INSTRUCTION MANUAL

MxOnda

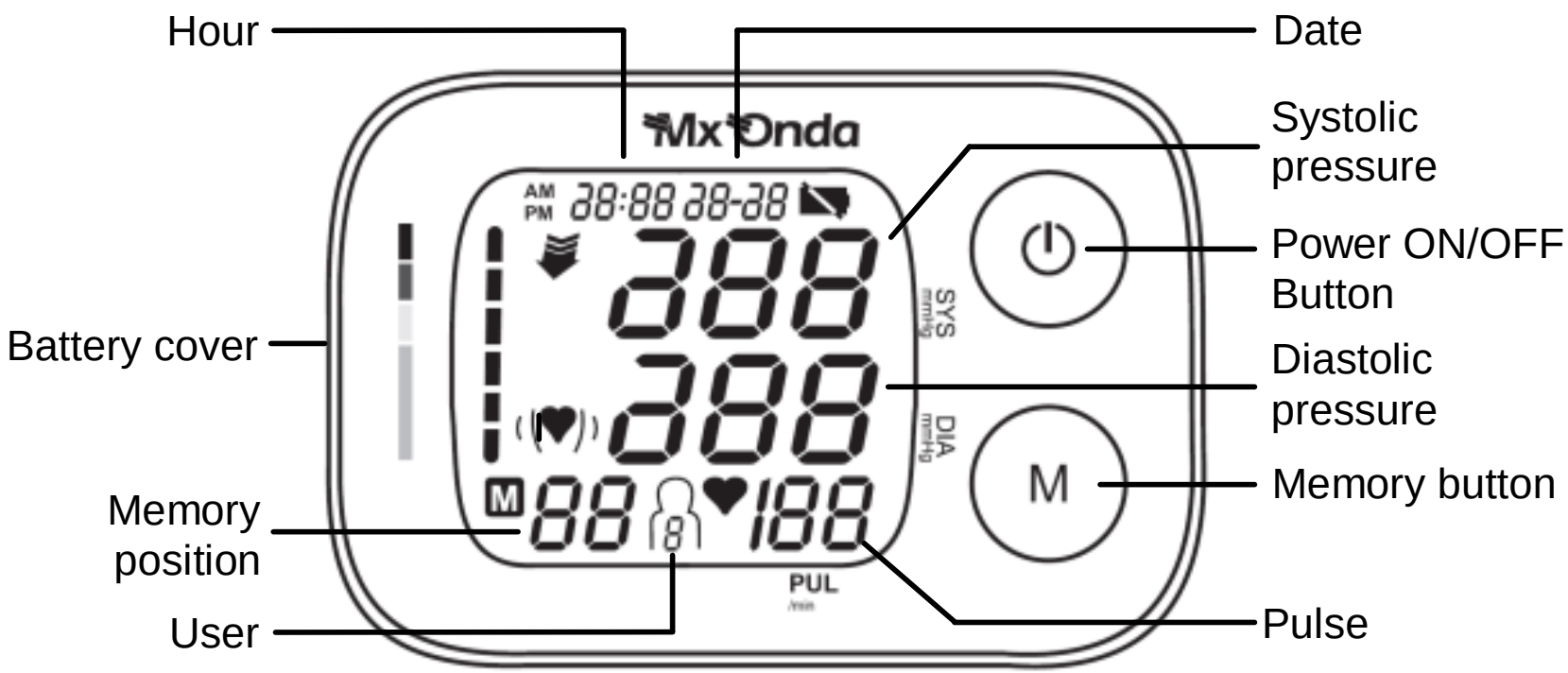
WRIST MEASUREMENT BLOOD PRESSURE MONITOR

MODEL: **MX-CP2396**

CE 0197

READ THIS MANUAL BEFORE OPERATING

NAME OF EACH PART



BEFORE USE THE BLOOD PRESSURE MONITOR

- Please read kindly these instructions and keeping for a later use.
- After unpacking, verifies that the apparatus is not damaged. In case of doubt it does not use it; contact with the service of technical assistance.

