CARDIOLINE

Walk200b

User manual

CE
1936

Rev. 16 – 29.03.2023

CARDIOLINE

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1. GENERAL INFORMATION

This manual is an integral part of the device and should always be available as support material to the clinical practitioner or the operator. Strict compliance with the information contained in this manual is an essential prerequisite for a proper and reliable use of the device.
Have the operator read the manual thoroughly as the information related to the different chapters is only described once.

1.1. Product life cycle

Considering the type of components chosen and the degradation of the electronic parts, the period of time during which this product is expected to remain suitable for its intended use, maintaining basic security and essential performance, will be 5 years.

1.2. Other important information

This manual was written with the utmost care. Should you find any details which do not correspond to those contained in this manual, please inform Cardioline SpA who will correct such inconsistencies as soon as possible.

The information contained in this manual is subject to change without notice.
All changes will be in compliance with the regulations governing the manufacturing of medical equipment.

The code relating to this manual is listed below.

Language	Code
ENGLISH	36529364_ENG

This manual refers to the software version sw. v. 200209.

2. SAFETY INFORMATION

Cardioline SpA will be held responsible for the safety, reliability and functionality of the devices only if:

the assembly operations, modifications or repairs are carried out by Cardioline SpA or by its Authorised Service Centre;

The device is used in compliance with the instructions provided in the use manual.

Always contact Cardioline SpA should you wish to connect any devices not mentioned in this manual.

Warnings

- This manual provides important information on proper use and safety of the device. Failure to comply with the described operating procedure, improper use of the device, ignoring the specifications and recommendations supplied, may cause severe physical injuries to the operators, patients and bystanders, or may damage the device.
- The device cannot be modified in any way.
- The device captures and presents the data that reflects the physiological condition of the patient; this information can be examined by specialist medical staff and will be useful in providing an accurate diagnosis. In any event, the data cannot be used as the only means to make an accurate diagnosis of the patient.
- The operators for whom this device is intended must have the required competence regarding medical procedures and the treatment of patients. They must also be sufficiently trained in using the device. Have the operator carefully read and understand the contents of the operator manual and the other annexed documents before using the device for clinical applications. Inadequate knowledge or training could be at a greater risk for the physical safety of operators, patients and bystanders, or could damage the device. If the operators are not trained on device use, it is recommended to contact Cardioline or their Authorised Distributor to schedule an adequate training course.
- In case of unexpected events or malfunctions, contact Cardioline or their Authorised Distributor immediately.
- The correct use is the pressure monitoring of adults. The recorder should be used only under medical supervision.
- The doctor must be certain that, according to the health of the patient, the use of the device will not damage blood circulation in the arm.
- Petechial haemorrhages or subcutaneous haematomas may occur in some patients; all patients must be told when putting on the cuff that if they experience pain they should switch off the equipment and inform the doctor.
- The doctor should explain to the patient that, particularly when sleeping, the equipment should be positioned in such a way that the tube cannot be compressed. If the patient is not fully competent, the equipment should be worn only under supervision.

- The shoulder strap or cuff tube can become entangled around the patient's neck and lead to strangulation; because of this risk from the tube and cuff, the recorder may not be used for patients who are legally incompetent, and must not get into the hands of unsupervised children.
- The air tube between the recorder and the cuff must never be knotted, compressed or stretched.
- The air tube may kink when inflated.
- The device is protected against the effects of a defibrillator discharge.
- The cuff is the applied part.
- To prevent death or any serious personal injuries during defibrillation, avoid contact with the device or the tube or the cuff.
- This device is designed to be used only with the probes and accessories specified in this manual.
- The cuff may cause skin irritation; check the skin for any irritations or inflammations.
- To prevent any infections, clean the reusable accessories after each use.
- The quality of the measurement may be adversely affected by the use of other medical equipment such as defibrillators and ultrasound machines.
- There is a risk of explosion. Do not use the device in the presence of flammable anaesthetics.
- There is no safety hazard if other equipment, such as pacemakers or other stimulators, is used simultaneously with the device; however, disturbance to the signal may occur.
- Do not use the device for direct cardiac applications
- The device is not designed for use with high-frequency (HF) surgical equipment, and does not provide any protective means against hazards to the patient.
- The operation may be adversely affected by the presence of strong magnetic fields such as those produced by electrosurgery equipment.
- The use of the device is not recommended in the presence of medical diagnostic imaging equipment such as the Magnetic Resonance Imaging (MRI) or Computerised Axial Tomography (CAT) in the same environment.
- Only use the recommended batteries. Using other types of batteries may cause danger of fire or explosion.
- The low battery warning is designed for the recommended batteries only. Using other types of batteries may lead to a lack of indication resulting in device failure.
- The case of the device is not protected against liquids penetration; devices in which liquid has infiltrated should be cleaned as quickly as possible and checked by an authorized Service Centre.
- Do not clean the device or the accessories by submersing them in liquid, autoclaving, or steam cleaning. This may cause serious damage to equipment or reduce its lifespan. Using non-specific detergents/disinfectants, failure to comply with the recommended procedures or contact with non-specific materials may cause additional risks to operators, patients or bystanders or may damage the device. Do not sterilise the device or the cuff with ethylene oxide gas (EO). Refer to Section 7 for instructions on proper cleaning and disinfection.

