OMRON





Automatic Blood Pressure Monitor

Model M6 Comfort

Instruction Manual

English

Français

Deutsch

Italiano

Español

Nederlands

Русский

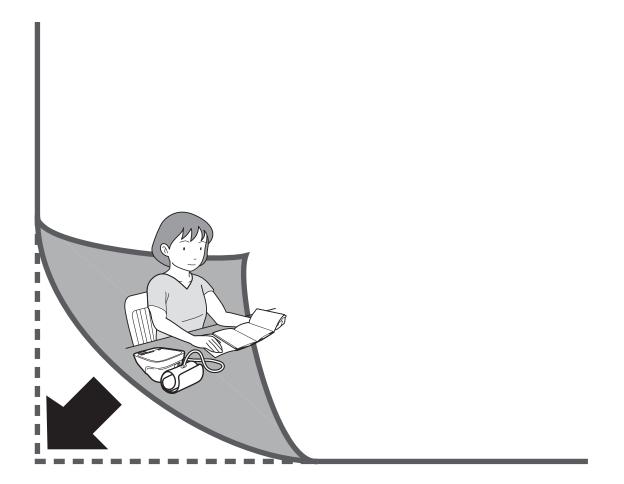
Türkçe

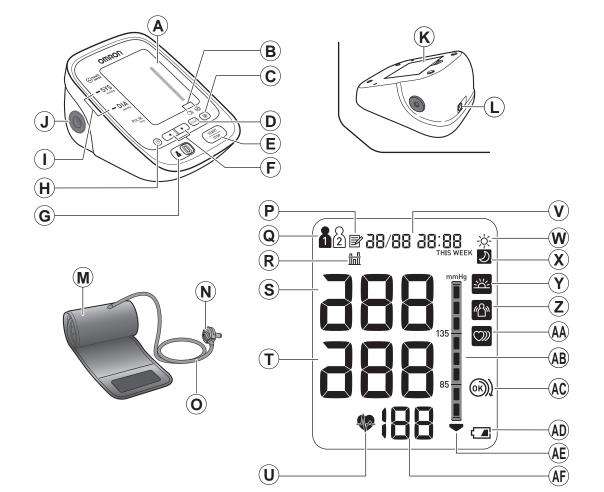
العربية

⊘ Intelli sense

All for Healthcare

IM-HEM-7321-E-02-07/2015 2298869-1B





Contents

Thank you for purchasing the OMRON M6 Comfort Automatic Blood Pressure Monitor.

The OMRON M6 Comfort is a compact, fully automatic blood pressure monitor, operating on the oscillometric principle. It measures your blood pressure and pulse rate simply and quickly. For comfortable controlled inflation without the need of pressure pre-setting or re-inflation the device uses its advanced "IntelliSense" technology.

Intended Use

This device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population who can understand this instruction manual with the arm circumference range printed on the arm cuff. The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with measurement result.

Im	oorta	nt Safety Information	1
1.	Kno	w Your Device	4
2.	Prep	oaration	7
		Battery Installation	
	2.2	Setting the Date and Time	8
3.		ng the Device	
	3.1	Applying the Arm Cuff	9
		How to Sit Correctly 1	
		Taking a Measurement 1	
		Using the Memory Function 1	
		,	

4.	Erro	or Messages and Troubleshooting.	.18	
	4.1	Error Messages	.18	
	4.2	Troubleshooting	.20	
5.		ntenance and Storage		
		Maintenance		
	5.2	Storage	.23	
		Optional Medical Accessories		
6.		cifications		
7.	War	ranty	.29	
	Some Useful Information about Blood			
	Pres	ssure	.30	



Please read this instruction manual thoroughly before using the device. Please keep for future reference. For specific information about your own blood pressure, CONSULT YOUR PHYSICIAN.

