Instruction Manual

M24/7 Ambulatory Blood Pressure Monitor

EN

All for Healthcare

www.omron-healthcare.com

Introduction

Thank you for purchasing the **OMRON M24/7** ambulatory blood pressure monitor.

The **OMRON M24/7** is a silent, compact and very reliable ambulatory blood pressure monitor.
A large LCD screen insures easy readability and its lightweight design provides for maximum patient comfort.
The **OMRON M24/7** operates with two 1.5V AA batteries (included in the package) or two 1.2V AA rechargeable batteries.
The device can store more than 400 automatic readings along with approximately 200 manual measurements and events in its solid-state memory for an unlimited length of time.
Extra measurements can be triggered, and events can be marked manually.
The device can be adjusted to the patient's lifestyle with a push of the **DAY/NIGHT** button.
It provides a voltage display function to show the status of the batteries - ensures that fresh batteries or properly charged batteries are used for the monitoring period.
The **OMRON M24/7** is quiet and equipped with multiple patient safety functions.
It can be connected to practically any standard PC with its optical USB interface cable.
The user-friendly software provides flexible programming as well as comprehensive analysis, presentation and reporting functions.
The **OMRON M24/7** has been clinically validated. Quality, safety and reliability of the product are demonstrated by its CE mark.

Content

Important Safety Information

	*Important Safety Information* This symbol on the **Omron M24/7** monitor is a warning that you should read the accompanying documentation (this manual).

Warning:

⚠	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury. The ambulatory blood pressure monitor should not be used if any of the following cases apply: • patients without an indication for ambulatory blood pressure monitoring • non-cooperative patients • patients in any way unable to operate a monitor as intended • patients requiring urgent / emergency cardiac care • unconscious or otherwise incapable patients • patients with serious mobility impairments without supervision • patients with coagulation disturbances • children without supervision • children under the age of 8 years
⚠	Though the blood pressure measurement algorithm used in the **OMRON M24/7** has been tested and found to function properly on patients with atrial fibrillation or other common arrhythmias, the oscillometric blood pressure measurement method is generally recommended for use only with special caution in patients with arrhythmias, Parkinson's disease, or other diseases with tremor.
⚠	Always consult a physician for the interpretation of the blood pressure measurements. Note that any blood pressure recording may be affected by the body position, the physiological condition of the patient, and other factors.
⚠	Take care to avoid blocking the air flow in the tube of the cuff and twisting the tube. Make sure the cuff and its tubing do not cause strangulation or a circulation problem. Should the patient experience arm numbness or pain remaining after any blood pressure reading is completed, the cuff should be removed to avoid permanent vascular or neural injury.

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) No user serviceable parts inside. The **OMRON M24/7** monitor contains high complexity electronic and fine mechanical components. If you have any problems, please refer your monitor to qualified service personnel.

CE 0120	**OMRON M24/7** described in this manual complies with the requirements of the EU Medical Devices Directive (93/42 EEC). 0120 is the identifier of Notified Body (SGS UK)
MDD IIa	MDD classification IIa. EMC class B. EMC group 1.
YYYY/nnnnnn	The first four digits of the serial number of a monitor show the year of production. The rest is the serial number.

	This symbol shows that according to regulations OMRON M24/7 should be handled as electronic waste during disposal.
	Classification of Applied Parts - Type CF

Recommended use of ambulatory blood pressure monitoring

The European Society of Hypertension has published recommendations for ambulatory blood pressure measurement (O'Brien, E. et al. on Behalf of the European Society of Hypertension Working Group on Blood Pressure Monitoring, European Society of Hypertension recommendations for conventional, ambulatory and home blood pressure measurement, Journal of Hypertension 2003, 21: 821-848).
Ambulatory blood pressure monitoring can benefit patients with in many situations.

Indications

- Suspected white-coat hypertension
- Suspected nocturnal hypertension
- To establish dipper status
- Resistant hypertension
- Elderly patient
- As a guide to antihypertensive drug treatment
- Type 1 diabetes
- Hypertension of pregnancy
- Evaluation of hypotension
- Autonomic failure

On the contrary, ambulatory blood pressure monitoring should be avoided in several situations.

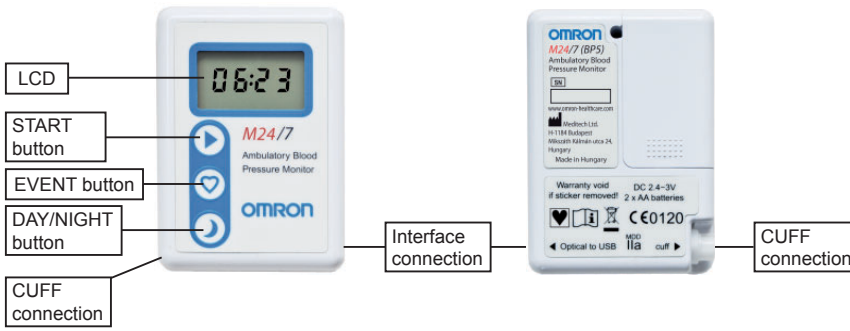
Contraindications

- Non-cooperative patients, unconscious or otherwise incapable patients
- Patients requiring urgent / emergency cardiac care
- Patients with coagulation disturbances
- Patients with serious mobility or other impairments without supervision
- Children without supervision; children younger than 8 years
- Though the blood pressure measurement algorithm used in the **OMRON M24/7** has been found to function properly on patients with atrial fibrillation or other common arrhythmias, the oscillometric blood pressure measurement method is generally recommended for use only with special caution in patients with arrhythmias, Parkinson's disease, or other diseases with tremors.