- Do not leave the air tube unattended in the presence of children as they could be accidentally strangled.
- The Walk200b device is designed to be connected to a PC. The system that consists of the Walk200b device and the non-medical PC equipment is defined as an electromedical system. The adoption of an electromedical system requires compliance with the requirements of the Directive.
- The use of a medical separation transformer must be used with the electromedical system consisting of the Walk200b, a PC and any other non-medical equipment (such as printer and monitor). Consult a CARDIOLINE® Service Centre for more detailed information. Alternatively, a PC compliant with medical standard EN60601-1 can be used. A separation transformer cannot be used unless compliance with the following conditions has been confirmed with absolute certainty:
    - After measurements taken according to the EN60601-1 standard, the dispersion currents in the case of the PC and of any other non-medical devices that are connected (monitor, printer, etc.) are less than 0.1 mA.
    - The non-medical devices in the system are connected outside the patient area, that is, not within 1.5 m of the patient and/or his or her bed.
    - If a separation transformer is not used, install the system in such a way that the operator cannot touch the patient and the case of the any non-medical equipment outside the patient area at the same time.
    - If the PC and any other non-medical devices that are connected (monitor, printer, etc…) are powered by the medical separation transformer, they may be located inside the “patient area”, i.e. within 1.5 m of the patient and/or his or her bed.
    - The PC and any other devices to be used in the system (monitor, printer, etc.) must only be connected to the separation transformer using the cables and any other accessories supplied with the system. Extension cords, socket adapters and other types of connections may not be used unless supplied with the system.
    - It is categorically forbidden to connect other equipment that is not part of the system to the separation transformer or to a multiple extension cord supplied with the system.
    - If a non-medical device that is part of the system is connected to a non-prescribed type of socket (a wall socket, for example), the system no longer complies with medical standards and the patient may be endangered.
    - If a non-standard device is connected to the socket of the separation transformer specified for the system devices, this could create situations of danger for the patient, operators or environment (overloading or overheating of the sockets and separation transformer.
    - The separation transformer and any multiple sockets connected to it must not be placed directly on the floor or any area that may be flooded, or in which dirt may accumulate. The transformer and sockets must be placed in an area that is easy to inspect, both for regular cleaning and for the required maintenance.
    - The installer must install the system in the optimum way to satisfy the safety regulations and provide the greatest facility and ease of use by both the user and the patient.
    - The user must ensure that cleaning and required maintenance of the system is performed. In particular, the separation transformer, the socket or sockets attached to it, and to the non-

medical device (PC) must be kept in a dry area, with no accumulation of dirt and dust. Check the integrity of the cables regularly.

- The earth used by the system must be efficient and compliant with the requirements for electrical systems for public and/or medical use.

- The device is in compliance with the requisite required by the Directive R&TTE on the devices of radio transmission. In order to protect the device from other devices not in accordance to the normative aforesaid, we suggest to put the device away from other devices that use the Bluetooth transmission.
- On first use, make sure that the device has not been damaged during transport and that it operates perfectly.
- The device has been calibrated by the manufacturer; a label inside the battery compartment shows the calibration's expiry date.
- It is recommended to check the calibration regularly - at least once every other year. The calibration may be verified by Cardioline or by any authorised service centre.
- The device may be used with the bag or the Walk200b Waterproof case mentioned in paragraph 8.2. The bags are not meant to come into direct contact with the body; it is therefore recommended to place them over a piece of clothing (e.g. a T shirt).

Attention

- The device and the accessories should be cleaned before use. Check the connections for any damage or excessive wear before each use. Replace the cable and cuff should they present any damage or be excessively worn.
- Do not pull or stretch the cuff tube as this could result in mechanical failures.
- There are no user-serviceable parts inside the device. The device can only be dismantled by qualified service personnel. Any malfunctioning or defective device must be excluded from use and be checked/repaired by qualified service personnel before being reused.
- When it is necessary to dispose of the device, its components and accessories (e.g.: batteries, cables, etc) and/or packaging material, comply with local standards for waste disposal.
- The recorder should not be exposed to direct sunlight and should not be placed near direct source of heat to prevent it from overheating
- Defective segments in the LCD's can cause wrong interpretation of measurement values and lead to false diagnosis. Defective LCD's must be replaced immediately by the manufacturer or an Authorised Service Centre.