Important Safety Information

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

(General Usage)

- ▲ Consult your physician before using the device in pregnancy including pre-eclampsia, or if diagnosed with arrhythmia or arteriosclerosis.
- ▲ Do not use the device on the injured arm or the arm under medical treatment.
- ▲ Do not apply the arm cuff on the arm while being on an intravenous drip or blood transfusion.
- ▲ Consult your physician before using the device on the arm with an arterio-venous (A-V) shunt.
- ▲ Do not use the device with other medical electrical (ME) equipment simultaneously.
- ▲ Do not use the device in the area the HF surgical equipment, MRI, or CT scanner exists, or in the oxygen rich environment.
- ▲The air tube or the AC adapter cable may cause accidental strangulation in infants.
- ▲ Contained small parts that may cause a choking hazard if swallowed by infants.

(AC Adapter (optional) Usage)

- ▲ Do not use the AC adapter if the device or the power cord is damaged. Turn off the power and unplug the power cord immediately.
- ▲ Plug the AC adapter into the appropriate voltage outlet. Do not use in a multi-outlet plug.
- ▲ Never plug in or unplug the power cord from the electric outlet with wet hands.

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

(General Usage)

- Always consult your physician. Self-diagnosis of measurement results and self-treatment are dangerous.
- ⚠ People with severe blood flow problems, or blood disorders, should consult a physician before using the device, as the arm cuff inflation can cause bruising.

Important Safety Information

⚠If there are any abnormalities during the measurement, remove the arm cuff.

⚠Do not use this device on infants or persons who cannot express their intentions.

♠Do not inflate the arm cuff more than necessary.

 \triangle Do not use the device for any purpose other than measuring blood pressure.

⚠Use only the approved arm cuff for this device. Use of other arm cuffs may result in incorrect measurement results.

△Do not use a mobile phone or other devices that emit electromagnetic fields, near the device. This may result in incorrect operation of the device.

⚠Do not disassemble the monitor or arm cuff.

⚠Do not use in a location with moisture, or a location where water may splash on the device. This may damage the device.

⚠Do not use the device in a moving vehicle (car, airplane).

⚠Do not take measurements more than necessary. It may cause bruising due to blood flow interference.

⚠ Consult your physician before using the device if you had a mastectomy.

(AC Adapter (optional) Usage)

⚠ Fully insert the power plug into the outlet.

⚠When disconnecting the power plug from the outlet, do not pull the power cord. Be sure to pull from the power plug safely.

⚠When handling the power cord, take care not to do the following:

Do not damage. Do not break it.

Do not tamper with it.

Do not forcibly bend or pull.

Do not bundle during use.

Do not pinch. Do not place under heavy objects.

⚠Wipe the dust off from the power plug.

⚠Unplug monitor when not in use.

⚠ Disconnect the power plug before cleaning.

⚠Use only the original AC adapter designed for this device. Use of unsupported adapters may damage and/or may be hazardous to the device.

Important Safety Information

(Battery Usage)

⚠ Do not insert the batteries with their polarities incorrectly aligned.

⚠Use only 4 "AA" alkaline or manganese batteries with this device. Do not use other types of batteries. Do not use new and used batteries together.

A Remove the batteries if the device will not be used for three months or more.

General Precautions

- Do not forcibly crease the arm cuff or the air tube excessively.
- Do not press the air tube while taking a measurement.
- To unplug the air plug, pull on the air plug at the connection with the monitor, not the tube itself.
- Do not drop the monitor or subject device to strong shocks or vibrations.
- Do not inflate the arm cuff when it is not wrapped around your arm.
- Do not use the device outside the specified environment. It may cause an inaccurate reading.
- Read and follow the "Important information regarding Electro Magnetic Compatibility (EMC)" in the "6. Specifications".
- Read and follow the "Correct Disposal of This Product" in "6. Specifications" when disposing of the device and any
 used accessories or optional parts.

1. Know Your Device

Open the rear cover page to read the following:

The alphabet in the rear cover page correspond to those in the body page.