1. Overview

1.1. Main Unit

Front side ***Back side***

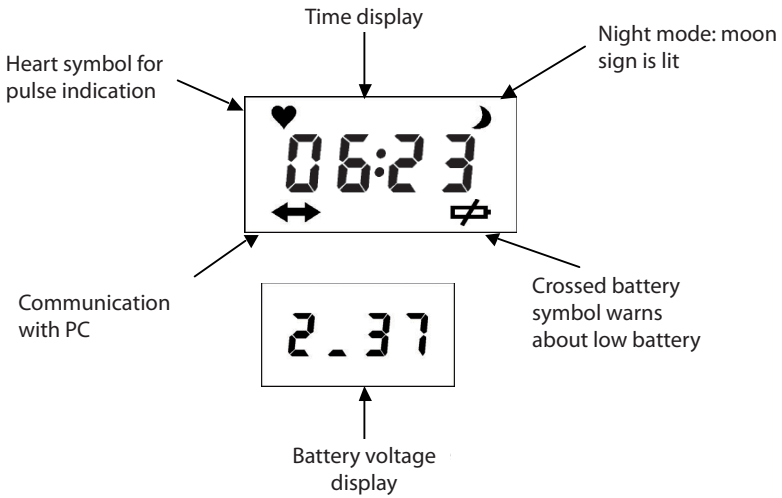


1.2. Arm Cuffs

The set contains 2 adult cuffs: normal size (24-32cm) and large size (32-42cm)

A. Arm Cuff
B. Air Plug
C. Air Tube

1.3. Display



For details of different display options see p. 11

1.4. Package Contents

one	(1)	OMRON M24/7 monitor unit
one	(1)	optical USB cable
one	(1)	carry pouch for monitor, with shoulder and waist straps
one	(1)	normal size neoprene cuff (latex-free, hand washable sleeve)
one	(1)	large size neoprene cuff (latex-free, hand washable sleeve)
four	(4)	1.5V AA alkaline batteries (LR6)
one	(1)	**OMRON BP Tracker Software** CD-Rom or DVD including all manuals
one	(1)	M24/7 Instruction Manual incl. template for patient diary
one	(1)	BP Tracker Software Instruction Manual

Important Note:
Doctor's Quick Guide and Patient's Quick Guide ONLY available on the CD-Rom Declaration of Conformity – to obtain a copy please contact your local OMRON Distributor.

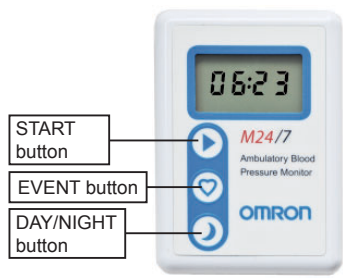
2. Operating Instructions

2.1. Working with the OMRON M24/7 Unit

The **OMRON M24/7** device is a compact, lightweight monitoring unit typically worn by the patient for 24 hours. The **OMRON M24/7** operates with two AA size batteries. The memory is capable of storing more than 600 measurements. Stepwise pressure deflation ensures quality measurements, even if disturbing environmental factors occur. You may find the battery compartment and the rating label on the backside housing. The serial number is placed on the rating label, however it is also stored electronically in the solid state memory of the device. On the front side of the housing, there is the LCD, the buttons of the device and the name of the device. The device can be connected to the USB port of a PC with an optoelectronic interface. The device has its socket positioned on the opposite side from the cuff connector. Patients can start extra blood pressure readings or mark symptomatic events.

2.2. Using the Buttons

On the front side of the housing, below the LCD, you may find three buttons: the **START** button is marked with a triangle, the **EVENT** button marked by a heart and the **DAY/NIGHT** button indicated by a crescent moon. If the device is turned on, then every button press is accompanied by a short beeping sound.



Cancel a blood pressure measurement

The patient can interrupt a blood pressure measurement by pressing a button at any time while the cuff is inflated. This will result in immediate fast cuff deflation. Such interruption is limited to the measurement in progress only and has no effect on further operation. This function is available with all three buttons.
Use this function only if the cuff is hurting the patient's arm.

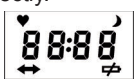
Manual blood pressure measurement

If it seems necessary, the patient can start an additional, manual blood pressure measurement by pressing the **START** button for less than 3 seconds. The result with a manual measurement marker will be stored in the memory of the device. Typical causes for this use: dizziness, palpitations (angina pectoris or headache).

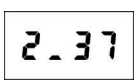
Switching the device off
Press and hold the **START** button for more than 10 seconds then release it when two horizontal segments appear on the LCD, this way the **OMRON M24/7** will be switched off. If you do not release the button in 2 seconds after the two horizontal segments appeared, the monitor will return to normal operation. This feature helps to avoid unintended power-off. **The device can only be switched on manually. While the monitor is switched off normal functions are not available, even prescheduled measurements will not be triggered. Therefore, only in case of a valid reason should the device be switched off.**

Switching the device on
The **OMRON M24/7** is switched on to normal operation if the **START** button is pressed and held for more than 3 seconds. If the device is switched off, no other functions are available.

