

Automatic Upper Arm Blood Pressure Monitor

جهاز قياس ضغط الدم الآلي القابل للتثبيت بأعلى الذراع

M7 Intelli IT (HEM-7361T-EBK) إم 7 أنتيلي أي تي**X7 Smart (HEM-7361T-ESL) اكس 7 سمارت****Read Instruction manual ① and ② before use.****FR** Lire le mode d'emploi ① et ② avant l'utilisation.**DE** Lesen Sie vor der Verwendung Gebrauchsanweisung ① und ②.**IT** Leggere il manuale di istruzioni ① e ② prima dell'uso.**ES** Lea el manual de instrucciones ① y ② antes del uso.**NL** Lees gebruiksaanwijzing ① en ② voor gebruik.**RU** Прочтите руководства по эксплуатации ① и ② перед использованием.**TR** Kullanmadan önce, kullanım kılavuzu ① ve ②'yi okuyun.**AR** اقرأ دليل الإرشادات ① و ② قبل الاستخدام.

EN

FR

DE

IT

ES

NL

RU

TR

AR

Symbols

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

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 the safety and operating instructions. **If you do not understand these instructions or have any questions, contact your OMRON retail outlet or distributor before attempting to use this monitor. For specific information about your own blood pressure, consult with your physician.**

1.2 Intended Use

The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population. The device detects the appearance of irregular heartbeats during measurement and indicates this via a symbol with the measurement results. It is mainly designed for general household use. 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 Electrocardiogram (ECG). If the Afib symbol appears, consult your physician.

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 Warning

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

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



2.2 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 an arm where intravascular access or therapy, or an arteriovenous (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.

- Consult with your physician before using this monitor if you have severe blood flow problems or blood disorders as cuff inflation can cause bruising.
- DO NOT take measurements more often than necessary because bruising, due to blood flow interference, may occur.
- ONLY inflate the 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 the possibility of Afib.
- During measurement, make sure that no mobile device or any other electrical device that emit 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 and/or cause an inaccurate reading.
- Avoid bathing, drinking alcohol or caffeine, smoking, exercising and eating for at least 30 minutes before taking a measurement.
- Rest for at least 5 minutes before taking a measurement.
- Remove tight-fitting, thick clothing and any accessories from your 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. 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 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.
- 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 13 of instruction manual (2) for additional information.
- 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 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 cleaning 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 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.

2.3 General Precautions

- 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.
- 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.

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
 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. After inserting the air plug securely and applying the arm cuff correctly, press the [START/STOP] button.
	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 7 of instruction manual (2).
	Air is leaking from the arm cuff.	Replace the arm cuff to the new one. Refer to section 14 of instruction manual (2).
 appears or a measurement cannot be completed after the arm cuff inflates.	You move or talk during a measurement and the arm cuff does 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 13 of instruction manual (2).
	Due to the systolic pressure is above 210 mmHg, a measurement cannot be taken.	
 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 13 of instruction manual (2).
 appears	You move or talk during a measurement. Vibrations disrupt a measurement.	Remain still and do not talk during a measurement.
 appears	The pulse rate is not detected correctly.	Apply the arm cuff correctly, then take another measurement. Refer to section 7 of instruction manual (2). Remain still and sit correctly during a measurement. If the "  " symbol continues to appear, we recommend you to consult with your physician.
   appears		
 does not flash during a measurement		

Display/Problem	Possible Cause	Solution
 appears	Blood pressure measurements were not taken correctly in an Afib mode measurement.	Apply the arm cuff correctly, then take another measurement. Refer to section 7 of instruction manual (2). Remain still and sit correctly during a measurement. Refer to section 8 of instruction manual (2).
 appears	The monitor has malfunctioned.	Press the [START/STOP] button again. If “Er” still appears, contact your OMRON retail outlet or distributor.
  appears	The monitor cannot connect to a smart device or transmit data correctly.	Follow the instructions shown in the “OMRON connect” app. If the “Err” symbol still appears after checking the app, contact your OMRON retail outlet or distributor.
 flashes	The 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 [START/STOP] button to cancel pairing and turn your monitor off.
 flashes	The monitor is ready to transfer your readings to the smart device.	Open the “OMRON connect” app to transfer your readings.
 flashes	More than 80 readings are not transferred. The date and time is not set.	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	100 readings are not transferred.	
 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 section 2 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.	