Monitor

- A Display
- B Cuff wrap guide lamp
- © Memory button
- DWeekly average button
- **ESTART/STOP** button
- **FUp/Down buttons**
- ©USER ID selection switch
- (H) Date/Time setting button
- Blood pressure colour indicator
- J Air jack
- **®** Battery compartment
- LAC adapter jack (for optional AC adapter)

Arm cuff

- MArm cuff (Arm circumference 22-42cm)
- N Air plug
- OAir tube

Display

- P Memory symbol
- **QUSER ID symbol**
- R Average value symbol
- Systolic blood pressure
- TDiastolic blood pressure
- W Heartbeat symbol (Flashes during measurement)
- ♥ Date/Time display
- Morning average symbol
- **★**Evening average symbol
- Morning hypertension symbol
- Z Movement error symbol
- Mirregular heartbeat symbol
- (AB) Blood pressure level indicator
- & Cuff wrap guide
- AD Low battery symbol
- **Æ** Deflation symbol
- (A) Pulse display / Memory number

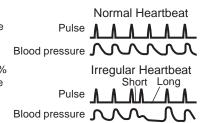
Display Symbols

Irregular Heartbeat Symbol ()

When the monitor detects an irregular rhythm two or more times during the measurement, the irregular heartbeat symbol () will appear on the display with the measurement values.

An irregular heartbeat rhythm is defined as a rhythm that is 25% less or 25% more than the average rhythm detected while the monitor is measuring the systolic and diastolic blood pressure.

If the irregular heartbeat symbol () isplays with your measurement results, we recommend you consult your physician. Follow the directions of your physician.



Movement Error Symbol ()

The movement error symbol is displayed if you move your body during the measurement. Please remove the arm cuff, and wait 2-3 minutes. Take another measurement, remain still during measurement.

Average Value Symbol ("")

The average value symbol is displayed when you press and hold the memory button for more than 3 seconds. The most recent average value appears on the display screen.

Cuff Wrap Guide Lamp (())

If the cuff was wrapped too loosely, it may cause unreliable results. If the wrapping of cuff is too loose, the cuff wrap guide Lamp () lights in "orange". Otherwise (i) lights in "green". This is the function which is used as an aid in determining if the cuff is wrapped snugly enough.

1. Know Your Device

Blood Pressure Colour Indicator

If your systolic or diastolic pressure is above the standard range (135 mmHg for the systolic blood pressure and/or 85 mmHg for the diastolic blood pressure), the blood pressure colour indicator will light in "orange" when the measurement result is displayed. If they are within the standard range, the blood pressure colour indicator will light in "green".



The JNC7* Guideline recommends the following guideline.

	General Guidelines for Blood Pressure		
	Prehypertension at Office	Hypertension at Home	
Systolic Blood Pressure	120-139 mmHg	135 mmHg	
Diastolic Blood Pressure	80-89 mmHg	85 mmHg	

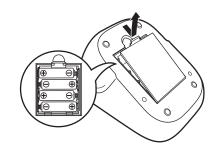
These are from statistical values for blood pressure.

^{*} JNC7: The Seventh Report, 2003 Dec, of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure.

2. Preparation

2.1 Battery Installation

- 1. Remove the battery cover.
- 2. Insert 4 "AA" batteries as indicated in the battery compartment.



3. Replace the battery cover.

Notes:

- When the low battery symbol () appears on the display, turn the monitor off, then replace all batteries at the same time. Long life alkaline batteries are recommended.
- The measurement values continue to be stored in memory even after the batteries are replaced.
- The supplied batteries may have a shorter life.

⚠ Disposal of used batteries should be carried out in accordance with the national/local regulations for the disposal of batteries.

2. Preparation

Open the rear cover page to read the following:

The letter identifiers on the rear cover page correspond to those in the body of this page.

2.2 Setting the Date and Time

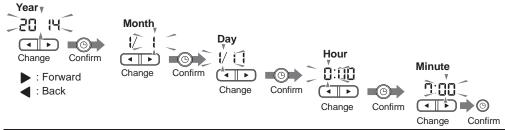
Set the monitor to the correct date and time before taking a measurement for the first time.

1. Press the (1) Date/Time setting ((2)) button.

The year flashes on the \bigvee Date/Time display.

2. Push ◀ or ▶ button to change the year.

Push () button to confirm the year and then the month flashes. Repeat the same steps to change the month, day, hour, and minutes.