Notes

- The movements of the patient may generate excessive noise and affect the quality of the signal or the correct analysis of the device.
- As defined by the IEC 60601-1 and IEC 80601-2-30 safety standards, the device is classified as follows:

- IP class equipment (internal power ME)
- Defibrillation-proof Type BF applied parts.
- Ordinary equipment.
- Not suitable for use in the presence of flammable anaesthetics.
- Continuous operation

- Accuracy of measurements taken with the device is compliant with IEC 80601-2-30.
- The device is a Class IIa in compliance with Directive 93/42/EEC.
- The device has IP 2x protection rating against the ingress of solid particles and water. It is therefore protected against solid particles with diameter greater than 12 mm. The Walk 200b Waterproof case (see para. 8.28.2) has IP 2x protection rating against the ingress of solid particles and water; it therefore protects the device against water drops falling at a maximum angle of 15° when used with the device. Without the Walk200b Waterproof case, the device is not protected against liquid penetration.
- The Walk200b Waterproof case is required for use in a domestic environment.
- In order to prevent damage to the device during transportation and storage (when still in its original packaging), comply with the following environmental conditions:

Ambient temperature.....	-20°C to 50°C
Relative humidity.....	15% to 95%

- The device is intended for use in hospitals or doctor's offices and should comply with the following environmental requirements:

Ambient temperature.....	+10°C to 40°C
Relative humidity.....	15% to 90%
Athmosferic pressure	700 hPa to 1060 hPa

- The measurements' accuracy level is ± 3 mmHg.

2.1. Warnings for the patient during the exam

The device was designed for Ambulatory Blood Pressure Monitoring (ABPM). The device can also perform continuous recordings for 24 hours.
Clinical practice requires the Patient to wear or carry the device inside or outside the hospital, in indoor premises as well as outdoors. It is therefore especially important for the patient to be sufficiently instructed regarding the operations they are authorised to perform and the related risks.

In particular, the following warnings must be explained to the patient:

- The device must be worn throughout the test;
- If the device is used inside the bag, it may not be removed;
- The device is not protected against the ingress of liquids, unless it is used inside the Walk200b Waterproof case (see para. 8.2). It should therefore never get wet;
- The device emits a sound to signal particular events, such as an empty battery. In such cases, contact the doctor of reference or the outpatient clinic for instructions;
- In case of pain during the measurement, turn off the device, remove the armband and contact a doctor.
- During the measurement procedure, the patient must be relaxed and keep the arm still. Excessive movement (e.g. flexing the muscles) may affect the results of the measurement. Walk slowly or stop during the measurement.
- If the armband detaches accidentally, contact the doctor of reference or the outpatient clinic for instructions;
- The device might be damaged by impacts and falls, which may cause it to malfunction and interrupt the test scheduled;
- Inform the patient that the cables and armbands must be kept away from children, as they pose a risk of suffocation or strangulation.
- The measurements' accuracy level is ± 3 mmHg.

NOTE: if the device is used in accordance with this manual and new batteries are used for every test, the patient must not replace the battery, as its life is compatible with the duration of the test.

3. ELECTROMAGNETIC COMPATIBILITY (EMC)

This device requires particular precautions regarding Electromagnetic Compatibility. It must therefore be installed and commissioned in compliance with the information on Electromagnetic Compatibility contained in this manual.
Portable and mobile radio communication equipment can affect operation of the device.
Using accessories, transducers or cables different than those specified in par. 8.2 can increase the emissions or decrease the immunity of the appliance.

Warnings

- This device is only intended to be used by professional healthcare personnel. This device could generate radio interference or disturb operation of the equipment in the vicinity. Therefore it could be necessary to take measures to mitigate these effects, such as re-directing or repositioning the device or shielding the room.
- The use of accessories and cables other than those recommended by Cardioline may cause an increase in emissions or a lowering in the protection of the system.
- The device must not be used near or superimposed to other equipment. If necessary, check that the device works according to its standard operation.

Electromagnetic compatibility during the use of the device is required with the surrounding devices.
An electronic device can generate or receive electromagnetic interference. The electromagnetic compatibility test (EMC) has been carried out on the electrocardiograph in compliance with the international EMC directive for medical equipment (IEC 60601-1-2). This IEC standard has been adopted as a European standard (EN 60601-1-2).

Fixed, portable and mobile equipment for RF communication may affect the protection of the medical equipment. See par. 3.1.4 for the recommended separation distance between the radio equipment and the device.

3.1.1. Guidance and Manufacturer's declaration - Electromagnetic emissions

The Walk200b is intended to operate in the electromagnetic environment specified below. The customer or the user of the Walk200b must guarantee that it is used in this environment.

Emission test	Compliance	Electromagnetic environment – guidance
Radio frequency (RF) emissions CISPR 11	Group 1	The Walk200b uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Radio frequency (RF) emissions CISPR 11	Class B	The Walk200b is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonics emissions IEC 61000-3-2	Not applicable	

Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

3.1.2. Guidance and Manufacturer's declaration - Electromagnetic immunity

The Walk200b is intended for use in the electromagnetic environment specified below. The customer or the user of the Walk200b should assure that it is used in such an environment.

Immunity test	Conformity	Compliance level	Electromagnetic Environmental Information
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical Fast Transient/ Burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV line(s) to line(s) +/- 2 kV line(s) to earth	+/- 1 kV line(s) to line(s) +/- 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruption and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (60% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Not applicable	The device operates with buffer batteries and is designed for continuous operation
Power frequency and magnetic field (50/60 Hz)	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the AC mains voltage prior to the application of the test level.

