

M7 Intelli IT AFib (HEM-7380T1-EBK)

ام7 انتلي اي تي افيب

Automatic Upper Arm Blood Pressure Monitor

Tensiomètre automatique brassard

Automatisches Oberarm-Blutdruckmessgerät

Misuratore automatico di pressione arteriosa da braccio

Monitor de presión arterial automático de brazo

Automatische bovenarmbloeddrukmeter

Измеритель артериального давления и частоты пульса автоматический

Otomatik Üst Kol Kan Basıncı Ölçüm Cihazı

جهاز قياس ضغط الدم الآلي القابل للتثبيت بأعلى الذراع

Instruction Manual 1: Safety and Other Information

Mode d'emploi 1 : Sécurité et autres informations

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Manuale di istruzioni 1: Sicurezza e altre informazioni

Manual de instrucciones 1: Seguridad y otra información

Gebruiksaanwijzing 1: Veiligheid en andere informatie

Руководство по эксплуатации 1: Информация о безопасности и другие сведения

Kullanım kılavuzu 1: Güvenlik bilgileri ve diğer bilgiler

دليل الإرشادات 1: الأمان ومعلومات أخرى

All for Healthcare

 Intelli
sense AFib

UK
CA
0086

CE 0197

EN

FR

DE

IT

ES

NL

RU

TR

AR

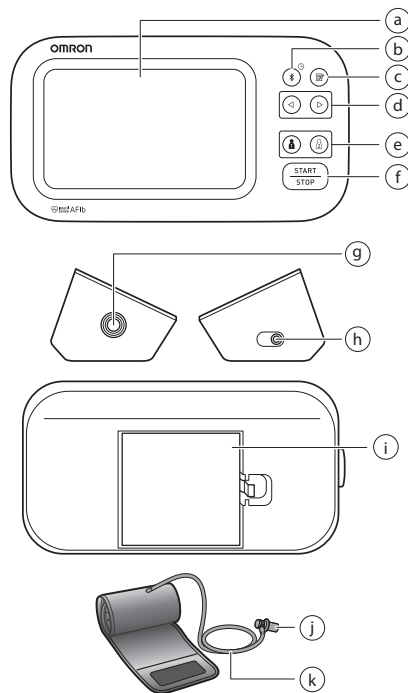
Symbols

Symboles / Symbole / Simboli /
Símbolos / Symbolen / Символы /
Semboller / الرموز

Overview

FR Présentation générale
DE Überblick
IT Presentazione del prodotto
ES Descripción general

NL Overzicht
RU Описание
TR Genel Bakış
AR نظرة عامة



a	Display Affichage Display	Display Pantalla Scherm	Дисплей Ekran الشاشة
b	[Connection] button [Date/Time] Bouton [Connexion] (Date/Heure) Verbindungstaste (Datum/Uhrzeit) Pulsante [Connessione] (Data/Ora) Botón [Conexión] (Fecha/Hora) Кноп [Verbindung] (Datum/tijd) Кнопка [Подключение] (Дата/Время) [Bağlantı] düğmesi (Tarih/Saat) الزر [الاتصال] (التاريخ/الوقت)		
c	[Memory] button Bouton [Mémoire] Taste [Speicher] Pulsante [Memoria] Botón [Memoria]		Кноп [Geheugen] Кнопка [Память] [Hafıza] düğmesi الزر [الذاكرة]
d	[Forward]/[Backward] buttons Boutons [Avant]/[Arrière] Vor-/Zurück-Tasten Pulsanti [Avanti]/[Indietro] Botones [Siguiente]/[Atrás] Knoppen [Vooruit]/[Terug] Кнопки [Вперед]/[Назад] [İleri]/[Geri] düğmeleri الزران [التقدم/الرجوع]		
e	[User ID 1]/[User ID 2] buttons Boutons [ID Utilisateur 1]/[ID Utilisateur 2] Tasten für Benutzer-ID 1/2 Pulsanti [ID utente 1]/[ID utente 2] Botones [ID de usuario 1]/[ID de usuario 2] Knoppen [Gebruikers-ID 1]/[Gebruikers-ID 2] Кнопки [Пользователь 1]/[Пользователь 2] [Kullanıcı Kimliği 1]/[Kullanıcı Kimliği 2] düğmeleri الزران [هوية المستخدم 1/هوية المستخدم 2]		
f	[START/STOP] button Bouton [START/STOP] [START/STOP]-Taste Pulsante [START/STOP] Botón [START/STOP]		Кноп [START/STOP] Кнопка [START/STOP] [START/STOP] düğmesi الزر [START/STOP]