- The packing material (plastic bags, etc.) does not have to be left within reach of the children, since they are a potential source of danger.
- The manufacturer declines any responsibility by damages derived from an inadequate, incorrect or imprudent use of the apparatus.
- This apparatus has been only designed for domestic use. In case of professional use, inadequate use or breach of the instructions, the manufacturer declines any responsibility; it does not accept any responsibility and the guarantee will lack validity.
- Please do not use the cuff other than supplied by the manufacturer, otherwise it may bring biocompatible hazard and might result in measurement error.
- No component can be maintained by user in the monitor. The circuit diagrams, component part, list, descriptions, calibration instructions, or other information with will assist the user´s appropriately qualified technical personnel to repair those parts of equipment with are designated reparably can be supplied.
- The device is not intended for use on children, pregnant women. (Clinical testing has not been conducted on children, pregnant women.).

 **WARNING**

THIS PRODUCT CAN NOT BE USED ON INFANTS

SYMBOLS SHOW IN THE DISPLAY

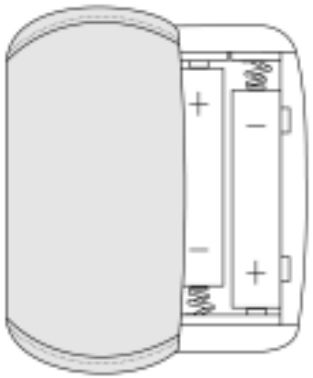
Symbol	Condition/cause
	Number of user
	This symbol appears when the pulse is located .
	The display shows this indication when have a irregular heartbeat.
	This symbol appears when the battery are low, and must be replaced.
	Inflate the wrist cuff
	The pressure in cuff is instable, or much remnant air in cuff
mmHg	Pressure in mercury millimetres
	Memory position

NOTICE BEFORE MEASUREMENT

- Avoid eating, smoking, and intensive activity 30 minutes before measuring.
- Please sit down while measuring. During measurement, please make sure the cuff stays at the same height as the heart. Either above or below the position, the accuracy will be affected.
- During measurement, do not speak or move body and arm.
- During measurement, keep you comfortable, steady and quiet.
- Measuring at the same arm each time because the blood pressure in different arm may change more than 40mmHg.
- Between each measurement, you need 3min to let blood circulation of the arm recover.
- The cuff size is suitable for adult's arm.
- The man with arrhythmia is not acceptable for this blood pressure monitor.
- Please avoid strong magnetism interfere, such as mobile telephone, microwave oven, etc.
- If you do not use the BPM for a long time, please take out the battery.
- Please wear the cuff on the left wrist
- Please do not share the cuff with other infective person to avoid cross-infection.
- Stay still, calm and rest for 5 minutes before blood pressure measurement.

BATTERY LOADING

To insert or change the batteries follow the next steps:



1. Open battery cover at the left of the machine.
2. Load two “AAA” size batteries. Please pay attention to the polarity.
3. Close the battery cover.

Notes:

- When replace the batteries the date and the hour will erase.
- The batteries contain polluting materials of environment, for that reason once exhausted the batteries, does not throw them to the sweepings, disposed in adapted for their recycled one.
- If it does not use the apparatus for a long period of time, extracts the batteries and keep in a dry place.
- Does not use 1.2 V rechargeable batteries.
- The patient is an intended operator.
- It is suggested that the blood pressure monitor be kept at least 30 cm away from other wireless devices, such as WLAN unit, microwave oven, etc
- Swallowing batteries and/or battery fluid can be extremely dangerous. Keep the batteries and the unit out of the reach of children and disabled persons.

- If you are allergic to plastic/rubber, please don't use this device.
- Do not use this unit in a moving vehicle, This may result in erroneous measurement.
- Consult your physician if you have any doubt about below cases:
  1. The application of the cuff over a wound or inflammation disease.
  2. The application of the cuff on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present
  3. The application of the cuff on the arm on the side of a mastectomy
  4. Simultaneously used with other monitoring medical equipments on the same limb
  5. Need to check the blood circulation of the user.
- Too frequent measurements may cause injury due to blood flow interference

When is necessary to change the batteries?