LCD check
Press and hold the **START** button 3 to 5 seconds to light up all segments of the LCD to check if they all work correctly.



Battery voltage check
Press and hold the **START** button for more than 5 seconds to display battery voltage on the LCD (e.g. 2_37, equal to 2.37 V, see example). After checking the voltage, please release the button, because after additional 5 seconds, the device may turn off. The unit will then return to displaying time. The voltage for fresh alkaline batteries should be over 3 V and for fully charged accumulators over 2.5 V.



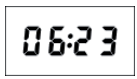
Set a patient event marker
The patient can mark any event without starting a manual blood pressure measurement by pressing the **EVENT** button briefly. A typical causes for this use is taking medicine. The patient should be instructed to record the reason for setting an event marker in a diary (see Patient's Quick Guide and template for patient diary at the end of this user manual).

Mark time of going to bed and rising from bed
If the DAY/NIGHT shift function is disabled during programming, the patient can press the **DAY/NIGHT** button to mark the time of going to bed (in the evening) and rising from bed (in the morning).

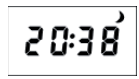
Manual DAY/NIGHT shift
If this function is enabled during the programming, then the patient can manually shift the measurement frequency period (day or night) by pressing the **DAY/NIGHT** button. The shift is available in the two hour period before the prescheduled shift.

2.3. Overview Display

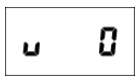
The **OMRON M24/7** shows important status information, the processes and results of individual readings on its LCD. The most important displays are listed here. In addition to these, a lot of extraordinary situations and errors have their own code displayed on the LCD. These codes are stored together with recorded data and listed in the **OMRON BP Tracker Software**. This helps service personnel in case of support issues.



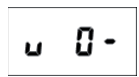
Normal status: time is displayed. Automatically set by PC



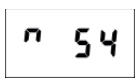
Night mode: time is displayed, moon sign is lit



Blood pressure measurement initiated. [mmHg]

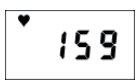


Blood pressure measurement initiated. [kPa]

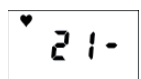


Pumping for measurement, current pressure is displayed [mmHg]

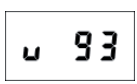
Pumping for measurement, current pressure is displayed [kPa]



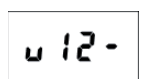
Heart symbol blinking: measurement in progress. [mmHg]



Heart symbol blinking: measurement in progress. [kPa]

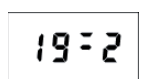


Deflation during measurement, current pressure displayed[mmHg]

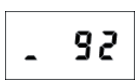


Deflation during measurement, current pressure displayed [kPa]

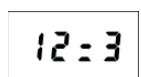
Systolic value of just completed measurement [mmHg]



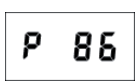
Systolic value of just completed measurement [19,2 kPa]



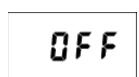
Diastolic value of just completed measurement [mmHg]



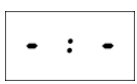
Diastolic value of just completed measurement [12,3 kPa]



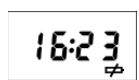
Pulse rate value of just completed measurement [beats per minute]



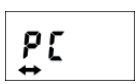
Blood pressure measurement cancelled by pressing a button



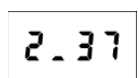
Event marker set due to button push



The crossed battery symbol warns about low battery

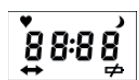


Communication with personal computer



Battery voltage display (2.37 V)

Error code display



LCD check: all segments are displayed

The monitor is switched off

The monitor must be programmed with the **OMRON BP Tracker Software** installed on the computer (for details see Software Manual). Once the pre-programmed time is reached, the monitor will start operating automatically and perform blood pressure measurements based on the monitoring plan. To obtain reliable BP readings, certain rules must be observed.

2.4. Rules of Monitoring

1. Inform the patient about the goal and expected results of the monitoring. Provide an event/patient diary and rules to observe. The Patient's Quick Guide will help the patient to remember what has been discussed with you.

   The Patient's Quick Guide can be given to the patient. It also includes a patient diary. This can be found at the end of this user manual, electronic versions are available on the CD-ROM or DVD.
2. Patients can fit the unit comfortably with the adjustable straps of the carry pouch.
3. It is advisable to wear a thin shirt under the ABP cuff. This does not influence the accuracy of blood pressure measurement, but it prevents problems caused by long-time wear of the cuff (sweat, itching, soreness, etc.).
4. The cuff should be properly placed and connected.
5. Patients should avoid excess movement during blood pressure measurements. They should hold their arm loose, slightly away from their chest.
6. Should the blood pressure measurements cause blood shots, torpidity or pain in the hand, the cuff should be removed from the arm immediately and disconnected from the monitor. Such occurrence should be reported to the physician as soon as possible or at the latest after the monitoring session.
7. Patients should not remove the monitor even at night. By loosening the straps, they can avoid problems when turning in their sleep. The monitor does not disturb most patients at night.
8. Patients may start extra blood pressure measurements with the **START** button of the **OMRON M24/7** monitor, marked with a triangle. They should mark events such as taking medication with the **EVENT** button, marked with a heart. They should also mark the time of going to bed and rising from bed, with the **DAY/NIGHT** button marked with a crescent moon. They may interrupt any single blood pressure measurement if necessary by pressing any button.
9. Should the batteries run down during a monitoring session, they can be simply replaced. Monitoring will continue, and data will not be lost.
10. Patients should never measure anybody else's blood pressure with an OMRON M24/7 during an ambulatory blood pressure monitoring session.