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

Notes:

- If the batteries have been replaced, the date and time setting will need to be reset.
- If the date and time are not set, "-/ -:--" appears during or after measurement.

3. Using the Device

Open both the front and rear covers to read the following:

The letter identifiers on the cover pages correspond to those in the body of this page.

3.1 Applying the Arm Cuff

Remove tight-fitting clothing or tight rolled up sleeve from your left upper arm. Do not place the arm cuff over thick clothes.

1. Insert N the air plug into J the air jack securely.

2. Apply the arm cuff to your left upper arm.

The bottom edge of the arm cuff should be a 1 to 2 cm above the elbow.

O Cuff should be positioned on the upper arm with the air tube pointing towards your hand.

3. Secure closed with the fabric fastener.

Notes:

- When you take a measurement on the right arm, the air tube will be at the side of your elbow. Be careful not to rest your arm on the air tube. ---
- The blood pressure can differ between the right arm and the left arm, and therefore also the measured blood pressure values can be different. OMRON recommends to always use the same arm for measurement. If the values between both arms differ substantially, please check with your physician which arm to use for your measurement.

3. Using the Device

3.2 How to Sit Correctly

To take a measurement, you need to be relaxed and comfortably seated, under comfortable room temperature. Avoid bathing, drinking alcohol or caffeine, smoking, exercising or eating 30 minutes before taking a measurement.

- · Sit on a chair with your feet flat on the floor.
- Sit upright with your back straight. --- C
- Sit with your back and arm being supported.
- The arm cuff should be placed on your arm at the same level as your heart. --- d

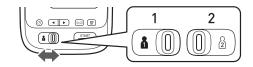
3.3 Taking a Measurement

Notes:

- To cancel a measurement, press the START/STOP button to release the air in the arm cuff.
- Remain still while taking a measurement.

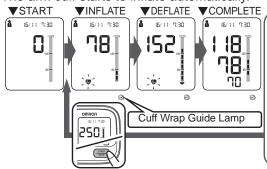
The monitor is designed to take measurements and store the measurement values in the memory for 2 people using USER ID 1 and USER ID 2.

1. Select your USER ID (1 or 2).



2. Press the START/STOP button.

The arm cuff starts to inflate automatically.



If your systolic pressure is more than 210 mmHg

After the arm cuff starts to inflate, press and hold the START/STOP button until the monitor inflates 30 to 40 mmHg higher than your expected systolic pressure.

Notes:

- The monitor will not inflate above 299 mmHg.
- Do not apply more pressure than necessary.

3. Using the Device

3. Remove the arm cuff.

4. Press the START/STOP button to turn the monitor off.

The monitor automatically stores the measurement result in its memory. It will automatically turn off after 2 minutes.

Note: Wait 2-3 minutes before taking another measurement. Waiting between measurements allows the arteries to return to the condition prior to taking a measurement.

Using the Guest Mode

The monitor stores measurement values for 2 users in the memory. The guest mode can be used to take a single measurement for another user. No measurement values are stored in the memory when the guest mode is selected.

1. Press and hold the START/STOP button for more than 3 seconds.



The USER ID symbol and the Date/Time display will disappear.

2. Release the START/STOP button when the Date/Time display turns off.

The arm cuff will start to inflate automatically.

⚠Always consult your physician. Self-diagnosis of measurement results and self-treatment are dangerous.

3.4 Using the Memory Function

The monitor automatically stores the results up to 100 sets for each user (1 and 2). It can also calculate an average value based on the last 3 measurement values taken within 10 minutes.

Notes:

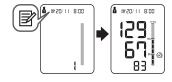
- If there are only 2 measurement values in the memory for that period, the average will be based on these 2 values.
- If there is 1 measurement value in the memory for that period, this is displayed as the average.
- If the memory is full, the monitor will delete the oldest value.
- When viewing the measurement value taken without setting the date and time, "-/ -:--" is displayed instead of the date and time.

To View the Measurement Values Stored in Memory

- 1. Select your USER ID (1 or 2).

The Memory number appears for a second before the pulse rate is displayed. The newest set is numbered "1".