When the screen shows the symbol  it indicates that the batteries are exhausted and must be replaced by other new ones.

SETTING THE CLOCK AND ADJUSTING THE DATE

The clock of this device is designed to indicate the hours in 12 or 24 hour format and the date in "month / day" mode. To set the date and time, proceed as follows:

With the blood pressure monitor turned off, press and hold the " ⏻" and **M** buttons for three seconds at a time. The digits of the time format will blink (Fig. 1).

1. Press the **M** button successively and select the time format.
2. Press the " ⏻ " button and the corresponding year digits will blink (Fig. 2),
3. Press the **M** button to select the year.
4. Press the " ⏻ " button and the month digits will blink (Fig. 3).
5. Press the **M** button repeatedly and select the month.
6. Press the " ⏻" button and the digits for the day will flash (Fig. 4).
7. Press the **M** button to set the day.
8. Press the " ⏻ " button and the corresponding hour digits will blink (Fig. 5).
9. Press the **M** button to set the hour.
10. Press the " ⏻ " button and the minute digits will blink (Fig. 6)
11. Press the **M** button to set the minutes.
12. Press the " ⏻ " button again to store the data.

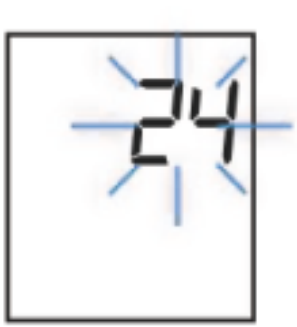


Fig. 1

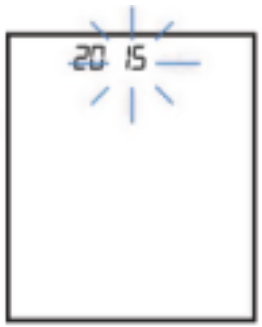


Fig.2

Fig. 3

Fig. 4

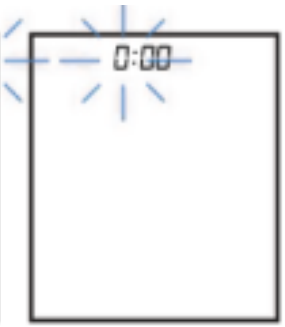


Fig. 5

Fig. 6

Notes:

- It is very important to keep the date and time updated as these are stored together with the measured values.
- When replacing the batteries, the date and time will be erased, and the display will show the menu for setting the date and time.
- During the setting of the clock and setting the date, if a minute passes without touching any buttons, the tensiometer will turn off and will not store the entered data.

WRIST CUFF CONNECTING

1. Be sure to place the wrist cuff on bare skin of left wrist, and place monitor on the centre of wrist.
2. Place wrist cuff 1-2 cm above wrist joint.
3. Wrist cuff connecting should make wrist feel no much tension. Don’t connect too tense (otherwise the measurement will be not precise.
4. If the cuff is too long, fix the over plus cuff on the Nylon fibulae of cuff.
5. Keep up right position on the same level of heart.
6. To avoid arm moving, place the plastic box of the monitor under the arm is recommended.

Note:

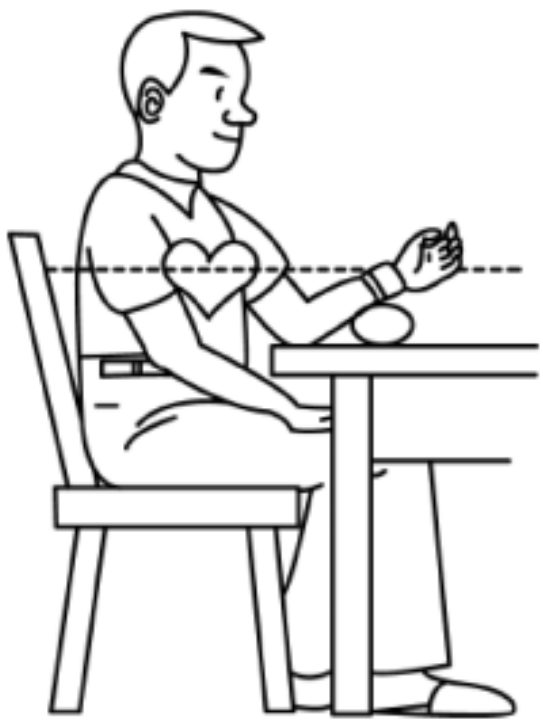
- When the cuff is dirty, detach it from the equipment, wash the cuff by hand with proper detergent and rinse it in the enough cold water, dry in air. Never iron it.
- This product can’t be used on infants and can’t be used on other uses than blood pressure measurement.