2.5. Monitoring Step by Step

Before you begin, you must have the **OMRON BP Tracker Software** properly installed and configured on your computer, and the monitor correctly connected (for details see Software Manual). To program your monitor, you will need the optical interface cable which is included in the set properly connected to your computer's USB port and the communication port (USB) correctly selected in the **OMRON BP Tracker Software.**

A successful monitoring session consists of the following steps:

1. ***Connecting the OMRON M24/7 monitor to the PC*** **(First connection only – not required to repeat with each session)**
   1. Connect the optical interface, which was delivered with the device, to the USB port of the PC.
   2. The other side of the optical USB interface cable, which is a two-point plastic connection, should be connected to the socket of the **OMRON M24/7**, in a way that the red plastic ring is directed to the lower side of the device.
   3. Start the **OMRON BP Tracker Software** and open the Options menu, then click on the **Communication** tab on the left side of the screen.
   4. On the appearing window, click on the **USB** option. Please connect the device to the PC (fresh/charged batteries, device switched on) as noted above then click on the **Test** button. Upon successful communication the software will display the serial number and the firmware version of the device.

2. ***Preparation of Monitoring Session***
   1. Inform your patient about the monitoring rules well in advance.
   2. Programming the measurement plan into the device:
      - Using PC: start the **OMRON BP Tracker Software** program
      - Optionally the device can be programmed without using a PC, for details see Manual Programming section.
   3. Enter new patient data or select patient from the database.
   4. Create a monitoring plan with respect to the patient's lifestyle.
   5. Insert two fresh or fully charged, AA size batteries into the battery compartment and check their voltage.
   6. Connect the monitor to the computer.
   7. Send the monitoring plan from the computer to the monitor unit.
   8. Apply the cuff to the patient with the device placed in the carry pouch.
   9. Give the Patient's Quick Guide to the patient along with detailed instructions about the rules and the usage of the device.

3. ***Evaluation***
   1. Remove the unit and cuff from the patient on his/her return.
   2. Ask for the Patient's Quick Guide /patient diary, and ask the patient for any events, symptoms, observations or complaints.
   3. Start the **OMRON BP Tracker Software**
   4. Connect the device to the PC and then transfer collected data from the monitor to your database.
   5. Analyze the blood pressure profile.
   6. Create and print a report.

2.6. Manual Programming

The **OMRON M24/7** can be programmed with using its buttons, without using a PC.

Programming Options

There are three different measurement plans which may be selected in case of manual programming. These plans are stored in the device's inside memory and they **cannot be changed**. The first plan which is also the default one in the **OMRON BP Tracker Software**, measurements every 15 minutes during daytime and 30 minutes during night. The second one provides less frequent measurements with 20 and 40 minutes respectively. The third version is based on 30 minute measurement intervals, independent of the time of day.

Other settings are the same in case of all three plans: cuff size not set, pressure limit 300 mmHg, enabled LCD display and disabled day/night shift. Daytime starts at 6:00, night time starts at 22:00, special session is disabled. Measurement period is exactly 24 hours.

Measurement Timing

The first measurement has a controlling purpose and it starts in the second minute after the programming, then in the next five minutes there are no measurements. The rest of the measurements are taken at specific 15/20/30/40 minute intervals and there are measurements at the 6:00 and 22:00 hour shifts. The last measurement is exactly 24 hours after the second measurement. Patient information can be selected or added later in the **OMRON BP Tracker Software.**

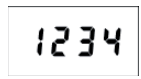
Manual Programming Step by Step

1. Push the measurement (triangle) and the day/night shift (moon) buttons simultaneously.
2. Keep them pushed, in 10 seconds the measurement options will be displayed for 3 seconds each along with the measurement frequencies. Then the clock will be displayed.
3. In order to choose the measurement plan, you must release the buttons while that plan is displayed. You will hear two beeps and the LCD will display four blinking "o" (oooo for four seconds). The process of programming takes approximately four seconds, then you will hear five beeps. For five seconds, the chosen plan will be displayed again for confirmation. If programming fails for some reason, the E90 error code will be displayed on the LCD.

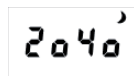
In case of manual programming there is no time setting, as the PC would be responsible for time synchronizing. If the time setting is imprecise then the time of measurements may be false. If you would like to use the manual programming function then **do not leave the device without batteries for a longer period**. If you do so then program the device with the PC once and then leave the batteries in it, so the time can be set by the PC.