Note: The cuff wrap guide result appears on the display with the measurement values. The cuff wrap guide lamp will not light.



- - : To the older values
 - To the more recent values

3. Using the Device

To View the Average Value

- 1. Select your USER ID (1 or 2).
- 2. Press and hold the

 button for more than 3 seconds.

Notes:

- If the previous measurement was taken without setting the date and time, the average value is not calculated.
- If there are no measurement values stored in the memory, the screen to the right is displayed.



To View the Weekly Average Value

The monitor calculates and displays weekly averages for the measurements taken in the morning and evening within 8 weeks for each user.

Note: The week begins Sunday at 2:00.

Select your USER ID (1 or 2).

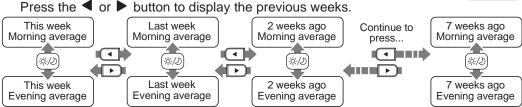
2. Press the 🌣/🗷 button.

The morning average for "THIS WEEK" appears on the display.

Note: The morning hypertension symbol () appears if the morning weekly average is above 135/85 mmHg.

Press the $\mbox{$\not\sim$}\slash\$





ΕN

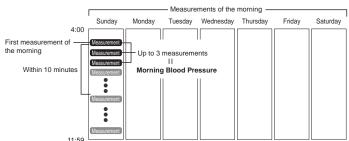
3. Using the Device

Note: If there are no measurement values stored in the memory, the screen to the right is displayed.



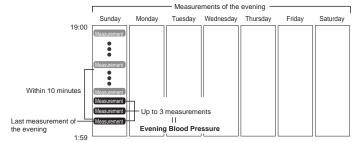
Morning Weekly Average

This is the average for the measurements taken during the morning (4:00 - 11:59) between Sunday and Saturday. An average for each day is calculated for up to three measurements taken within 10 minutes of the first measurement of the morning.



Evening Weekly Average

This is the average for the measurements taken during the evening (19:00 - 1:59) between Sunday and Saturday. An average for each day is calculated for up to three measurements taken within 10 minutes of the last measurement of the evening.



3. Using the Device

To Delete All the Values Stored in Memory

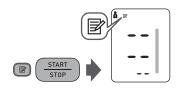
The values stored in the memory are deleted by USER ID.

- 1. Select your USER ID (1 or 2).
- 2. Press the Memory button, while the memory symbol (☑) appears.

3. While holding the

button down, press the START/STOP button for more than 3 seconds.

Note: You cannot partially delete the values stored in the memory. All values for the user you select will be deleted.



4.1 Error Messages

Display	Cause	Solution
	Irregular heartbeats are detected.	Remove the arm cuff. Wait 2-3 minutes and then take another measurement. Repeat the steps in section 3.3. If this error continues to appear, contact your physician.
<u>~</u> }\	Movement during measurement.	Carefully read and repeat the steps in section 3.3.
O))	Arm cuff is applied too loosely.	Apply the arm cuff tighter. Refer to section 3.1.
	The batteries are low.	You should replace the batteries with new ones ahead of time. Refer to section 2.1.
	The batteries are exhausted.	You should replace the batteries with new ones at once. Refer to section 2.1.

Display	Cause	Solution
	Air plug is disconnected.	Insert the air plug securely. Refer to section 3.1.
Εŀ	Arm cuff is applied too loosely.	Apply the arm cuff tighter. Refer to section 3.1.
	Air is leaking from the arm cuff.	Replace the arm cuff with a new one. Refer to section 5.3.
	Movement during measurement and the arm cuff has not been inflated sufficiently.	Repeat measurement. Remain still and do not talk during measurement. Refer to section 3.3.
E5		If "E2" appears repeatedly, inflate the arm cuff manually until it is 30 to 40 mmHg above your previous measurement result. Refer to section 3.3.
E3	The arm cuff was inflated above 299 mmHg when inflating the arm cuff manually.	Do not inflate the arm cuff above 299 mmHg. Refer to section 3.3.
E4	Movement during measurement.	Repeat measurement. Remain still and do not talk during measurement. Refer to section 3.3.
E S	Clothing is interfering with the arm cuff.	Remove any clothing interfering with the arm cuff. Refer to section 3.1.
Er	Device error.	Contact your OMRON retail outlet or distributor.