CORRECT POSTURE TO USE A BLOOD PRESSURE MONITOR

The position of pressure monitor in relation to the heart is extremely important to be able to obtain a correct measurement.

If the pressure monitor is placed above or under the height of the heart the values of the measurement can more decrease or increase respectively, of significant form with respect to the real value.

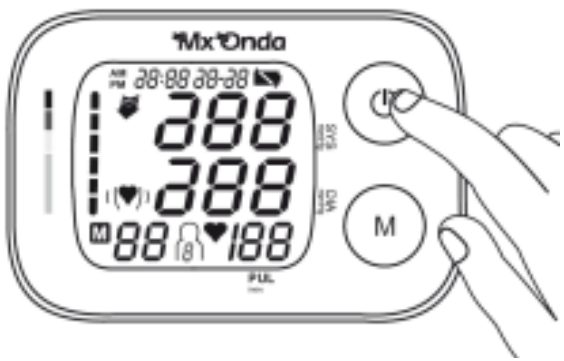
- Always to measure the blood pressure on seated position.
- Place his left elbow on a table or similar surface.
- Place the arm in such a way that pressure monitor is to the height of the heart, the hand will have to be open (to see illustration).
- Relax the arm and you place it of such form that can see its internal side.
- If You it wishes it can use the protective case to support the arm.
- Be seated with your feet flat on the floor, and don’t cross your legs.



MEASURING PROCESS

The blood pressure has four independent memories (, , and) for four different users. In each memory, up to 30 measurements are automatically stored and you must select the desired memory position before carrying out the measurement.

1. Once placed the blood pressure on the wrist:

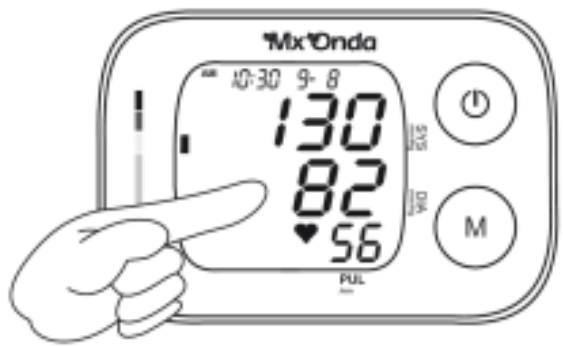


- Press the on / off button , the display will show all the digits and then show the number of the last user who used the device.
- If you want to change user press the memory button (M) successively and choose the desired user (, , or) otherwise wait a few seconds and the device will start the measurement process.
- If the screen shows the symbol " " it indicates that the wristband contains air and this will be expelled, then the wristband will be inflated automatically.
- During the inflation of the wristband the device will automatically select the pressure level, depending on each person.