Software
The **OMROM M24/7** programmed manually can be used with the **OMRON BP Tracker Software** version 1.14.6 or newer.
Manual programming LCD displays:


Normal status: time is displayed


10 second delay state: time is displayed but with no double-dot


1. measurement plan: 15/30 minute day/night intervals


2. measurement plan: 20/40 minute day/night intervals


3. measurement plan: 30/30 minute day/night intervals


Programming in progress: blinking signal

2.7. Batteries

The **OMRON M24/7** ambulatory blood pressure monitor operates with two 1.5V AA batteries or two 1.2V AA rechargeable batteries. Use only standard long-life (alkaline) batteries, or standard NiCd or NiMH rechargeable batteries of the proper size. Do not use lithium batteries. Do not mix different battery types, do not mix new and old batteries. Never use batteries of low or unknown quality or pre-used batteries, as they may not cover the power needs of the monitor, and they may damage the monitor, as they may contain acidic electrolytes which may leak and corrode electronic components. Never use batteries damaged in any way. Should the batteries run down during a monitoring session, they can be replaced. Monitoring will continue and data will not be lost. If you do not use the monitor, it is advisable to remove batteries since they may run down due to the constant small power consumption of the integrated circuits of the device. Data in the monitor are not lost even if batteries run down or are removed. Used batteries may fall under the category of hazardous waste and should be disposed of properly.

Important! It is strongly recommended to use freshly charged accumulators or new batteries with every patient so that batteries do not run down during monitoring, even in case of very high blood pressure values and/or a long monitoring session. After inserting batteries in M24/7monitors, it is advised to check their voltage before programming the monitors. Do not start a new monitoring session with low batteries. The typical voltage for two fully charged rechargeable batteries should be over 2,5 V, and for fresh alkaline batteries, over 3 V. It is possible to check battery voltage with the **START** button. (Please check the Using the buttons section for more details.)

Important! If a monitor is not used for a long period, the in-built backup cell ensuring the operation of the internal clock may get discharged. In this case keep freshly charged batteries in the monitor for at least one day; this will recharge the backup cell. It is possible to use the monitor afterwards. If the backup cell is not properly charged, the internal clock may work incorrectly, and the monitor may not start measurements in due time.

A set of new, high capacity batteries will enable the **OMRON M24/7** monitor to perform 250 blood pressure measurements during a 24-48 hours long monitoring session. If you opt to use alkaline batteries, choose high capacity, long-life products to enable reliable operation. A small crossed battery sign on the LCD shows low battery voltage.

In order to change batteries, take the monitor out of the holder carry pouch and remove the battery compartment cover on the back-side. Place two new, long-life AA alkaline batteries or two properly charged, high capacity AA rechargeable batteries into the compartment as shown in the polarity drawing. Close the compartment.

2.8. Cuffs and their application

The OMRON M24/7 comes with 2 cuffs, normal and large adult size (see below). The bladders are made of neoprene and are latex-free. It is advisable to wear a thin shirt or blouse under the cuff. This does not influence the accuracy of blood pressure measurements but it prevents possible problems caused by long-time wear (sweating, itching, etc.). ***Place the cuff on the upper arm so that the rubber tube points towards the patient's shoulder and the bladder is placed above the brachial artery, if possible.*** Contrary to the usual placement with the tube pointing downwards, the advantage is that the patient can wear a loose jacket over the cuff. Connect the rubber tube of the cuff into the air plug connector, which you can find on the long edge closer to the buttons of the OMRON M24/7 monitor. Connect the cuff turning it clockwise with slight pressure.

Note: It is recommended that the cuff be applied as tightly as acceptable for the patient. A too loose cuff will cause much longer blood pressure measurement times and possibly aborted measurements. With an overly loose cuff, the monitor must pump to tighten the cuff on the arm and then it must reach the pressure necessary for measurement. This causes considerable inconvenience for the patient and results in less data for evaluation. If the patient removes the cuff for a period during the monitoring session, it should be re-applied with appropriate tightness, with help from another person, if necessary. Should blood pressure measurements cause blood shots, torpidity or pain in the hand after an individual measurement, the cuff should be removed from the arm and disconnected from the monitor. Such occurrence should be reported to the physician at once after the monitoring session.

OMRON M24/7 recognizes and functions with three different cuff sizes. Please set the appropriate cuff size to be used during the programming of the device. Attention: inappropriate setting of the cuff size may lead to device malfunctioning, which is inconvenient for the patient and may lead to an unsuccessful measurement.

Name	Bladder dimensions	Sleeve dimensions	Arm circumference range*
Small cuff (child)	9 x 18 cm	11 x 32 cm	under 24 cm
Normal cuff	12 x 25 cm	15 x 56 cm	24-32 cm
Large cuff	15 x 33 cm	17 x 77 cm	32-42 cm

* When properly applied, the end of the sleeve (the one closer to the tube) should fall in the indicated range.

The cuff is the component which, by definition of the relevant standard, is protected against a defibrillator discharge.

Caution!

Substitution of a cuff different from that supplied might result in measurement error and/or in certain cases cause damage to the main monitor unit.

3. Care and Maintenance

3.1. Handling Errors and Problems

Below you can find a list of potential error code displays, their meaning and a description of the error code.