g	Air jack Prise à air Luftschlauchbuchse Presa per il tubo dell'aria Toma de aire	Luchtslangaansluiting Воздушное гнездо Hava jaki مقبس خرطوم الهواء
h	AC adapter jack (for optional AC adapter) Prise pour l'adaptateur secteur (pour adaptateur secteur en option) Netzteilanschluss (für das optionale Netzteil) Presa per l'alimentatore CA (per l'alimentatore CA opzionale) Toma del adaptador de CA (para el adaptador de CA opcional) Netadapteraansluiting (voor de optionele netadapter) Гнездо адаптера переменного тока (приобретаемого дополнительно) AC adaptörü jaki (isteğe bağlı AC adaptörü için) مقبس مهايئ التيار المتردد (لمهايئ التيار المتردد الاختياري)	
i	Battery compartment Compartiment des piles Batteriefach Vano batterie Compartimento de las pilas	Batterijvak Отсек для элементов питания Pil bölmesi حجيرة البطاريات
j	Air plug Prise de gonflage Luftschlauchstecker Attacco del tubo dell'aria Conector para tubo de aire	Plug van de luchtslang Воздушный штекер Hava tapası قابس خرطوم الهواء
k	Air tube Tuyau à air Luftschlauch	Tubo dell'aria Tubo de aire Luchtslang Воздуховодная трубка Hava borusu خرطوم الهواء

1. Introduction

Thank you for purchasing the OMRON Automatic Upper Arm 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 Upper Arm 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 OMRON retail outlet or distributor 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. 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 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
- evaluate 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 OMRON retail outlet or distributor.

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 section 10 of instruction manual 2 for additional information.
- Stop using this monitor and consult with your physician if you experience skin irritation or discomfort.

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 screening feature evaluates 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 screening 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

- After the pairing process is completed, 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 ⚠ 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.

- 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 6.
- During measurement, observe the arm 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 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 6.
- DO NOT use this monitor after the durable period has ended. Refer to section 6.
- 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 7 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 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.













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. If the problem persists, please 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 8 of instruction manual 2.
	Air is leaking from the arm cuff.	Replace the arm cuff with a new one. Refer to section 15 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 section 10 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 section 10 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 8 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 OMRON retail outlet or distributor.
E rr 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 OMRON retail outlet or distributor.

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 8 of instruction manual 2. Remain still and sit correctly during a measurement.
 /  appears		If the irregular heartbeat symbol "  / 
 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 80 readings stored in memory.	Pair or transfer your readings to the "OMRON connect" app so you can keep them in memory in the app, and this symbol disappears.
	The date and time is not set.	
 appears	100 readings are stored in memory, and new readings will replace the old readings.	
 flashes	Batteries are low.	Replacing all 4 batteries with new ones is recommended. Refer to section 4 of instruction manual 2.
 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, 8 and 9 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 OMRON retail outlet or distributor.	
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 OMRON retail outlet or distributor.	