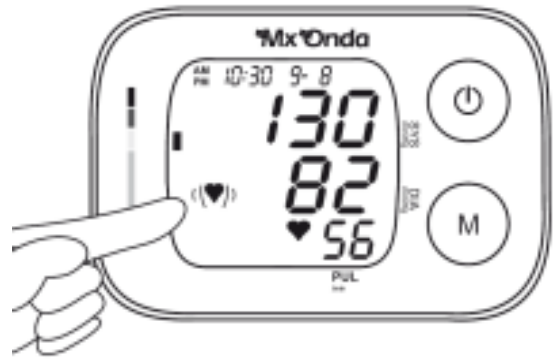
2. Once the wristband is inflated and the pulse is localized, the " ♥ " symbol will begin to flash at the pulse rate, the wristband will begin to deflate at constant speed and the display will show the value of the pressure decreasing

Note: To avoid errors during measurement do not move your wrist and do not talk. At any time during the measurement you can turn off the appliance by pressing the button

3. Once the measurement is complete, the display will show the systolic pressure value (SYS), the diastolic pressure value (DIA) in millimeters of mercury (mmHg) and the pulses per minute (PUL n / min). In the illustration, the systolic pressure was 130 mmHg, the diastolic pressure was 82 mmHg and the pulse was 56 beats per minute. The measured values together with the date and time are automatically stored in the memory.



4. If the screen shows the symbol (♥) it indicates that there is a possible alteration in the heart rate. A normal heart of a body at rest beats between 60 and 100 palpitations per minute with a rhythm rhythm. This rhythm can increase with physical exercise, stress or with some diseases. Other causes that produce alterations in the heart rate are cholesterol, diabetes, obesity and certain medications or drugs, such as caffeine or tobacco.



5. On the left side of the screen is the pressure indicator according to the classification criteria of the World Health Organization (WHO). This indicator consists of four marks or colors: green (normal tension), yellow (prehypertension), orange (high tension) and red (hypertension).

At the end of the measurement, a rectangle flashing indicating the pressure will appear next to this indicator.
In the illustration, the rectangle is in the yellow zone (prehypertension). This information is generic and only serves as a reference.

6. If you want to make a new measurement, you must turn off and on the appliance again, but keep in mind the following suggestions:

- After carrying out the blood pressure measurement, if you want to make a new measurement in the same person you should wait for 3 to 5 minutes, so that the blood circulation returns to normal. This time varies according to each person.
- The blood pressure values depend on many factors, so it is not possible to provide a valid diagnosis by virtue of a single measurement. For this reason, by measuring the blood pressure regularly, a more complete follow-up of the patient can be carried out.

TURN OFF

To turn off the blood pressure monitor press the **“ ⏻”** button. However, once the measurement is completed, the appliance will automatically turn off after 1 minute.

Note: It may happen that the device shuts down if it is close to equipment that generates interference or electrostatic discharge.

READING MEMORY RESULTS

This device has four independent memories ( ,  ,  and ) for four different users and up to 30 measurements are stored in each memory. The

storage in the memory (previously selected) is carried out automatically, the last measurement is recorded in position 1, moving the penultimate measurement to position 2 and so on. When the capacity of the selected memory is complete when performing a new measurement, the first position will be deleted.

To access the memory press the **M** button and the screen will show the last user number selected, to change the user press the " ⏻" button successively and the screen will show the chosen user as well as the total of measurements (Fig. 1), press **M** button or wait a few seconds and the screen will show the average of all the measurements made in the memory of the selected user (Fig. 2).

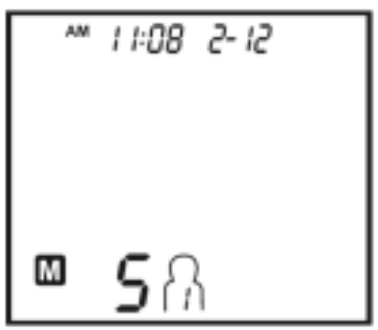


Fig. 1

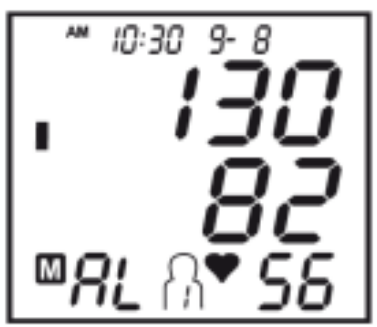


Fig.2

Fig. 3

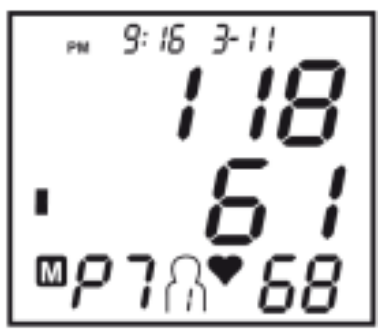


Fig. 4

If you press the **M** button again, the display will show the average of the last 7 measurements taken before noon (Fig. 3). Pressing the **M** button again the screen will show the average of the last 7 measurements made after 1 noon