3.1.3. Guidance and Manufacturer's declaration - Electromagnetic immunity

The Walk200b is intended for use in the electromagnetic environment specified below. The customer or the user of the Walk200b should assure that it is used in such an environment.

Emission test	IEC 60601 test level	Compliance level	Electromagnetic Environmental Information
Conducted RF IEC 61000-4-6	3 V rms From 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the Walk200b, including cables, than the recommended separation

Radiated RF IEC 61000-4-3	3 V/m From 80 MHz to 2.5 GHz	3 V/m	distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**: $d = \left[\frac{3.5}{3Vrms}\right]\sqrt{P}$ $d = \left[\frac{3.5}{3V/m}\right]\sqrt{P}$ From 80 MHz to 800 MHz $d = \left[\frac{7}{3V/m}\right]\sqrt{P}$ From 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a), should be less than the compliance level in each frequency range (b). Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Walk200b is used exceeds the applicable RF compliance level above, the Walk200b should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Walk200b.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

3.1.4. Recommended separation distances between portable and mobile RF communications equipment and the Walk200b

The Walk200b is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Walk200b can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Walk200b as recommended below, according to the maximum output power of the communications equipment.

Maximum rated power output of the transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 KHz to 800 MHz	800 MHz to 2.5 GHz	800 MHz to 2.5 GHz
	$d = [\frac{3,5}{V_1}]\sqrt{P}$	$d = [\frac{3,5}{E_1}]\sqrt{P}$	$d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

4. SYMBOLS AND LABEL

4.1. Explanation of the symbols

Symbol	Description
	Comply with the instructions in the use manual
 1936	CE marking – compliance with the European Union directives
	Manufacturer
	Reference number (product code)
	Serial Number
	Lot number
 20XX	Year of manufacture
	Type BF equipment – defibrillation protection
	Device with RF communication
	Separate collection of electrical waste and electronic equipment
	Consult instructions for use
	Temperature variation
	Humidity variation
	Keep dry
	No Latex

PVC	No PVC
DEHP	No DEHP

4.2. Device label

5. INTRODUCTION

5.1. Purpose of the manual

This manual deals with the Walk200b device.
The manual represents a guide for the execution of the following operations:

- Reasonable use of the device, of the function keys and of the sequence of menus.
- Execution of an exam. (Section 6)
- Maintenance and troubleshooting. (Section 7)

5.2. Recipients

This manual is intended for professional healthcare operators. They are therefore presumed to have specific knowledge of medical procedures and terminology, as required by clinical practice.

5.3. Intended use

Walk200b is an outpatient non-invasive Ambulatory Blood Pressure (ABP) recorder for 24-hour monitoring.
The device measures the systolic and diastolic blood pressure and the heart rate. The pressure is measured with the application of the oscillometric method.
The recorder can communicate with a computer via a wireless Bluetooth channel.
The device is indicated for use in healthcare: hospitals, medical clinics and offices of any size.
The device is designed to perform and record blood pressure measurements that may be used for the assessment and diagnosis of the patient's condition.
For the specific application and the related clinical practice, an interruption of the recording, which may make it necessary to repeat the test, has no impact on patient safety.

- The device is indicated for the performance and recording of BP measurements over a period of 24 hours at specific intervals.
- The device may not be used for monitoring blood pressure in intensive therapy or during surgery.
- The device is not intended for use as a physiological monitor of vital signs.
- The device is not intended as the only means of diagnosis. The test results must always be checked and validated by a specialist doctor.
- The device is indicated for use on adults and children.
- The device is not intended for use on newborns.
- There are no limits in terms of gender or race.

- The device is indicated for use by a doctor or personnel acting on the order of an authorised doctor, trained in the use of devices measuring ambulatory blood pressure.

The device is indicated for use by patients adequately informed by the doctor of the following warnings:

- The device must be worn throughout the tests;
- If the device is used inside the bag, it must never be removed;
- The device is not protected against the ingress of liquids, unless it is used inside its protective carry case. It should therefore not get wet;
- If the armband disconnects accidentally, contact the doctor of reference or the outpatient clinic for instructions;
- The device may be damaged by impacts and falls, which may impair its proper operation and interrupt the tests scheduled;
- Inform the patient that the armband and cables must be kept away from children, as they pose a risk of suffocation or strangulation.