Unsuccessful measurements

E 1 aborted measurement	the measurement timeout is over, the measurement had to be aborted (the patient was moving)
E 2 (Off) manually interrupted	the measurement was stopped by pressing a button (the display differs from others: “OFF” on the LCD)

E 3 battery rundown	the AA batteries exhausted during measurement
E 4 batteries changed	the AA batteries were replaced during the measurement – not shown on LCD
E 8 pressure limit exceeded	the pressure in the pneumatic system exceeded the preset pressure limit
E 9 temporary disturbance	external electric signals (e.g., static discharge) disturbed the operation of the device

Cuff related errors

E 31	cuff missing or loose; there was no cuff connected to the device; maybe the cuff is too loose on the patient's arm
E 32	cuff tubbing clogged; the cuff is clogged or the rubber tube is broken
E 33	device or cuff leakage or cuff is loose. There is a hole in the cuff or it is very loose on the patient's arm
E 34	cuff not on patient's arm or not connected

Faulty device

E 90	device error: the device could not measure due to a hardware error
E 99	device error: the device could not measure

3.2. Protection, cleaning and washing

OMRON M24/7 ambulatory blood pressure monitors are not specially protected against spills or ingression of water or other liquids. Do not immerse the monitor in water or any cleaning fluid, and protect it from spills and splashes. **Do not expose it to heavy rain or steam, and do not wear it in a wet environment e.g: shower, bath, or swimming pool.** In case of the minor effects of a wet environment, wipe off water drops with a dry cloth. Keep the monitor in a normal dry room for at least one hour before use if condensation is suspected. In case of ingress of water in the monitor, remove batteries from the unit, and refer the unit to authorized service. Never place a monitor unit in a disinfecting or sterilizing machine! Recommended cleaning method is to wipe the monitor with a disinfectant cleaning tissue, e.g., Henkel Ecolab Incides, or a similar product. Alternatively, wipe with a slightly damp cloth then dry it with an antistatic tissue. Do not expose monitors to extreme heat or radiation, including long exposure to direct strong sunlight.

To wash the cuff please do the following:

1. Remove the bladder.
2. Wash by hand the sleeve with lukewarm water and regular washing liquid suitable for black material. Rinse well.
3. If required, wipe the bladder with a disinfectant cleaning tissue.
4. Allow both bladder and sleeve to air dry.
5. Replace bladder in the sleeve.

3.3. Maintenance and Storage Conditions

Temperature: -20 - 50 °C

Humidity: 10 - 95 %, non condensing

Regular checks, warranty, service

Verification of pressure measurement accuracy is recommended biannually. OMRON M24/7 monitors are covered by a two-year warranty. This warranty does not cover any malfunction or defects arising from improper use, the use of inadequate accessories, accident, theft, or use of the device outside operating environmental specifications or intended measurement range. Removing the closing label from the back side of the device voids this warranty. There are no user serviceable parts inside the **OMRON M24/7** monitors; they contain high complexity electronic and fine mechanical components. If you have any problems, please refer the monitor to qualified service personnel. All consequences of improper servicing are the sole responsibility of the user. Contact OMRON or your distributor for service information.

3.4. Correct Disposal of this Product

OMRON M24/7 should be disposed of according to your local regulations for disposal of hazardous waste.

3.5. Accessories

Art. Nr.	Product Description
BP4-A012-NP	M24/7 cuff, small, neoprene, white plug
BP4-A010-NP	M24/7 cuff, normal, neoprene, white plug
BP4-A011-NP	M24/7 cuff, large, neoprene, white plug
BP4-A011-LNP	M24/7 cuff, Extra large, neoprene, white plug
GPC-A015	M24/7 sleeve, small
GPC-A013	M24/7 sleeve, normal
GPC-A014	M24/7 sleeve, large
GPC-A001	M24/7 carry pouch

4. Technical Data

4.1. Technical parameters

Power supply:
2 AA rechargeable NiCd or NiMH batteries or 2 AA alkaline batteries

Display:
liquid-crystal

Data storage:
internal solid state memory

Data transmission:
USB optical cable

PC interface:
USB interface

Operating environment:
Temperature: 10 - 45 °C
Humidity: 10 - 95 %, non condensing
Atmospheric pressure: 70 - 106 kPa

Storage conditions:
Temperature: -20 - 50 °C
Humidity: 10 - 95 %, non condensing

Size (H x W x D):
70 x 99 x 30 mm

Weight:
app. 240 g (batteries included)

Blood pressure measurement method:
oscillometric

Blood pressure maximum storage:
over 400 automatic measurements

Pressure measurement range:
0-300 mmHg
0-40 kPa*

Static accuracy:
± 3 mmHg or 0,4 kPa or ± 2% of measured value (stability: 2 years)

Blood pressure measurement range indication:
30-260 mmHg
4-35 kPa*

Pulse rate measurement range:
40-200 beat per minute

Blood pressure measurement accuracy:
The OMRON M24/7 has been clinically validated

Pressure sensor:
piezo-resistive

Inflation:
automatically controlled pump

Safety:
maximum inflation 300 mmHg (40 kPa*);
independent safety release valve

Deflation and rapid air release:
automatic pressure release valve

Please note that the **OMRON M24/7** might not meet its performance specifications if stored or used outside the specified environmental conditions.
*Measuring and LCD displaying in kPa values is an option which can be selected in the **OMRON BP Tracker Software**. The unit of measurement can be changed later in the database.

	For information on cuffs and their application, see 2.8.
	This symbol shows that according to regulations OMRON M24/7 should be handled as electronic waste during disposal.
	Blood pressure measurements determined with the algorithm of an OMRON M24/7 monitor on adults are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultation method Korotkoff phase V, within the limits prescribed by the American National Standard for Electronic or Automated Sphygmomanometers. The algorithm used in the OMRON M24/7 also fulfils the requirements of the British Hypertension Society Validation Protocol for Automated Blood Pressure Measuring Devices.

