- When using an optional AC adapter, make sure not to place your monitor in a location where it is difficult to plug and unplug the AC adapter.
- We recommend keeping batteries in your monitor at all times, even if you choose to use the optional AC adapter. If only the AC adapter is used without keeping batteries in your monitor, you may need to reset the date and time each time you unplug and plug back the AC adapter. The readings will not be deleted.

### Battery Handling and Usage

- Disposal of used batteries should be carried out in accordance with local regulations.
- The supplied batteries may have a shorter life span than new batteries.
- Replacing batteries will not delete previous readings.

## 3 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 of the monitor. If the problem persists, refer to the table below.

| Display/Problem | | Possible Cause | Solution |
|---|---|---|---|
| E1 | appears or the arm cuff does not inflate. | The [START/STOP] button was pressed while the arm cuff is not applied. | Press the [START/STOP] button again to turn the monitor off. |
| | | Air plug is not completely plugged into the monitor. | Insert the air plug securely. |
| | | The arm cuff is not applied correctly. | Apply the arm cuff correctly, then take another measurement. Refer to section 6 of instruction manual 2. |
| | | Air is leaking from the arm cuff. | Replace the arm cuff with a new one. Refer to section 13 of instruction manual 2. |
| E2 | appears or a measurement cannot be completed after the arm cuff inflates. | Moving or talking during a measurement causes the arm cuff to not inflate sufficiently. | Remain still and do not talk during a measurement. If “E2” appears repeatedly, inflate the arm cuff manually until the systolic pressure is 30 to 40 mmHg above your previous readings. Refer to the end of instruction manual 2. |
| | | The systolic pressure is above 210 mmHg and a measurement cannot be taken. | |
| E3 | appears | The arm cuff is inflated exceeding the maximum allowable pressure. | Do not touch the arm cuff and/or bend the air tube while taking a measurement. If inflating the arm cuff manually, refer to the end of instruction manual 2. |
| E4 | appears | Moving or talking during a measurement results in vibrations that disrupt the measurement. | Remain still and do not talk during a measurement. |
| E5 | appears | The pulse rate is not detected correctly. | Apply the arm cuff correctly, then take another measurement. Refer to section 6 of instruction manual 2. Remain still and sit correctly during a measurement. |
| Er | appears | The monitor has malfunctioned. | Press the [START/STOP] button again. If “Er” still appears, contact your local OMRON representative. |
| Err | 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” still appears after checking the app, contact your local OMRON representative. |

| Display/Problem | Possible Cause | Solution |
|---|---|---|
|  appears | The pulse rate is not detected correctly. | Apply the arm cuff correctly, then take another measurement. Refer to section 6 of instruction manual 2. Remain still and sit correctly during a measurement. If the irregular heartbeat symbol "  " continues to appear, it is recommended that you consult with your physician. |
|  appears | | |
|  does not flash during a measurement | | |
|  flashes | The monitor is waiting for pairing with the smart device. | Refer to section 5 of instruction manual 2 for pairing your monitor with your smart device, or press the [START/STOP] button to cancel pairing and turn your monitor off. |
|  flashes | • There are more than 48 readings in memory to be transferred.<br>• Your monitor is not paired with a smart device.<br>• The batteries were replaced. | Pair or transfer your readings to the "OMRON connect" app so you can keep them in memory in the app, and this symbol disappears. |
|  flashes | Batteries are low. | Replacing all 4 batteries with new ones is recommended. Refer to section 4 of instruction manual 2. |
|  and  appears, or the monitor is turned off unexpectedly during a measurement. | Batteries are depleted. | Immediately replace all 4 batteries with new ones. Refer to section 4 of instruction manual 2. |
| Nothing appears on the display of the monitor. | Battery polarities are not properly aligned. | Check the battery installation for proper placement. Refer to section 4 of instruction manual 2. |
| Readings appear too high or too low. | Blood pressure varies constantly. Many factors including stress, time of day, and/or how you apply the arm cuff, may affect your blood pressure. Review sections 2, 6 and 7 of instruction manual 2. | |
| 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 local OMRON representative. | |
| Any other problem occurs. | Press the [START/STOP] button to turn the monitor off, then press it again to take a measurement. If the problem continues, remove all batteries and wait for 30 seconds. Then re-install the batteries. If the problem still persists, contact your local OMRON representative. | |

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# 4 Maintenance

## 4.1 Maintenance

To protect your monitor from damage, follow the directions below:
Changes or modifications not approved by the manufacturer will void the user warranty.