4.2 Troubleshooting

Problem	Cause	Solution
	Arm cuff is applied too loosely.	Apply the arm cuff tighter. Refer to section 3.1.
The measurement result is extremely high (or low).	Movement or talking during measurement.	Remain still and do not talk during measurement. Refer to section 3.3.
Arm cuff pressure does not rise.	Clothing is interfering with the arm cuff.	Remove any clothing interfering with the arm cuff. Refer to section 3.1.
	The air connector is not securely connected into the air jack.	Make sure that the air tube is connected securely. Refer to section 3.1.
Anni cuii pressure does not rise.	Air is leaking from the arm cuff.	Replace the arm cuff with a new one. Refer to section 5.3.
Arm cuff deflates too soon.	The arm cuff is loose.	Apply the arm cuff correctly so that it is firmly wrapped around the arm. Refer to section 3.1.
Cannot measure or the results are too low or too high.	The arm cuff has not been inflated sufficiently.	Inflate the arm cuff so that it is 30 to 40 mmHg above your previous measurement result. Refer to section 3.3.

Problem	Cause	Solution	
Nothing happens when you press the	The batteries are empty.	Replace the batteries with new ones. Refer to section 2.1.	
buttons.	The batteries have been inserted incorrectly.	Insert the batteries with the correct (+/-) polarity. Refer to section 2.1.	
Other problems.	 Press the START/STOP button and repeat measurement. Replace the batteries with new ones. If the problem continues, contact your OMRON retail outlet or distributor. 		

5. Maintenance and Storage

5.1 **Maintenance**

To protect your device from damage, please observe the following:

- Store the device and the components in a clean, safe location.
- Do not use any abrasive or volatile cleaners.
- Do not wash the device and any components or immerse them in water.
- Do not use petrol, thinners or similar solvents to clean the device.











- Use a soft and dry cloth, or a soft and moistened cloth and neutral soap to clean on the monitor and the arm cuff.
- Changes or modification not approved by the manufacturer will void the user warranty. Do not disassemble or attempt to repair the device or components. Consult your OMRON retail outlet or distributor.

Calibration and Service

- The accuracy of this device has been carefully tested and is designed for a long service life.
- It is generally recommended to have the device inspected every 2 years to ensure correct functioning and accuracy. Please consult your OMRON retail outlet or distributor.

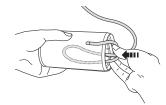
5.2 **Storage**

Keep the device in its storage case when not in use.

1. Unplug the air plug from the air jack.

2. Gently fold the air tube into the arm cuff.

Note: Do not bend or crease the air tube excessively.



3. Place the monitor and the arm cuff in the storage case.

Do not store the device in the following situations:

- . If the device is wet.
- Locations exposed to extreme temperatures, humidity, direct sunlight, dust or corrosive vapours.
- Locations exposed to vibrations, shocks or where it will be at an angle.



5. Maintenance and Storage

5.3 Optional Medical Accessories

(within the scope of EC Medical Device Directive 93/42/EEC)

Arm cuff

Arm circumference 22-42 cm

AC adapter



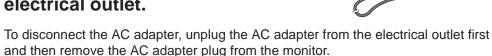
Intelli Cuff L-9911730-8 (Model: HEM-FL31)





Using the Optional AC Adapter

- 1. Insert the AC adapter plug into the AC adapter jack on the rear side of the monitor.
- 2. Plug the AC adapter into an electrical outlet.