(Fig. 4). The average value of all the results which is measured from 5 o’clock to 9 o’clock in last 7 days in the current user memory zone. The average value of all the results which is measured from 18 o’clock to 20 o’clock in last 7 days in the current user memory zone

Press the **M** button for the fourth time to access the different memory locations, press repeatedly to check all the memory positions of the selected user. In any of the cases mentioned above the screen will show the stored values; Maximum tension (systolic), minimum tension (diastolic), pulse and condition according to the classification criteria of the World Health Organization.

Notes:

- The memories will remain stored even when the device does not have the batteries installed.
- If there are no stored measurements, the display will show the digits " 0 ".
- At any time you can exit memory mode by pressing the “ ⏻ ” button, or allow 1 minute to pass without pressing any button

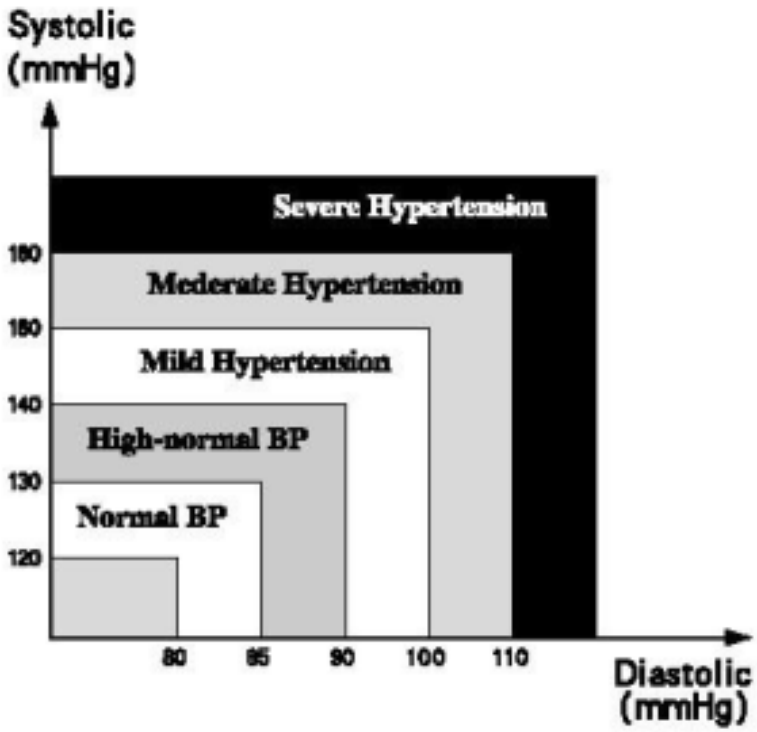
Deleting measurements from the memory

To clear all memory locations, access the memory and then press and hold the **M** button for three seconds.

ASSESSING HIGH BLOOD PRESSURE FOR ADULTS

The follow standards for assessing high blood pressure (without regard to age or gender) have been established as a guide line. Please note that other risk factors (e.g. diabetes, obesity, smoking, etc.) need to be taken into consideration and may affect these figures. Consult with your physician for accurate assessment.

CLASSIFICATION OF BLOOD PRESSURE FOR ADULTS



BLOOD PRESSURE CLASSIFICATION	SBP mmHg	DBP mmHg	COLOR INDICATOR
Optimal	<120	<80	GREEN
Normal	120-129	80-84	GREEN
High-Normal	130-139	85-89	GREEN
Grade 1 Hypertension	140-159	90-99	YELLOW
Grade 2 Hypertension	160-179	100-109	ORANGE
Grade 3 Hypertension	≥ 180	≥ 110	RED

SBP. systolic blood pressure;DBP. diastolic blood pressure

TECHNICAL ALARM DESCRIPTION

The monitor will show 'HI' or 'Lo' as technical alarm on LCD with no delay if the determined blood pressure (systolic or diastolic) is outside the rated range specified in part SPECIFICACIONS. In this case, you should consult a physician or check if your operation violated the instructions.