Display/Problem	Possible Cause	Solution
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 batteries. If the problem still persists, contact your OMRON retail outlet or distributor.	
Troubleshooting for Afib indicator function:		
What is different between the Afib indicator function and ECG?	The Afib indicator function and ECG use completely different technologies. An ECG measures the electrical activity of the heart and can be used to diagnose Afib. The Afib indicator function detects irregular heartbeat and can suggest the possibility of Afib with a sensitivity of 95.5% and specificity of 93.8%. Refer to section 11 for details.	
If the "⊠" symbol does not appear, it means there is no possibility of Afib?	Even if the "⊠" symbol does not appear, there is still a possibility of Afib.	
Should I consult with my physician if the "⊠" symbol appears?	We recommend you to consult with your physician because there is a possibility of Afib. However, the "⊠" symbol may be displayed for other reasons, such as other heart arrhythmias.	
What is different between Afib indicator function and irregular heart beat function?	The irregular heartbeat function detects irregularities in the pulse waves in one measurement. The Afib indicator function suggests the possibility of Afib when blood pressure is measured 3 consecutive times.	
What should I do if the "⊠" symbol sometimes appears?	Afib does not always have symptoms. We recommend you to consult with and follow the directions of your physician.	
I have been diagnosed with Afib by the physician, but the "⊠" symbol does not appear.	Afib may not occur at the time of specific blood pressure with measurements. We recommend you to consult with your physician regularly.	
Is the blood pressure reading reliable when the "⊠" 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.* In Afib mode, the blood pressure measurement is taken 3 times, and the average is displayed. The monitor will indicate an error message (E5/E6) if the influence of the irregular heartbeat is too severe to give a measurement result. If this occurs repeatedly, we recommend that you consult with your physician.	

* Prof. Roland Asmar et al. European Society of Hypertension Recommendations for Conventional, Ambulatory and Home Blood Pressure Measurement

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 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 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, 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.

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.

Caution

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

5.2 Storage

- Keep your monitor in the storage case when not in use.
 1. Remove the arm cuff from the monitor.

Caution

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.
- Store your monitor and other components in a clean, safe location.
 - 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.
 - To protect your monitor during storage, an optional LCD cover is available as accessory. Refer to section 15 of Instruction Manual (2).

5.3 Cleaning

- Do not use any abrasive or volatile cleaners.
- Use a soft dry cloth or a soft cloth moistened with mild (neutral) detergent to clean 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 clean 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 (HEM-7361T-EBK) / X7 Smart (HEM-7361T-ESL)
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: $\pm 5\%$ 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: IP20 Optional AC adapter: IP21 (HHP-CM01) or IP22 (HHP-BFH01)
Rating	DC6 V 4.0 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	Approximately 1000 measurements (using new alkaline batteries) The number of times may decrease when using Afib mode because one Afib indication consists of 3 regular measurements.
Durable period (Service life)	Monitor: 5 years / Cuff: 5 years / 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: approximately 460 g (not including batteries) Arm cuff: approximately 163 g
Dimensions (approximately value)	Monitor: 191 mm (W) × 85 mm (H) × 120 mm (L) / Arm cuff: 145 mm × 532 mm (air tube: 750 mm)
Cuff circumference applicable to the monitor	220 to 420 mm
Memory	Stores up to 100 readings per user
Contents	Monitor, arm cuff (HEM-FL31), 4 "AA" batteries, Instruction Manual (1) and (2), setup instructions, storage case
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. 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 optional AC adapter HHP-CM01 is 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.

* 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

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.

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-7361T-EBK/ESL conforms to the EN60601-1-2:2015 Electromagnetic Compatibility (EMC) standard.

Further documentation in accordance with this EMC standard is available at OMRON HEALTHCARE EUROPE at the address mentioned in this instruction manual or at: www.omron-healthcare.com.

9. Guidance and Manufacturer's Declaration

- 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 equipments type HEM-7361T-EBK/ESL 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.
- 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.