5.4. Description of the device

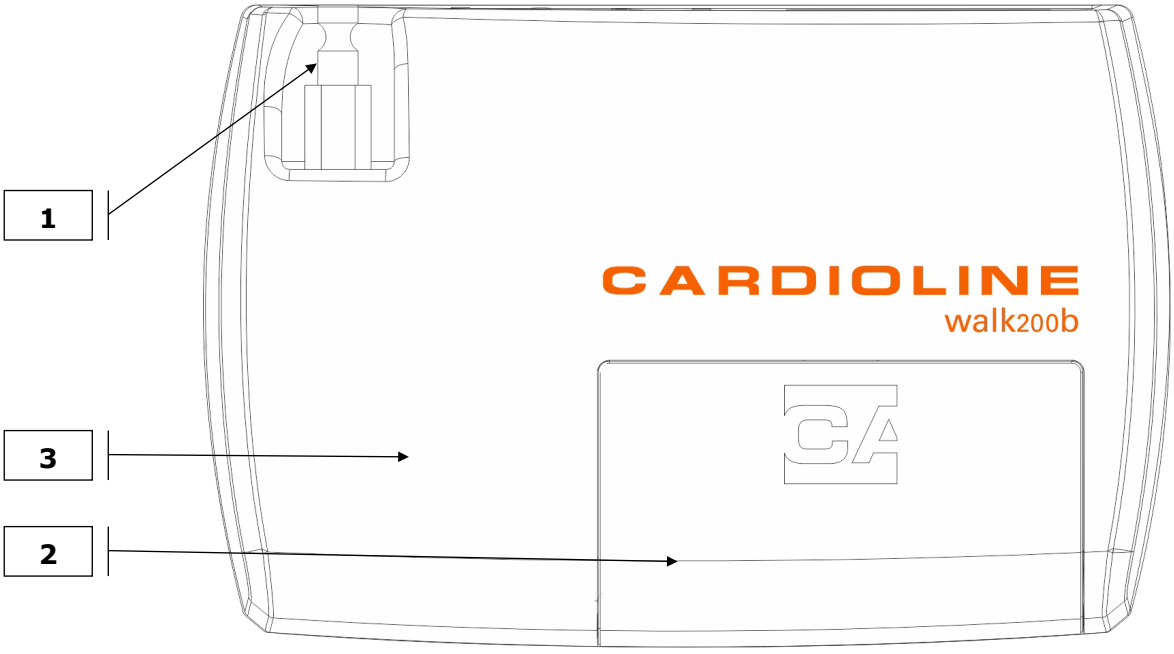
The device is a blood pressure monitoring recorder lasting 24 hours or more designed to perform ambulatory monitoring tests during 24 hours or more.
Depending on the configuration purchased, the device may be equipped with a Bluetooth and/or USB connection, through which it may be connected to a PC thanks to the dedicated software that is installed on said PC. The connection works for both test preparation and download procedures.
The device is powered by battery.
The device includes:

1. Patient cable and cuff
2. Pouch
3. 2 batteries (AA 1.5V)

User manual

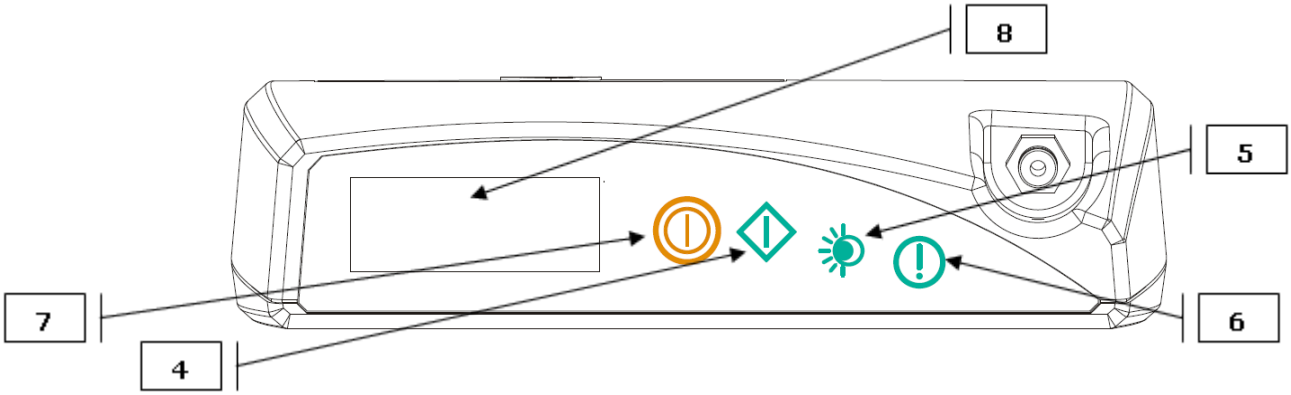
5.4.1. General overview

Rear view:



1. cuff tube / air connector
2. Battery compartment
3. Bluetooth interface (not visible)

Top view:



4. Start Key
5. Day/Night Key
6. Event Key
7. ON/OFF Key
8. LCD Display

5.4.2. Keys

ON/OFF 

This key switches the Walk200b recorder on and off. To prevent switching it on or off by mistake, the key reacts only after 2 seconds. As with all other keys blood pressure measurement can also interrupted prematurely, causing the pressure in the cuff to be released rapidity. Warning: switch the unit on again to continue.