4. 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 a high level of comfort, provided that it is properly operated and maintained as described in the instruction manual. This product is warranted by OMRON for a period of 5 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:

- A. Transport costs and risks of transport.
 - B. Costs for repairs and / or defects resulting from repairs done by unauthorised persons.
 - C. Periodic check-ups and maintenance.
 - D. Failure or wear of optional parts or other attachments other than the main device itself, unless explicitly warranted above.
 - E. Costs arising due to non-acceptance of a claim (those will be charged for).
 - F. Damages of any kind including personal caused accidentally or from misuse.
 - G. Calibration service is not included within the warranty.
 - H. Optional parts have a one (1) year warranty from date of purchase. Optional parts include, but are not limited to the following items: cuff and cuff tube. 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, visit our website (www.omron-healthcare.com) for contact information. 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.

5. Maintenance

5.1 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.

5.2 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.
 1. Remove the arm cuff from the monitor. The air plug is designed to fit securely into the monitor so it does not accidentally unplug from the monitor when in use. When removing the arm cuff from the monitor, pull the air plug out from the monitor in a straight motion, holding the plug and not using the tube. You will hear a "click" sound as the cuff plug is removed from the monitor.

Precaution

To unplug the air plug, pull on the plastic air plug at the base of the tube, not the tube itself.

2. Gently fold the air tube into the arm cuff. Note: Do not bend or crease the air tube excessively.
 3. 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.

5.3 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.

5.4 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.

6. Specifications

Product Category	Electronic Sphygmomanometers
Product description	Automatic Upper Arm Blood Pressure Monitor
Model (Code)	M7 Intelli IT AFib (HEM-7380T1-EBK)
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 pressure release valve
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	Monitor: IP21 Optional AC adapter: IP21 (HHP-CM01) or IP22 (HHP-BFH01)
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. 700 measurements (using new alkaline batteries) The number of times may decrease when using TruRead mode because one TruRead mode consists of 3 regular measurements.
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. 440 g (not including batteries) Arm cuff: approx. 163 g
Dimensions	Monitor: approx. 191 mm (W) × 85 mm (H) × 117 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 100 readings per user
Contents	Monitor, arm cuff (HEM-FL31), 4 "AA" batteries, Instruction Manual 1 and 2, storage case, blood pressure pass
Protection against electric shock	Internally powered ME equipment (When using only batteries) Class II ME equipment (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 81060-2:2014 and EN ISO 81060-2:2019 + A1:2020 (excluding pregnant and pre-eclampsia patients). In the clinical validation study, K5 was used on 85 subjects for determination of diastolic blood pressure.
- This device has been validated for use on pregnant and pre-eclampsia patients according to the Modified European Society of Hypertension Protocol*.
- This device has been validated for use on diabetic (Type II) population**.
- 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 adapter HHP-CM01 are protected against vertically falling water drops which may cause issues during a normal operation. The optional AC adapter HHP-BFH01 is protected against oblique falling water drops which may cause issues during a normal operation.
- Operation mode classification complies with IEC 60601-1.
- Communication with a smart device is paired and encrypted according to Bluetooth Low Energy specifications. Pairing requires user interaction.

*Topouchian J et al. Vascular Health and Risk Management 2018;14 189-197
 ** Chahine M.N. et al. Medical Devices: Evidence and Research 2018;11 11 -20

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.

7. 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.



8. Important Information regarding Electromagnetic Compatibility (EMC)

HEM-7380T1-EBK conforms to the EN 60601-1-2 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 HEM-7380T1-EBK on the website.

9. Guidance and Manufacturer's Declaration

- Hereby, OMRON HEALTHCARE Co., Ltd., declares that the radio equipments type HEM-7380T1-EBK 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. The AFib algorithm was developed using several databases published by PhysioNet that are available under the ODC Attribution License. For more information, please visit the product page: www.omron-healthcare.com
- 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.