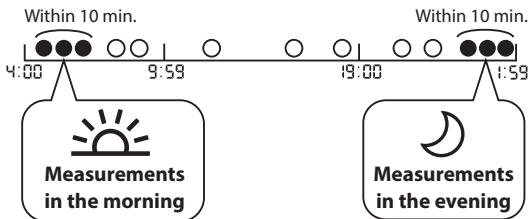
10. How to Calculate Weekly Averages

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. Useful 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 (also called Afib or AF) is a quivering or irregular heartbeat (arrhythmia) that can lead to blood clots, stroke, heart failure and other heart-related complications. During atrial fibrillation, the heart's two upper chambers (the atria) beat chaotically and irregularly — out of coordination with the two lower chambers (the ventricles) of the heart. Episodes of atrial fibrillation can come and go, or you may develop atrial fibrillation that doesn't go away and may require treatment.

Afib indicator function detects the possibility of Afib with an accuracy of 94.2% (with sensitivity of 95.5% and specificity of 93.8%) as demonstrated in the study* with Single-lead ECG as reference measurement.

*M. Ishizawa, T. Noma, T. Minamino et al., Multiple measurements with automated blood pressure monitor can detect atrial fibrillation with high sensitivity and specificity in general cardiac patients, ESC Congress 2018

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 وصف الرموز



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

FR Partie appliquée - Type BF Degré de protection contre les chocs électriques (courant de fuite)
DE Anwendungsteil - Typ BF Schutz vor Stromschlägen (Ableitstrom)
IT Parti applicate - Tipo BF Livello di protezione contro le folgorazioni (corrente di dispersione)
ES Partes en contacto: Tipo BF Grado de protección contra descargas eléctricas (corriente de fuga)

NL Toegestap onderdeel - Type BF- beschermingsgraad tegen elektrische schokken (lekstroom)
RU Рабочая часть аппарата - Тип BF Степень защиты от поражения электрическим током (токи утечки)
TR Uygulanan parça - Tip BF Elektrik çarpmasına karşı koruma derecesi (kaçak akım)

AR جزء مطبق من النوع BF - درجة الحماية ضد الصدمات الكهربائية (التيار المتسرب)



Class II equipment. Protection against electric shock

FR Équipement de classe II. Protection contre les chocs électriques
DE Gerät der Klasse II. Schutz vor Stromschlägen
IT Apparecchiatura di Classe II. Protezione contro le folgorazioni
ES Equipo de Clase II. Protección contra descargas eléctricas

NL Apparaat van Klasse II. Bescherming tegen elektrische schokken
RU Оборудование класса II. Защита от поражения электрическим током
TR Sınıf II ekipman. Elektrik çarpmasına karşı koruma

AR جهاز من الفئة II. الحماية ضد الصدمات الكهربائية

IP XX

Ingress protection degree provided by IEC 60529

FR Degré de protection selon CEI 60529
DE Grad des Eindringenschutzes gemäß IEC 60529
IT Livello di protezione IP in base a IEC 60529
ES Grado de protección según la norma internacional IEC 60529

NL Beschermingsklasse volgens IEC 60529
RU Степень защиты, обеспечиваемая оболочкой, в соответствии со стандартом IEC 60529
TR Su girmesine karşı koruma derecesi IEC 60529 tarafından verilmiştir

AR درجة الحماية من التسرب وفقاً لمعيار IEC 60529



CE Marking

FR Marquage CE
DE CE-Kennzeichnung
IT Contrassegno CE
ES Marcado CE

NL CE-merkteken
RU Знак соответствия директиве EC
TR CE İşareti

AR علامة التوافق مع اللجنة الأوروبية (CE)