Start 

You have to press the start button to begin a 24 hours measurement session, and to perform a measurement outside of measuring cycles previously indicated. **Attention:** The physician must verify the reliability of the values of the first measurement, so that we can continue with successive measurements correct, and the proper positioning of the cuff. In the event of an error, follow the directions in the paragraph "preparation for the measurement and search of errors". When you press the START button, on the display appears the number of measurements recorded up to that moment, and start the manual measurement. During the first measurement the cuff will inflate gradually. Once the necessary pressure in the cuff for the measurement of the systolic blood pressure value has been determined, that value will be stored and will be reached automatically in the subsequent automatic measurements. The patient can use the START button to record an additional manual measurement outside of the recording protocol.

Night and day 

This key allows waking and sleeping phases differentiated when recording, wich is important from the point of view of statistical evaluation and graphic presentation. Briefly: the patient is instructed to operate the DAY/NIGHT Key on going to bed and again when getting up in the morning. This adjusts the monitoring interval to suit the individual patient and helps you in assessing the BP profile. As well as adjusting the interval, the appropriate notes are shown on the printout. If this key is not operated, the change in interval will take place according to the protocol selected

Event Marker 

This key allows the patient to record the time at which medication in taken or any events happen that may cause blood pressure to rise or fall.
Pressing this key directly triggers a measurement. The patient should note the reason for pressing the Event Key in the event diary.

5.4.3. Display

The LCD display is located on the front of the recorder housing. It displays useful information for the doctor and patient on measurement data, monitor settings and measurement errors.

5.4.4. Acoustic signals

The acoustic signals used consist of single or multiple beeps.
The following signals are emitted:

- 1 beep: Switching on or off, start and completion of a measurement (except for night intervals), removal of interface cable, end of IR communication, set-up and end of Bluetooth communication, and measuring error
- 3 beep: system error
- Continuous beep: Serious system error (e.g. cuff pressure is greater than 15 mmHg for more than 10 seconds outside of a measurement)
- Combined beeps: When deleting measurements manually, first one beep is emitted and 2 seconds later 5 beeps

5.4.5. Cuff connection

The cuff connection is fitted on the front of the recorder housing. This metal plug is used to connect the recorder with the cuff via the cuff tube and the metal cuff socket.

NOTE: Both the doctor and the patient should be aware that the metal plug (air connector) must always engage with an audible "click". Otherwise there will be a leaky connection between recorder and the tube that will produce incorrect measurements.

6. EXECUTION OF AN EXAM

6.1. Initial startup

- Connect the cuff tube with one of the cuffs supplied (according to instructions in par. 6.3), by pushing it onto the plastic connector.
- Connect the cuff tube with the socket on the front of the recorder housing.
- First check that the batteries have been inserted correctly. You should always use fully charged batteries for a new monitoring session. Alternatively, you can use alkaline batteries. Take care to insert the batteries the right way round.

NOTE: Use only the Ni-Mh rechargeable batteries with minimum capacity of 1500 mAh and maximum capacity of 2450 mAh (AA) or alkaline batteries 1,5 V (AA). Other types of batteries with higher capacity o lithium ones MUST NOT be used.

NOTE: It is recommended that the rechargeable Ni-Mh batteries be charged and discharged a few times before using them with the device..

6.2. Preparation for use

6.2.1. Switching on

Always check the condition of your recorder first, before you give it to a patient. You can do this by observing the initial displays shown on the recorder shortly after switching it on.
Press the ON/OFF key and look at the following sequence of displays should appear:

- Battery status (Volts): for Ni-Mh rechargeable batteries min. 2.75; for alkaline batteries min. 3.10
- Display segment test: 999:999 to 000:000; Along with the numbers, all the other LCD symbols are shown. Check whether all segments are being shown correctly and completely (the complete code is constantly being checked for correctness in the background)
- Current 24 hour time : Example: 12:55

If a fault occurs during the internal test, the recorder shows E004 on the display and emits an acoustic signal. For safety reasons, use of the recorder is blocked. Return the recorder to your specialist dealer or directly to Cardioline.

6.2.2. Clearing memory

The memory must be cleared before each monitoring session, i.e. no blood pressure data from the previous patient must be left in the memory. However, should values still be present, you can delete them with the delete function of the analysis software.
You can clear the memory manually, by holding the START key for more than 5 seconds. A number will appear in the display indicating the number of measurements present in the memory (after the prompt clr). To confirm that you want to erase the memory press and hold the event key (within 5 seconds after the prompt clr). The following prompt 000 in the display confirms that the memory has been erased.

6.2.3. Setting the time/date

The Walk200b has an internal buffer battery that allows the clock to continue running even after the batteries have been removed. You should nevertheless check the time and date before each measurement series.
The time and date can be set with the CUBE analysis software. You can also set the time and date manually by holding the START key and then pressing the EVENT key. Now you are in the "Set time" mode. Use the START key to change the number in question, and use the EVENT key to jump to the next.

6.2.4. Inserting patient data (ID)

The recorder must be prepared inserting the patient data (ID), so that measurements are allocated correctly when reading out.
Patient data can be transmitted to the recorder using one of the compatible Cardioline software (Cubeabpm, webuploader or Device Web Manager). Please refer to the user manual of these software for more instructions.