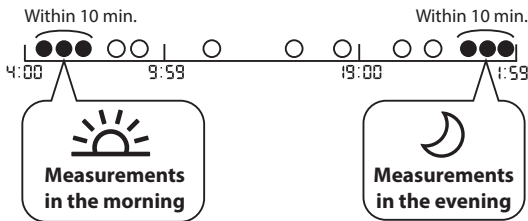
10. How to Calculate Weekly Averages

Morning Weekly Average Calculation

This is the average for the measurements taken during the morning (4:00 - 9:59) between Sunday and Saturday. The 2 or 3 readings taken within the first 10 minute timeframe in the morning between 4:00 - 9:59 will be used to calculate the morning average for each day.

Evening Weekly Average Calculation

This is the average for the measurements taken during the evening (19:00 - 1:59) between Sunday and Saturday. The 2 or 3 readings taken within the last 10 minute timeframe in the evening between 19:00 - 1:59 will be used to calculate the evening average for each day.



11. 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 (AFib) means the most common type of non-sinus tachyarrhythmia. This symptom may create blood clots. This can lead to major health problems, including strokes, transient ischemic attacks (TIAs), and pulmonary emboli (PEs); depending which chamber of the heart has the blood clot in it.



Possible AFib Detection



OMRON's trademarked technology alerts you once possible AFib is detected, even with a single measurement.

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 screening feature ONLY evaluates 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 screening feature and ECG?

The possible AFib screening feature uses pulse wave detection to detect a possibility of AFib. ECG measures the electrical activity of the heart and can be used by a physician to diagnose AFib.



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 screening feature evaluates 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.

Symbols Description

FR Description des symboles
DE Beschreibung der Symbole
IT Descrizione dei simboli
ES Descripción de los símbolos

NL Beschrijving van symbolen
RU Описание символов
TR Simgelerin Açıklaması
AR شرح الرموز

- | | | | |
|---|---|---|---|
| 1.  | 2.  | 3. IP XX | 4.  |
| 5.  | 6.  | 7.  | 8.  |
| 9.  | 10.  | 11.  | 12.  |
| 13.  | 14.  | 15.  | 16.  |
| 17. LATEX FREE | 18.  | 19.  | 20.  |
| 21.  | 22.  | 23.  | 24.  |
| 25.  | 26.  | 27.  | |

1.

Applied part - Type BF Degree of protection against electric shock (leakage current)

Pièce appliquée - Type BF Degré de protection contre les chocs électriques (courant de fuite)

Anwendungsteil - Type BF Schutz vor Stromschlägen (Ableitstrom)

Parti applicate - Tipo BF Livello di protezione contro le folgorazioni (corrente di dispersione)

Partes en contacto: Tipo BF Grado de protección contra descargas eléctricas (corriente de fuga)

Toegepast onderdeel - Type BF-beschermingsgraad tegen elektrische schokken (lekstroom)

Рабочая часть аппарата - Степень защиты от поражения электрическим током (токи утечки) Тип BF

Uygulanan parça - Tip BF Elektrik çarpmasına karşı koruma derecesi (kaçak akım)

الجزء المطبق: درجة الحماية ضد الصدمات الكهربائية (التيار المتسرب) للنوع BF

2.

Class II equipment. Protection against electric shock

Équipement de classe II. Protection contre les chocs électriques

Gerät der Klasse II. Schutz vor Stromschlägen

Apparecchiatura di Classe II. Protezione contro le folgorazioni

Equipo de Clase II. Protección contra descargas eléctricas

Apparatuur van Klasse II. Bescherming tegen elektrische schokken

Изделие класса II Защита от поражения электрическим током

Sınıf II ünite. Elektrik çarpmasına karşı koruma

جهاز من الفئة II. الحماية ضد الصدمات الكهربائية

3.