4.2. Safety Concerns

Electric shock hazard protection

OMRON M24/7 monitors meet relevant shock hazard protection standards. **OMRON M24/7** monitors operate with two 1.5V AA batteries or two 1.2V AA rechargeable batteries. This excludes all electric shock hazards, even in the unlikely case of multiple device errors. Use only standard long-life (alkaline) batteries, or standard NiCd or NiMH rechargeable batteries of the proper size. Do not use lithium batteries. Do not mix different battery types, do not mix new and old batteries, do not use damaged batteries.

Many personal computers do not meet certain shock hazard protection standards or strict safety regulations applicable to medical devices. Therefore, during the computer-based use of OMRON monitors, keep at least a 2 meter distance between patient and computer. This is the required minimum safety distance. **OMRON M24/7** monitors communicate using a plastic optical cable, whose 4 m standard length allows for the required safety distance. The plastic optical cable ensures perfect electric separation and reduces the effects of external electric noise. It does not conduct electricity.

Biocompatibility

To avoid infection risks, and for general hygienic reasons, the device, cuff and tubing should never contact the patient's skin directly.

Hazardous materials

Used batteries qualify as hazardous waste and should be disposed of properly. OMRON monitors do not contain any materials qualified as pharmaceutical substance or tissue of animal origin. They emit no material hazardous to humans.

Risk of incorrect diagnosis

The basic intended use of **OMRON M24/7** monitors is to record blood pressure and pulse rate values. Patients should be informed about rules of cooperative behaviour; proper handling of the monitor used, and expected results of monitoring in advance. **OMRON M24/7** monitors only provide data to support diagnostic decisions of a qualified physician; they do not automatically provide a diagnosis of any kind. During the evaluation of recorded blood pressure values, possible artefacts due to external disturbances, motion artefacts, and electrical noise should be observed and handled with caution.

4.3. EMC Information

Medical electrical equipment should be used with precautions according to EMC, and must be installed according to the EMC notices disclosed in this manual as mobile RF transceivers could adversely affect it.

Directive and declaration of manufacturer – Electromagnetic Emission		
The **OMRON M24/7** is suitable for use in the specified electromagnetic environment. The purchaser or user of the **OMRON M24/7** should assure that it is used in an electromagnetic environment as described below		
Emission test	***Compliance***	***Electromagnetic Environment***
Radiated and conducted RF emission CISPR 11	Group 1	**OMRON M24/7** uses RF energy only for its internal function. Therefore, the emission is very low and not likely to cause any interference in nearby electronic equipment.
Radiated and conducted RF emission CISPR 11	Class B	**OMRON M24/7** is suitable for use in domestic establishments and in establishments directly connected to the low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emission IEC61000-3-2	Not applicable	---
Voltage fluctuations / Flickers IEC61000-3-3	Not applicable	---

Directive and declaration of manufacturer – Electromagnetic immunity			
OMRON M24/7 is suitable for use in the specified electromagnetic environment. The purchaser or user of **OMRON M24/7** should assure that it is used in an electromagnetic environment as described below.			
Immunity test	***IEC60601-1-2 test level***	***Compliance level***	***Electromagnetic environment***
Electrostatic discharge (ESD) IEC 61000-4-2	±6KV contact ±8KV air	±8KV air	Floors are wood, concrete or ceramic tile, or floors are covered with synthetic material and the relative humidity is at least 30 percent.
Electrical fast transient/burst IEC 61000-4-4	±2KV for power supply lines ±1KV for input/ output lines	Not applicable	Mains power quality is that of a typical commercial and/or hospital environment.
Surge IEC 61000-4-5	±1KV differential mode ±2KV common mode	Not applicable	Mains power quality is that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip) for 0.5 cycle; 40% U_T (60% dip) for 5 cycles; 70% U_T (30% dip) for 25 cycles; <5% U_T (>95% dip) for 5 sec.	Not applicable	Mains power quality is that of a typical commercial and/or hospital environment. If the user of **OMRON** M24/7 requires CLINICAL UTILITY during power mains interruptions, it is recommended that parts of the **OMRON M24/7** system where applicable be powered from an uninterruptible power supply.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields are at levels characteristic of a typical location in a typical commercial and/or hospital environment.
Note: U_T is the nominal voltage of mains.			

Directive and declaration of manufacturer – Electromagnetic immunity			
OMRON M24/7 is suitable for use in the specified electromagnetic environment. The purchaser or user of **OMRON M24/7** should assure that it is used in an electromagnetic environment as described below.			
Immunity test	***IEC60601-1-2***	***Compliance level***	***Electromagnetic environment***
Conducted RF IEC 6100-4-6	$3V_{eff}$ 150KHz - 80MHz	Not applicable	Portable and mobile RF communications equipment are used no closer to any part of **OMRON M24/7**, including cables, than the Recommended Separation Distance calculated the formula written below. **Recommended Separation distance:** $d=[3.5/V_1]\sqrt{P}$
Radiated RF IEC 61000-4-3	3V/m 80MHz – 2.5GHz	3V/m	$d=[3.5/3V/m]\sqrt{P}$; (80MHz – 800MHz) $d=[7/3V/m]\sqrt{P}$; (800MHz – 2.5GHz) where: P is the highest radiated power disclosed by the manufacturer of transmitter [W]; d is the recommended separation distance [m].
1. note: in case of frequency 80MHz or 800 MHz, the formula for the higher range is applicable. 2. note: These are guidelines. Actual conditions may vary.			