6.2.5. Setting the measurement protocol

The protocols can be set using the Cubeabpm software
Each interval is configurable with measurements from 5, 10, 15, 20, 25, 30, 40, 50, 60, 90 and 120 minutes.
By scheduling an interval of automatic measurements every 5 minutes (minimum interval) for both day and night, in 24h you will have the opportunity to make N. 288 measurements.
In addition to the programmed automatic measurements, pressing the Event Marker button will allow you to start additional manual measurements to the preset duty cycle until a maximum of 300 measurements are reached in total.

You can also set the protocols manually by pressing the DAY/NIGHT button and then pressing the EVENT button. Use the START button to change protocol, and then confirm with the EVENT button.

Protocol	Interval	Measurements per hours	Acoustic signal	Measurements shown on display
1	08:00 ÷ 23:59	4	YES	YES
	00:00 ÷ 07:59	2	NO	
2	08:00 ÷ 22:59	4	YES	YES

Protocol	Interval	Measurements per hours	Acoustic signal	Measurements shown on display
	23:00 ÷ 07:59	1	NO	
3	07:00 ÷ 21:59	4	YES	NO
	22:00 ÷ 06:59	2	NO	
4	08:00 ÷ 23:59	4	YES	NO
	00:00 ÷ 07:59	2	NO	
5	18:00 ÷ 09:59	4	YES	YES
	10:00 ÷ 17:59	2	NO	
6	07:00 ÷ 23:59	4	YES	YES
	00:00 ÷ 06:59	2	NO	
7	06:00 ÷ 22:59	4	YES	NO
	23:00 ÷ 05:59	2	NO	
8	07:00 ÷ 09:00	6	YES	YES
	08:59 ÷ 23:59	4	YES	
	00:00 ÷ 06:59	2	NO	
9	09:00 ÷ 08:59	30	NO	YES
10 telemedicine	08:00 ÷ 07:59	30	YES	NO

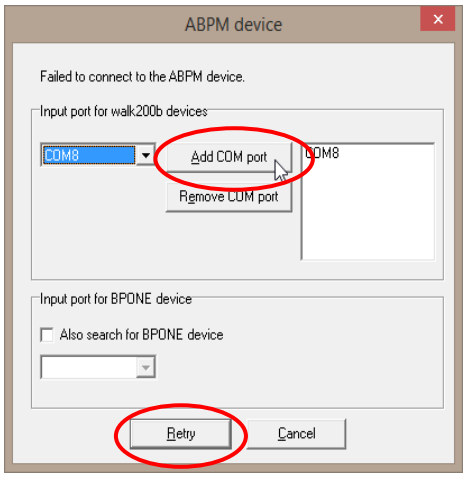
NOTE: protocols 1,2 and 10 are set as standard, but can be changed. Protocol 5 is suitable for night time activity (night shift). Protocol 9 is the Schellong-test.

6.2.6 Activation of the connection with the PC

Setting patient data or the measurement protocol via software, as indicated in the previous paragraphs, requires the Walk200b to be connected to the computer on which the software is installed.

If the device is equipped with a **USB connection**:

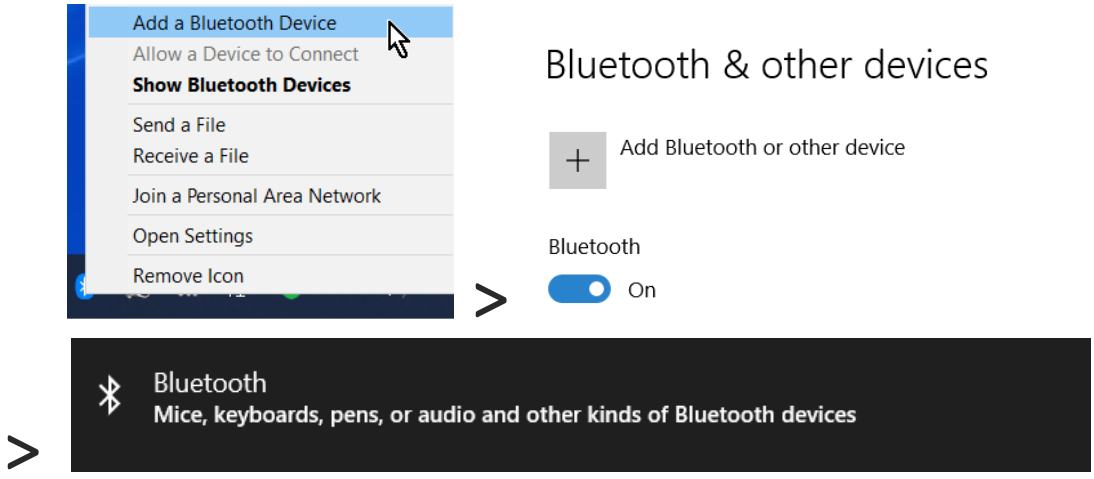
- Open the recorder's battery door and put in the batteries, then close the door;
- Connect the device to the PC using the supplied USB cable, make a note of which COM port has been assigned to the USB cable by opening the "Device Manager" in the Ports section (COM and LPT)
- Press the key ⏻ to turn on the recorder, wait for CO to appear on the screen
- When prompted, select the outgoing COM port from the drop-down menu and press the Add COM port button;
- Press the **Retry** button;