6. Specifications

Product description Automatic Blood Pressure Monitor

Model OMRON M6 Comfort (HEM-7321-E)

LCD digital display Oscillometric method Measurement method

Pressure: 0 to 299 mmHg Pulse: 40 to 180 heats / min

Accuracy Pressure: +3 mmHa Pulse: ±5% of display reading

Fuzzy-logic controlled by electric pump Inflation Automatic pressure release valve

100 measurements with date and time for each user (1 and 2) Memory

DC6V 4W

Power source 4 "AA" batteries 1.5V or optional AC adapter

(Adapter S-9515336-9, INPUT AC100-240V 50/60Hz 0.12A) (Adapter UK-9983666-5, INPUT AC100-240V 50/60Hz 15VA) Approximately 1000 measurements (using new alkaline batteries)

= Type BF

Internally powered ME equipment (When using only the batteries)

= Class II ME equipment (Optional AC adapter) +10°C to +40°C / 30 to 85% RH

-20°C to +60°C / 10 to 95% RH / 700-1060hPa

IP 20

Monitor: Approximately 380g without batteries

Arm cuff: Approximately 163g

Monitor: Approximately 124 (w) mm × 90 (h) mm × 161 (l) mm Arm cuff: Approximately 145 mm × 532 mm (air tube: 750 mm)

22 to 42 cm

Nylon, polyester, polyvinyl chloride

Monitor, arm cuff, instruction manual, storage case, battery set, blood pressure pass

Display

Measurement range

Deflation

Rating

Battery life Applied part

Protection against electric shock

Operating temperature/ humidity

Storage temperature/ humidity/ air pressure

IP classification

Weight

Outer dimensions

Cuff circumference Cuff / Tube material

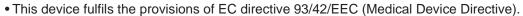
Package contents

6. Specifications

Notes:

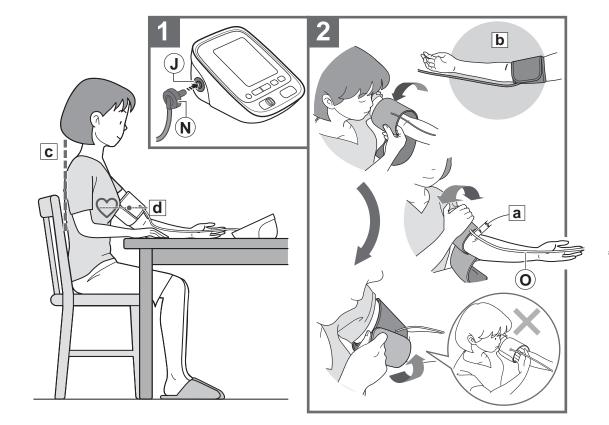
- These specifications are subject to change without notice.
- In the clinical validation study, the 5th phase was used on 85 subjects for determination of diastolic blood pressure.
- This device has not been validated for use on pregnant patients.

C€0197



- This device 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.
- This OMRON device is produced under the strict quality system of OMRON HEALTHCARE Co. Ltd., Japan. The core component for OMRON devices, which is the Pressure Sensor, is produced in Japan.

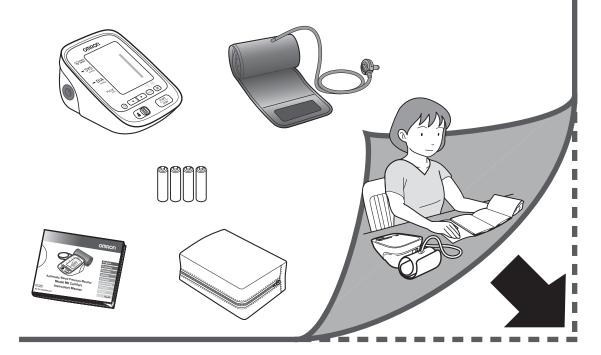
EN



Check following components!

Vérifier les composants suivants!
Prüfen Sie folgende Teile des Lieferumfangs!
Controllare i componenti indicati di seguito!
¡Compruebe los siguientes componentes!

Controleer de volgende onderdelen! Проверьте следующие компоненты! Aşağıdaki bileşenleri kontrol edin! تحقق من المكونات التالية!





Made in Vietnam Hergestellt in Vietnam Fabricado en Vietnam

OMRON Service Après Vente Nº Vert 0 800 91 43 14 www.omron-healthcare.com

> Prodotto in Vietnam Fabriqué en Vietnam Geproduceerd in Vietnam Сделано во Вьетнаме Vietnam'da Üretilmistir صنع في فيتنام