The technical alarm condition (outside the rated range) is preset in the factory and cannot be adjusted or inactivated. This alarm condition is assigned as low priority according to IEC 60601-1-8.

The technical alarm is non-latching and need no reset. The signal displayed on LCD will disappear automatically after about 8 seconds.

TROUBLESHOOTING (1)

Problem	Possible cause	Solution
LCD display shows abnormal result	The cuff position was not correct or it was not properly tightened	Apply the cuff correctly and try again.
	Body posture was not correct during testing	Review the “BODY POSTURE DURING MEASUREMENT” sections of the instructions and re-test.
	Speaking, arm or body movement, angry, excited or nervous during testing	Re-test when calm and without speaking or moving during the test.
	Irregular heartbeat (arrhythmia)	It is inappropriate for people with serious arrhythmia to use this Electronic Sphygmomanometer.

TROUBLESHOOTING (2)

Problem	Possible cause	Solution
LCD shows low battery symbol	Low Battery	Change the batteries
LCD shows “Er 0”	Pressure system is unstable before measurement	Don’t move and try again.
LCD shows “Er 1”	Fail to detect systolic pressure	
LCD shows “Er 2”	Fail to detect diastolic pressure	
LCD shows “Er 3”	Pneumatic system blocked or cuff is too tight during inflation	Connect the cuff correctly and try again. If the monitor is still abnormal, please contact the local distributor or the factory
LCD shows “Er 4”	Pneumatic system leakage or cuff is too loose during inflation	
LCD shows “Er 5”	Cuff pressure above 300mmHg	Measure again after five minutes. If the monitor is still abnormal, please contact the local distributor or the factory.
LCD shows “Er 6”	More than 3 minutes with cuff pressure above 15 mmHg	
LCD shows “Er 7”	EEPROM accessing error	
LCD shows “Er 8”	Device parameter checking error	
LCD shows “Er A”	Pressure sensor parameter error	
No response when you press button or load battery.	Incorrect operation or strong electromagnetic interference.	Take out batteries for five minutes, and then reinstall all batteries.

CLEANING AND MAINTENANCE

- Clean the plastic surface of the unit with a humid cloth and dries it with another dry one. It does not use abrasive alcohol nor products and it does not allow that the unit between in contact with volatile agents like gasoline, disolvents, etc.
- Clean the cuff with a dry cloth.
- If it does not think to use the time apparatus for a long period, extracts the batteries and keep it in a fresh place.
- Does not mix the old and new batteries, nor of different types
- When it does not use the apparatus places it in protective case.
- The cuff integrity is maintained after 1.000 open-close cycles of the closure.
- It is recommended the performance should be checked every 2 years or after repair. Please contact the service centre.
- Does not expose east apparatus to extreme temperatures, exposed to the direct solar light, is in places with excess of dust, humidity or next to equipment that generates heat.
- It is recommended the cuff should be disinfected 2 times every week if needed (for example, in hospital or in Clinique). Wipe the inner side (the side contacts skin) of the cuff by a soft cloth squeezed after moistened with Ethyl alcohol (75-90%), then dry the cuff by airing.
- Clean the cuff after the usage of every 200 times is recommended

- The monitor can maintain the safety and performance characteristics for a minimum of 10.000 measurements or three years.
- Not servicing/maintenance while the monitor is in use.
- The monitor requires 6 hours to warm from the minimum storage temperature between uses until the monitor is ready for its INTENDED USE when the ambient temperature is 20 °
- The monitor requires 6 hours to cool from the maximum storage temperature between uses until the monitor is ready for its INTENDED USE when the ambient temperature is 20 °C
- Do not attempt to disassemble this monitor.