UKCA marking

FR Marquage UKCA
DE UKCA-Kennzeichnung
IT Marchio UKCA
ES Marcado UKCA

NL UKCA-markering
RU Маркировка UKCA
TR UKCA işareti

AR علامة تقييم التوافق الخاص بالمملكة المتحدة



Serial number

FR Numéro de série
DE Seriennummer
IT Numero di serie
ES Número de serie

NL Seriennummer
RU Серийный номер
TR Seri numarası

AR الرقم المتسلسل








LOT number



FR Numéro de LOT
DE LOT-Nummer
IT Numero di lotto
ES Número de lote



NL Partijnummer
RU Номер ПАРТИИ
TR Parti numarası

AR رقم التشغيل

UDI	Unique device identifier FR Identifiant unique des dispositifs DE Produktidentifizierungsnummer IT Identificatore univoco del dispositivo ES Identificador único del producto	NL Unieke apparaat-ID RU Уникальный идентификатор устройства TR Benzersiz cihaz tanımlayıcısı AR معرّف الجهاز الفريد
MD	Medical device FR Dispositif médical DE Medizinprodukt IT Dispositivo medico ES Producto sanitario	NL Medisch apparaat RU Медицинский прибор TR Tibbi cihaz AR جهاز طبي
REF	Indicates the manufacturer's catalogue number FR Indique le numéro de catalogue du fabricant DE Angabe der Hersteller-Katalognummer IT Indica il numero di catalogo del produttore ES Indica el número de catálogo del fabricante	NL Geeft het catalogusnummer van de fabrikant aan RU Указывает номер в каталоге производителя TR Üreticinin katalog numarasını belirtir AR للإشارة إلى رقم القائمة الخاص بالشركة المصنعة
	Temperature limitation FR Limitation de température DE Temperaturbegrenzung IT Limite di temperatura ES Limitación de la temperatura	NL Temperatuurbegrenzing RU Температурный диапазон TR Sıcaklık sınırlaması AR حدود درجة الحرارة المناسبة
	Humidity limitation FR Limitation d'humidité DE Luftfeuchtigkeitsbegrenzung IT Limite di umidità ES Limitación de la humedad	NL Vochtigheidsbegrenzing RU Диапазон влажности TR Nem sınırlaması AR حدود الرطوبة المناسبة

	Atmospheric pressure limitation FR Limitation de pression atmosphérique DE Luftdruckbegrenzung IT Limite di pressione atmosferica ES Limitación de la presión atmosférica	NL Luchtdrukbeperking RU Диапазон атмосферного давления TR Atmosferik basınç sınırlaması AR حدود الضغط الجوي المناسب
	Indication of connector polarity FR Indication de la polarité des connecteurs DE Anzeige der Steckerpolarität IT Indicazione della polarità dei connettori ES Indicación de la polaridad del conector	NL Indicatie van polariteit van aansluiting RU Индикация полярности разъема TR Bağlantı polarite göstergesi AR علامة تشير إلى قطبية الموصل
	For indoor use only FR Pour un usage à l'intérieur uniquement DE Nur für die Nutzung in Innenbereichen IT Solo per uso in interni ES Para uso solo en interiores	NL Alleen voor gebruik binnenshuis RU Для использования только внутри помещений TR Sadece iç mekanda kullanım için AR صالِح للاستخدام في الأماكن المغلقة فقط

	OMRON's trademarked technology for blood pressure measurement	
	FR Technologie brevetée OMRON pour la mesure de la pression artérielle	NL Technologie voor bloeddrukmeting onder handelsmerk van OMRON
	DE Markenrechtlich geschützte Technologie von OMRON zur Blutdruckmessung	RU Зарегистрированная технология измерения артериального давления OMRON
	IT Tecnologia brevettata OMRON per la misurazione della pressione arteriosa	TR OMRON'un kan basıncı ölçümü için ticari markalı teknolojisidir
	ES La tecnología de OMRON para medir la presión arterial	AR تقنية العلامة التجارية OMRON لقياس ضغط الدم
	Identifier of cuffs compatible for the device	
	FR Identificateur des brassards compatibles avec l'appareil	NL Identificatie van manchetten die compatibel zijn met het apparaat
DE Kennzeichnung der mit dem Gerät kompatiblen Manschetten	RU Манжеты, совместимые с устройством	
IT Identifica i bracciali compatibili con il dispositivo	TR Cihaz ile uyumlu kollukların tanıtım işareti	
ES Identificador para manguitos compatibles con el dispositivo	AR علامات تحديد الشروط الضاغطة المتوافقة مع الجهاز	

	Marker on the cuff to be positioned above the artery	
	FR Repère sur le brassard, à positionner au-dessus de l'artère	NL Markering op de manchet die boven de slagader moet worden geplaatst
	DE Markierung auf der Manschette, die oberhalb der Arterie liegen muss	RU Указатель на манжете для расположения над артерией
	IT Contrassegno sul bracciale da posizionare al di sopra dell'arteria	TR Kolluk üzerindeki işaretin konumu arterin üzerine gelmelidir
	ES La marca del manguito debe colocarse sobre la arteria	AR علامة بالشريط الضاغطة للإشارة إلى وجوب وضعه فوق الشريان
	Manufacturer's quality control mark	
FR Marque de contrôle de la qualité du fabricant	NL Symbool voor kwaliteitscontrole van fabrikant	
DE Qualitätskontrollzeichen des Herstellers	RU Отметка производителя о контроле качества	
IT Contrassegno controllo qualità del produttore	TR Üreticinin kalite kontrol işareti	
ES Marca del control de calidad del fabricante	AR علامة التحكم في الجودة الخاصة بالشركة المصنعة	
LATEX FREE	Not made with natural rubber latex	
	FR Ne contient pas de latex de caoutchouc naturel	NL Bevat geen natuurrubberlatex
	DE Enthält kein Naturlatex	RU Не содержит натуральный латекс
	IT Non contiene lattice di gomma naturale	TR Doğal kauçuk lateksten üretilmemiştir
	ES No contiene látex de caucho natural	AR تم التصنيع دون استخدام لاتيكس المطاط الطبيعي