Ingress protection degree provided by IEC 60529

Degré de protection selon CEI 60529

Grad des Eindringenschutzes gemäß IEC 60529

Livello di protezione IP in base a IEC 60529

Grado de protección según la norma internacional IEC 60529

Beschermingsklasse volgens IEC 60529

Степень защиты, обеспечиваемая оболочками, согласно IEC 60529

Su girmesine karşı koruma derecesi IEC 60529 tarafından verilmiştir

درجة حماية الدخول المقدمة بواسطة معيار IEC 60529

4. **CE Marking**
Marquage CE
CE-Kennzeichnung
Contrasegno CE
Marcado CE
CE-merkteken
Знак соответствия директиве ЕС
CE İşareti
علامة التوافق مع اللجنة الأوروبية (CE)
5. **UKCA Marking**
Marquage UKCA
UKCA-Kennzeichnung
Marchio UKCA
Marcado UKCA
UKCA-markering
Знак соответствия требованиям для Великобритании
UKCA İşareti
UKCA علامة
6. **Serial number**
Numéro de série
Seriennummer
Numero di serie
Número de serie
Seriennummer
Порядковый (серийный) номер
Seri numarası
الرقم المتسلسل
7. **Unique device identifier**
Identifiant unique des dispositifs
Produktidentifizierungsnummer
Identificatore univoco del dispositivo
Identificador único del producto
Unieke apparaat-ID
Уникальный идентификатор медицинского изделия в Европейском Союзе
Benzersiz cihaz tanımlayıcısı
معرف الجهاز الفريد

8. **Medical device**
Dispositif médical
Medizinprodukt
Dispositivo medico
Producto sanitario
Mischig apparaat
Медицинское изделие в соответствии с правилами/директивой по медицинским изделиям Европейского Союза
Tıbbi cihaz
جهاز طبي
9. **Temperature limitation**
Limitation de température
Temperaturbegrenzung
Limite di temperatura
Limitación de la temperatura
Temperatuurbegrenzing
Температурный диапазон
Sıcaklık sınırlaması
حدود درجة الحرارة المناسبة
10. **Humidity limitation**
Limitation d'humidité
Luftfeuchtigkeitsbegrenzung
Limite di umidità
Limitación de la humedad
Vochtigheidsbegrenzing
Диапазон влажности
Nem sınırlaması
حدود الرطوبة المناسبة
11. **Atmospheric pressure limitation**
Limitation de pression atmosphérique
Luftdruckbegrenzung
Limite di pressione atmosferica
Limitación de la presión atmosférica
Luchtdrukbeğrenzing
Ограничение атмосферного давления
Atmosferik basınç sınırlaması
حدود الضغط الجوي المناسب

12. **Indication of connector polarity**
Indication de la polarité des connecteurs
Anzeige der Steckerpolarität
Indicazione della polarità dei connettori
Indicación de la polaridad del conector
Indicatie van polariteit van aansluiting
Полярность разъема адаптера
Bağlantı polarite göstergisi
علامة تشير قطبية الموصل
13. **For indoor use only**
Pour un usage à l'intérieur uniquement
Nur für die Nutzung in Innenbereichen
Solo per uso in interni
Para uso solo en interiores
Alleen voor gebruik binnenshuis
Для использования только внутри помещений
Sadece iç mekanda kullanım için
صالح للاستخدام في المناطق المغلقة فقط

14. **OMRON's trademarked technology alerts you once possible AFib is detected, even with a single measurement.**
La technologie brevetée d'OMRON vous alerte dès qu'un risque de fibrillation auriculaire est détecté, même avec une seule mesure.
Die markenrechtlich geschützte Technologie von OMRON warnt bei möglichem Vorhofflimmern – auch bei einer Einzelmessung.
La tecnologia brevettata da OMRON avvisa l'utilizzatore una volta rilevata la potenziale presenza di fibrillazione atriale, anche con una misurazione singola.
La tecnología de OMRON le notifica la detección de una posible fibrilación auricular incluso con una única medición.
De technologie voor bloeddrukmeting onder handelsmerk van OMRON waarschuwt u wanneer mogelijk AFib is gedetecteerd, zelfs bij een enkele meting.
Зарегистрированная технология OMRON сразу предупреждает Вас о выявлении вероятности ФП, даже при однократном измерении.
OMRON'un ticari markalı teknolojisi, tek bir ölçümle bile olası AFib tespit edilidiginde sizi uyandır.