**⚠ Precaution**

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

## 4.2 Storage

- Keep your monitor and other components in the storage case when not in use.
- Store your monitor and other components in a clean, safe location.
- Gently fold the air tube into the arm cuff. Note: Do not bend or crease the air tube excessively.
- Place your monitor and other components in the storage case.
- Do not store your monitor and other components:
  - If your monitor and other components are wet.
  - In locations exposed to extreme temperatures, humidity, direct sunlight, dust or corrosive vapors such as bleach.
  - In locations exposed to vibrations or shocks.

## 4.3 Wiping the Monitor

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

## 4.4 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.

# 5 Specifications

| | |
|---|---|
| Product description | Automatic Blood Pressure Monitor |
| Model | IQ BT (HEM-7194T1-FL) |
| Display | LCD digital display |
| Cuff pressure range | 0 to 299 mmHg |
| Blood pressure measurement range | SYS: 60 to 260 mmHg<br>DIA: 40 to 215 mmHg |
| Pulse measurement range | 40 to 180 beats / min. |
| Accuracy | Pressure: ±3 mmHg<br>Pulse: ±5 % of display reading |
| Measurement method | Oscillometric method |
| Transmission method | **Bluetooth**® Low Energy |
| Wireless communication | Frequency range: 2.4 GHz (2400 - 2483.5 MHz) / Modulation: GFSK<br>Effective radiated power: < 20 dBm |
| Operation mode | Continuous operation |
| IP classification | Monitor: IP21<br>Optional AC adapter: IP21 (HHP-CM01, HHP-KSM01) / IP22 (HHP-OH01) |
| Rating | DC6 V 4 W |
| Power source | 4 “AA” batteries 1.5 V or optional AC adapter (INPUT AC 100 - 240 V 50 - 60 Hz 0.12 - 0.065 A) |
| Battery life | Approx. 1500 measurements (Using new alkaline batteries and included arm cuff. Depending on the type of battery and arm cuff.) |
| Durable period (Service life) | Monitor: 5 years or the time when reaching 30000 times of use. / Cuff: 5 years or the time when reaching 10000 times of use. / Optional AC adapter: 5 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 | Monitor: approx. 350 g (not including batteries)<br>Arm cuff: approx. 163 g |

| | |
|---|---|
| Dimensions | Monitor: approx. 165 mm (W) × 70 mm (H) × 98 mm (L) / Arm cuff: approx. 145 mm × 532 mm (air tube: 750 mm) |
| Cuff circumference applicable to the monitor | 22 to 42 cm |
| Memory | Stores up to 60 readings per user |
| Contents | Monitor, arm cuff (HEM-FL31), 4 “AA” batteries, storage case, Instruction Manual 1 and 2, warranty card |
| Protection against electric shock | Internally powered ME equipment (when using only batteries)<br>Class II ME equipment (when using optional AC adapter) |
| Applied part | Type BF (arm cuff) |

### Note

- These specifications are subject to change without notice.
- This monitor is clinically investigated according to the requirements of EN ISO 81060-2:2014 and complies with EN ISO 81060-2:2019+A1:2020 +A2:2024. 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 and optional AC adapter are protected against solid foreign objects of 12.5 mm diameter and greater such as a finger. The monitor and optional AC adapters HHP-CM01 and HHP-KSM01 are protected against vertically falling water drops which may cause issues during a normal operation. The optional AC adapter HHP-OH01 is protected against oblique falling water drops which may cause issues during a normal operation.
- Operation mode classification complies with IEC 60601-1.
- This monitor communicates with a smart device using Bluetooth Low Energy. Pairing requires user interaction and the transmitted data is encrypted.
- Please refer to “UDI [8012] x.x.x” for the software version/build number; “x.x.x” may consist of a set of 2 to 6 numbers.