Waste electrical products must not be disposed of with household waste. This equipment should be taken to your local recycling centre for safe treatment. Remove the batteries from the product before disposing of it.

This product complies with European Directives RoHS (2011/65/CE), on the restriction of use of certain dangerous substances in electrical and electronic appliances.

“MX, MX ONDA” and his logos, are trademarks of MX ONDA, S.A.

SPECIFICATION

Measuring method	Oscillometric
Measuring range	60 – 260 mmHg (Systolic) 40 – 199 mmHg (Diastolic) 40 – 180 pulses/min (pulse)
Cuff pressure:	0 – 300 mmHg
Measuring accuracy	± 3 mmHg (pressure)
Pulse rate:	Less than 60: ±3bpm More than 60 (incl.) : ±5%
Power source	Batteries 2 x 1.5 V ⎓ SIZE AAA)
Power consumption	1,2 W
Battery life	Approx. 200 times
Pressurisation	Automatic air pump
Deflation	Automatic
Operating environment	+10°C a +40°C, ≤ 85% RH
Storage environment	-20°C a +50°C, ≤ 85% RH
Wrist circumference range	140 – 195 mm
Wrist cuff size	300 x 70 (L, W)
Unit size	89 x 60 x 31 mm (L, W, H)
Weight	69.5 gr.

All components belonging to the pressure measuring system, including accessories: pump, valve, sensor.

EXPLANATION OF SYMBOLS ON UNIT

 Symbol for" THE OPERATION GUIDE MUST BE READ"(The sign background colour: blue The sign graphical symbol: white)

 Symbol for "WARNING"

 Symbol for "TYPE BF APPLIED PARTS" (The cuff is type BF applied part)

 Symbol for "MANUFACTURER"

CE 0197 Symbol for "COMPLIES WITH MOD93/42/EEC REQUIREMENTS

 Symbol for "DATE OF MANUFACTURE"

 Symbol for "EUROPEAN REPRESENTATION"

 Symbol for "SERIAL NUMBER"

IP22 The first characteristic numeral symbol for Degrees of protection against access to hazardous parts and against solid foreing objects. The second characteristic numeral symbol for "Dregrees of protection against ingress of water.

ELECTROMAGNETIC COMPATIBILITY INFORMATION

Table 1 - Emission

Phenomenon	Compliance	Electromagnetic environment
RF emissions	CISPR 11 Group 1, Class B	Home healthcare environment
Harmonic distortion	IEC 61000-3-2 Class A	Home healthcare environment
Voltage fluctuations and flicker	IEC 61000-3-3 Compliance	Home healthcare environment

Table 2 - Enclosure Port

Phenomenon	Basic EMC standard	Immunity test levels
		Home Healthcare Environment
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Radiated RF EM field	IEC 61000-4-3	10V/m 80MHz-2.7GHz 80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table 3
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz

Table 3 – Proximity fields from RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Immunity test levels
		Professional healthcare facility environment
385	380-390	Pulse modulation 18Hz, 27V/m
450	430-470	FM, ±5kHz deviation, 1kHz sine, 28V/m
710	704-787	Pulse modulation 217Hz, 9V/m
745		
780		
810	800-960	Pulse modulation 18Hz, 28V/m
870		
930		
1720	1700-1990	Pulse modulation 217Hz, 28V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217Hz, 28V/m
5240	5100-5800	Pulse modulation 217Hz, 9V/m
5500		
5785		

This product complies with the dispositions of the Directive of the Council on sanitary products 93/42/EEC, of the European Parliament, and has been proven and tried in agreement the norms **EN 1060-3, EN1060-1**.

The Electronic Sphygmomanometers corresponds to the below standards：ISO81060-2: 2013(Non-Invasive Sphygmomanometers –Part 2: Clinical Validation Of Automated Measurement Type).

Mark **CE 0197** indicates that this product complies the European Directives. All components to the pressure measuring system, including accessories: Pump, Valve, LCD, Cuff, Sensor.

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04/2019