15.

Identifier of cuffs compatible for the device

Identificateur des brassards compatibles avec l'appareil
Kennzeichnung der mit dem Gerät kompatiblen Manschetten
Identifica i bracciali compatibili con il dispositivo
Identificador para manguitos compatibles con el dispositivo
Identificatie van manchetten die compatibel zijn met het apparaat
Манжеты совместимые с устройством
Cihaz ile uyumlu kollukların tanıtım işareti
علامات تحديد الشروط الضاغطة المتوافقة مع الجهاز

17.

Not made with natural rubber latex

Ne contient pas de latex de caoutchouc naturel
Enthält kein Naturlatex
Non contiene lattice di gomma naturale
No contiene látex de caucho natural
Bevat geen natuurrubberlatex
Не содержит натуральный латекс
Doğal kauçuk lateksten üretilmemiştir
تم التصنيع دون استخدام لاتيكس المطاط الطبيعي

20.

Need for the user to follow this instruction manual thoroughly for your safety. (Background: blue)

L'utilisateur doit suivre attentivement ce mode d'emploi pour votre sécurité. (Fond : bleu)
Damit die Sicherheit gewährleistet ist, muss der Benutzer diese Gebrauchsanweisung sorgfältig befolgen. (Hintergrund: blau)
Per la propria sicurezza, l'utente deve seguire attentamente il presente manuale di istruzioni. (Sfondo: blu)
Es necesario que el usuario siga rigurosamente este manual de instrucciones para su seguridad. (Fondo: azul)
Noodzaak voor de gebruiker om zich voor de eigen veiligheid zorgvuldig aan deze gebruiksaanwijzing te houden (Achtergrond: blauw)
Обратитесь к руководству по эксплуатации (Фон: синий)
Güvenlik açısından kullanıcının bu kullanım kılavuzuna dikkatle uyması gerekir. (Arka plan: mavi)
حاجة المستخدم إلى اتباع الإرشادات الواردة في دليل الإرشادات بالكامل للحفاظ على السلامة. (الخلفية: زرقاء)

16.

Artery mark

Marque d'artère
Arterienmarkierung
Contrassegno per l'arteria
Marca de la arteria
Adersymbol
Маркер артерии
Arter işareti
علامة دالة على الشريان

19.

Need for the user to consult this instruction manual

L'utilisateur doit consulter le présent mode d'emploi
Der Benutzer muss diese Gebrauchsanweisung lesen
L'utente deve consultare il presente manuale di istruzioni
Es necesario que el usuario consulte este manual de instrucciones
Noodzaak voor de gebruiker om deze gebruiksaanwijzing te raadplegen
Необходимо ознакомиться с данным руководством по эксплуатации
Kullanıcının bu kullanım kılavuzuna başvurması gerekir
حاجة المستخدم إلى الرجوع إلى المعلومات الواردة بتدليل الإرشادات هنا

21.

Direct current

Courant continu
Gleichstrom
Corrente diretta
Corriente directa
Gelijkstroom
Постоянный ток
Doğru akım
التيار المباشر

22.

Alternating current

Courant alternatif
Wechselstrom
Corrente alternata
Corriente alterna
Wisselstroom
Переменный ток
Alternatif akım
التيار المتناوب

23.

Date of manufacture

Date de fabrication
Herstellungsdatum
Data di fabbricazione
Fecha de fabricación
Productiedatum
Дата изготовления в формате ГГГГММДД
Üretim tarihi
تاريخ التصنيع

24.