### About a wireless communication interference

The Bluetooth option in the product is used to connect to dedicated apps on mobile devices to synchronize date/time data from mobile device to the product, and to synchronize measurement data from the product to mobile device. Further handling of the data on the mobile device is up to the user’s discretion. This product operates in an unlicensed ISM band at 2.4 GHz where any third party can intercept the radio waves, willfully or accidentally, for any unknown purpose. In the event this product is used near other wireless devices such as microwave and wireless LAN, which operate on the same frequency band as this product, there is a possibility that interference may occur. If interference occurs, stop the operation of the other devices or relocate this product away from other wireless devices before attempting to use it.

## 6 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.

## 7 Important Information regarding Electromagnetic Compatibility (EMC)

This device conforms to the EN 60601-1-2:2015+A1:2021 Electromagnetic Compatibility (EMC) standard.
Further documentation in accordance with this EMC standard is available at https://healthcare.omron.com/electro-magnetic-compatibility
Refer to the EMC information for this device on the website.

## 8 Guidance and Manufacturer’s Declaration

- Hereby, OMRON HEALTHCARE Co., Ltd., declares that this device is in compliance with Directive 2014/53/EU.
- The full text of the EU declaration of conformity is available at the following internet address:
  https://www.omronhealthcare-ap.com/ap/support
- 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.

- Please report to the manufacturer and the regulatory authority in which you are established about any serious incident that has occurred in relation to this device.

# 9 Additional Information

### What is Blood Pressure?

Blood pressure is a measure of the force of blood flowing against the walls of the arteries. Arterial blood pressure is constantly changing during the course of the heart's cycle.
The highest pressure in the cycle is called the Systolic Blood Pressure; the lowest is the Diastolic Blood Pressure. Both pressures, the Systolic and Diastolic, are necessary to enable a physician to evaluate the status of a patient's blood pressure.

### What is Arrhythmia?

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

### What is AFib?

Atrial fibrillation is an arrhythmia that can be asymptomatic and intermittent and can lead to stroke and heart failure.
This device detects the possibility of Atrial Fibrillation, so you can consult your doctor for early diagnosis and treatment, which may prevent stroke or heart failure.

### Possible AFib Detection

Intelli sense AFib™

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

The state in which " AFib " symbol is displayed can influence your blood pressure measurements and make it difficult to get an accurate reading. If this occurs, it is recommended that you consult with your physician.

### What is the difference between the possible AFib detection feature and ECG?

The possible AFib detection feature uses pulse wave detection to detect a possibility of AFib with a sensitivity of 95.1 % and specificity of 98.6 %* (data based on a substantially equivalent device). ECG measures the electrical activity of the heart and can be used by a physician to diagnose AFib.

* Janik M et al. Diagnostic accuracy for detecting atrial fibrillation using a novel machine learning algorithm in a blood pressure monitor. Heart Rhythm. 2024 Apr 30:S1547-5271(24)02520-7

### If the " AFib " symbol does not appear, does it mean there is no possibility of AFib?

Even if the " AFib " symbol does not appear, there is still a possibility of AFib. If taking a measurement at a time when AFib does not occur, possible AFib might not be detectable. This monitor cannot detect all forms of AFib.

**⚠ Warning**

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

### Should I consult with my physician if the " AFib " symbol appears?

It is recommended that you consult with your physician if the " AFib " symbol appears. This symbol may be displayed for other reasons, such as other heart arrhythmias.

### What should I do if the " AFib " symbol sometimes appears?

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

### I have been diagnosed with AFib by my physician, but the " AFib " symbol does not appear.

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

### Is the blood pressure reading reliable when the " AFib " symbol or the irregular heartbeat symbol " ♡ " appears?

AFib or an irregular heartbeat can influence your blood pressure measurements and make it difficult to get an accurate reading. Repeated measurements may be required to overcome variabilities.* The monitor will indicate an error message (E5) if the influence of the irregular heartbeat is too severe to give a measurement result. If this occurs repeatedly, it is recommended that you consult with your physician.

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