Recommended separation distance			
OMRON M24/7 is intended to be used in electromagnetic environment with controlled RF disturbances. The purchaser or user of M24/7may help to reduce electromagnetic disturbances by defining the separation distance between the transportable or mobile RF telecommunication equipment (transmitters) and **OMRON M24/7**, depending on the highest output power of the telecommunication equipment.			
	Separation distance in function of the frequency of the transmitter [m]		
The highest output power of the transmitter [W]	***150KHz – 80MHz*** $d=[3.5/V_1]\sqrt{P}$	***80MHz – 800MHz*** $d=[3.5/E_1]\sqrt{P}$	***800MHz – 2.5GHz*** $d=[7/E_1]\sqrt{P}$
0.01	Not applicable	0.12	0.23
0.1	Not applicable	0.38	0.73
1	Not applicable	1.2	2.3
10	Not applicable	3.8	7.3
100	Not applicable	12	23
If this table does not contain the highest output power of the transmitter, the d separation distance [m] can be calculated by the formula, depending on the frequency of the transmitter, where P is the rated highest output power of the transmitter [W]. 1. note: in case of frequency 80MHz or 800 MHz, the formula for the higher range is applicable. 2. note: These are guidelines. Actual conditions may vary.			

AMBULATORY BLOOD PRESSURE MONITORING

PATIENT DIARY

Name:

Date of birth:

Monitoring date:

8:00-8:30	20:00-20:30
8:30-9:00	20:30-21:00
9:00-9:30	21:00-21:30
9:30-10:00	21:30-22:00
10:00-10:30	22:00-22:30
10:30-11:00	22:30-23:00
11:00-11:30	23:00-23:30
11:30-12:00	23:30-24:00
12:00-12:30	0:00-0:30
12:30-13:00	0:30-1:00
13:00-13:30	1:00-1:30
13:30-14:00	1:30-2:00
14:00-14:30	2:00-2:30
14:30-15:00	2:30-3:00
15:00-15:30	3:00-3:30
15:30-16:00	3:30-4:00
16:00-16:30	4:00-4:30
16:30-17:00	4:30-5:00
17:00-17:30	5:00-5:30
17:30-18:00	5:30-6:00
18:00-18:30	6:00-6:30
18:30-19:00	6:30-7:00
19:00-19:30	7:00-7:30
19:30-20:00	7:30-8:00

Complete the activity diary during the monitoring session using the numbered guide as shown below to reduce your work. Careful completion will help the physician evaluate the data recorded. Do not forget to record the time you awake and go to sleep.

1 = Working
2 = Housework (what kind)
3 = Walking
4 = Exercise (what kind)
5 = Driving
6 = Travelling
7 = Eating
8 = Watching TV
9 = Relaxing
10 = Sleeping

Medication taken during the measurement:push the button marked with heart.

1.
2.
3.
4.
5.

4.4. Product Warranty Information

(a) MONITOR WARRANTY. The main monitor unit will be free from defects in materials and workmanship under normal use and service for a period of two (2) years from the date of receipt. This warranty covers the monitor unit only. This warranty does not cover any accessories that might come with the monitor unit.

(b) ACCESSORIES WARRANTY. The non-disposable accessories delivered with the monitor unit will be free from defects in materials and workmanship under normal use and service for a period of one (1) year from the date of receipt. This warranty does not cover disposable accessories, packaging materials, accumulators and batteries, cuffs, or any of their components.

(c) CUFF WARRANTY. The cuff(s) will be free from defects in materials and workmanship under normal use and service for a period of six (6) months from the date of receipt. This warranty covers the cuff(s) delivered with a monitor unit exclusively.

(d) SOFTWARE WARRANTY. The **OMRON BP Tracker Software** under normal use will perform substantially in accordance with the accompanying written/electronic documents for a period of ninety (90) days from the date of receipt.

This warranty does not cover any malfunction or defects of the monitor unit or any of its accessories arising from improper use, the use of inadequate accessories, accident, theft, or use of the monitor unit outside its operating specifications and intended measurement range. Removing the closing label from the back side of the monitor unit, or opening the unit any other way voids this warranty.

EXCLUSION OF BIOHAZARD. OMRON will not accept for repair potentially infectious products or accessories, especially pouches and cuffs, that might have been in direct contact with the patient, and could not be, or (potentially) were not, properly disinfected, even within the warranty period. If a problem occurs within the warranty period, such accessories will be replaced without any physical inspection, reserving the rights to hold an inspection when found necessary.

NO OTHER WARRANTIES. OMRON disclaims all other warranties, either expressed or implied, including, but not limited to, implied warranties of merchantability and fitness for a particular purpose, with regard to the monitor unit, any accessory or other accompanying hardware, and the **OMRON BP Tracker Software**.

NO LIABILITY FOR CONSEQUENTIAL DAMAGES. In no event shall OMRON be liable for any special, incidental, indirect, or consequential damages whatsoever (including, without limitation, damages for loss of business profits, business interruption, loss of business information, loss of data, or any other pecuniary loss) arising out of the use of or inability to use the monitor unit, its accessories and/or the **OMRON BP Tracker Software**, even if OMRON has been advised of the possibility of such damages.

Product Serial number _____

Details of fault _____

Name & Address _____

_____

_____

_____

OMRON Customer Services becomes the owner of all exchanged units

Remarks

Made in Hungary

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