Efficiency level of power supply

Niveau d'efficacité de l'alimentation électrique
Effizienz der Stromversorgung
Livello di efficienza dell'alimentazione
Grado de eficiencia de la alimentación
Efficiëntieniveau van de voeding
Уровень эффективности источника питания
Güç kaynağının verimlilik seviyesi
مستوى كفاءة مصدر الطاقة

25.

Prohibited action

Action interdite
Verbotene Aktion
Operazione proibita
Acción prohibida
Verboden handeling
Запрещенное действие
Yasaklanmış eylem
إجراء محظور

26.

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.

Indique des niveaux de rayonnement non ionisant, potentiellement dangereux, généralement élevés, ou un équipement ou des systèmes, par exemple dans le domaine médical électrique, incluant des émetteurs RF ou utilisant intentionnellement de l'énergie électromagnétique RF pour le diagnostic ou le traitement. Als Hinweis auf allgemein erhöhte, potenziell gefährliche Stufen nicht-ionisierender Strahlung oder als Hinweis auf Geräte oder Systeme zum Beispiel im medizinisch-elektrischen Bereich, etwa HF-Übertragungsgeräte, bzw. auf solche, die elektromagnetische HF-Strahlung zur Diagnose oder Behandlung verwenden. Indica livelli generalmente elevati, potenzialmente pericolosi, di radiazioni non ionizzanti oppure indica apparecchiature o sistemi, ad esempio per le aree elettromedicali in cui sono presenti trasmettitori RF o in cui viene intenzionalmente applicata energia elettromagnetica a radiofrequenza per la diagnosi o il trattamento.

Para indicar niveles de radiación no ionizante generalmente elevados y potencialmente peligrosos, o bien para indicar equipos o sistemas, como los usados en el ámbito electromédico, que incorporen transmisores de radiofrecuencia o que apliquen energía electromagnética de radiofrecuencia intencionadamente para diagnósticos o tratamientos.

Geeft in het algemeen verhoogde, potentieel gevaarlijke niveaus aan van niet-ioniserende straling of duidt op apparatuur of systemen, bijvoorbeeld in de medische elektrische omgeving, die RF-zenders bevatten of die opzettelijk elektromagnetische RF-energie toepassen voor diagnose of behandeling.

Для указания повышенных и потенциально опасных уровней неионизирующей радиации или же оборудования или систем (например, в зоне размещения медицинского электрооборудования), включающих в себя радиопередатчики или устройства, использующие радиочастотную электромагнитную энергию в целях диагностики или терапии.

Genellike yüksek ve zararlı olabilecek iyonlaşmayan radyasyon seviyelerini belirtir veya RF vericileri içeren veya tanı ya da tedavi amacıyla bilinçli olarak RF elektromanyetik enerji uygulayan (örneğin medikal elektrik alanında bulunan) ekipman ve sistemleri belirtir.

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27.

Recycle mark X: Material number Y: Material abbreviation Refer to 97/129/EC for more information.

Marque de recyclage X: Numérotation des matériaux Y: Abréviation pour les matériaux Voir 97/129/CE pour plus d'informations.

Recyclingsymbol X: Materialnummer Y: Materialabkürzung Weitere Informationen siehe 97/129/EG.

Simbolo di riciclaggio X: Codice materiale Y: Abbreviazione materiale Fare riferimento a 97/129/CE per ulteriori informazioni.

Marca de reciclaje X: Número de material Y: Abreviatura del material Consulte 97/129/CE para más información.

Recycleer markering X: Materiaalnummer Y: Materiaalafkorting Raadpleeg 97/129/EG voor meer informatie.

Знак переработки X: Числовое обозначение материала Y: Подробнее о сокращенном названии материалов см. 97/129/EC.

Gerî dönüřüm işareti X: Malzeme numarası Y: Malzeme kısaltması Daha fazla bilgi için bkz. 97/129/EC.

علامة إعادة التدوير X: رقم المادة Y: اختصار المادة راجع 97/129/EC للمزيد من المعلومات.

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Note

Note

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