	<p>Arm circumference</p> <p>FR Circonférence du bras DE Armmumfang IT Circonferenza del braccio ES Perímetro de brazo AR محيط الذراع</p> <p>NL Armomtrek RU Окружность плеча TR Kol çevresi</p>
	<p>Necessity for the user to consult this instruction manual</p> <p>FR L'utilisateur doit consulter le mode d'emploi DE Der Benutzer muss diese Gebrauchsanweisung lesen IT L'utente deve consultare il presente manuale di istruzioni ES Es necesario que el usuario consulte este manual de instrucciones AR ضرورة رجوع المستخدم إلى دليل الإرشادات هذا</p> <p>NL De gebruiker dient deze gebruiksaanwijzing te raadplegen RU Необходимость для пользователя обратиться к данному руководству по эксплуатации TR Kullanıcı, bu kullanım kılavuzuna başvurmaldır AR ضرورة رجوع المستخدم إلى دليل الإرشادات هذا</p>
	<p>Need for the user to follow this instruction manual thoroughly for your safety.</p> <p>FR L'utilisateur doit suivre attentivement ce mode d'emploi pour votre sécurité. DE Damit die Sicherheit gewährleistet ist, muss der Benutzer diese Gebrauchsanweisung sorgfältig befolgen. IT Per la propria sicurezza, l'utente deve seguire attentamente il presente manuale di istruzioni. ES Es necesario que el usuario siga rigurosamente este manual de instrucciones para su seguridad. AR حاجة المستخدم إلى اتباع دليل الإرشادات بالكامل للحفاظ على السلامة.</p> <p>NL Voor de eigen veiligheid dient de gebruiker zich zorgvuldig aan deze gebruiksaanwijzing te houden. RU В целях обеспечения безопасности строго следуйте указаниям в данном руководстве по эксплуатации. TR Güvenlik açısından kullanıcının bu kullanım kılavuzuna dikkatle uyması gerekir.</p>

	<p>Direct current</p> <p>FR Courant continu DE Gleichstrom IT Corrente diretta ES Corriente directa AR التيار المباشر</p> <p>NL Gelijkstroom RU Постоянный ток TR Doğru akım</p>
	<p>Alternating current</p> <p>FR Courant alternatif DE Wechselstrom IT Corrente alternata ES Corriente alterna AR التيار المتناوب</p> <p>NL Wisselstroom RU Переменный ток TR Alternatif akım</p>
	<p>Date of manufacture</p> <p>FR Date de fabrication DE Herstellungsdatum IT Data di fabbricazione ES Fecha de fabricación AR تاريخ التصنيع</p> <p>NL Productiedatum RU Дата изготовления TR Üretim tarihi</p>
	<p>Prohibited action</p> <p>FR Action interdite DE Verbotene Aktion IT Operazione proibita ES Acción prohibida AR إجراء محظور</p> <p>NL Verboden handling RU Запрещенные действия TR Yasaklanmış eylem</p>



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.

FR Pour indiquer des niveaux généralement élevés, potentiellement dangereux, de rayonnement non ionisant, ou pour indiquer l'équipement ou les systèmes, par exemple dans le domaine de l'électricité médicale qui comprennent des émetteurs RF ou qui utilisent intentionnellement l'énergie électromagnétique RF pour le diagnostic ou le traitement.

DE 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.

IT 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).

ES 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 electro médico, que incorporen transmisores de radiofrecuencia o que apliquen energía electromagnética de radiofrecuencia intencionadamente para diagnósticos o tratamientos.

NL 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.

RU 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.

TR Genellikle 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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