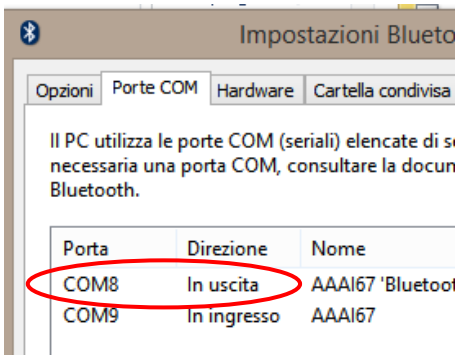
NOTES: Once programmed via USB, any button on the recorder must be pressed to exit PC connection mode.

If the device is equipped with a **Bluetooth connection**:

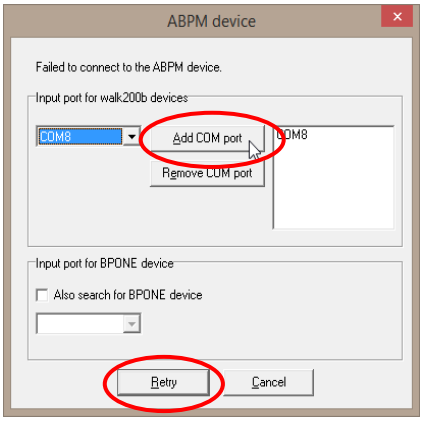
- Open the recorder's battery door and put in the batteries, then close the door;
- Press the key to turn on the recorder, wait for the clock to appear on the screen;
- Press the key for 5 seconds to activate the Bluetooth connection, BT should appear on the screen;
- On first activation, you must carry out the pairing procedure;
- On the PC, click on the Bluetooth icon and select *Add new Bluetooth device > Add Bluetooth or other type of device > Bluetooth > Select the walk200b serial number*; if asked, use the pairing code **6624**.



- Wait until Windows has finished the installation, then click again on *Other Bluetooth options and COM ports*;
- Note down the output COM port and serial number;

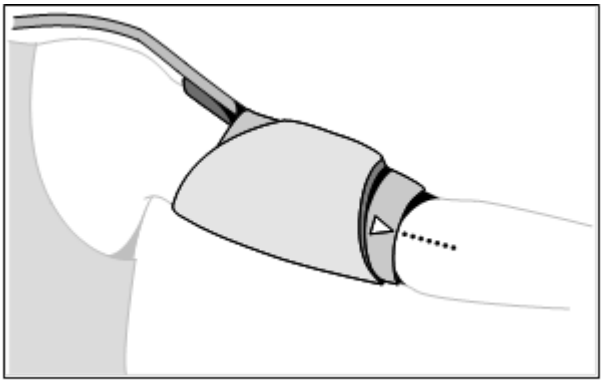


- When asked, select the output COM port from the drop-down menu and press the key *Add COM port*;
- Press the **Retry** key;



6.3. Putting on the recorder

Put the equipment pouch on the patient. By varying the length of the strap you can use it either as a hip belt or a shoulder strap. Alternatively, use a normal belt that matches the patient's clothing.
Now fit the cuff on the patient; correct cuff fit is extremely important for accurate measurement (see figure beloe). The cuff can also be worn over the shirt or blouse. We recommend that the cuff be fitted on the bare upper arm. In this case, bring the tube out between the buttons of the shirt or blouse, around the back of the neck to the ABP monitor on the right-hand side.



Placing the cuff

Please note the following points:

1. When putting the recorder on the patient, the recorder must not be connected to other external equipment.
2. The cuff must fit so that the air tube cannot be kinked or compressed at any point. The tube connection on the cuff should therefore be directed upwards. The air tube should allow free movement of the upper arm and should run over the back of the neck to the other side of the body.
3. It is essential to ensure that the artery symbol lies over the brachial artery. When the cuff fits correctly, the metal strip is on the outer side of the upper arm (elbow side).
4. The material loop must cover the skin under the metal strip.
5. The lower edge of the cuff should be about 2 cm above the bend of the patient's elbow.
6. The cuff should fit relatively snugly on the upper arm. Correct fit can be checked by a simple test: there should be room to slip one finger under the cuff.
7. The correct cuff size is also important if blood pressure is to be measured correctly.
8. To obtain reproducible results, standardised monitoring conditions are required, so the cuff must be the correct size for the patient. Using the tape measure supplied, measure the circumference at the middle of the upper arm and select the appropriate cuff:

Upper arm circumference	cuff
14-20 cm	XS
20 - 24 cm	S
24 - 32 cm	M
32 - 38 cm	L
38 - 55 cm	XL

9. Connect the air tube from the cuff to the ABP recorder.
10. Push the tube firmly over the connection until a click is heard as it engages; to disconnect, simply pull back the outer metal ring on the plug.
11. The recorder is now correctly fitted and ready for use.

NOTE: The bag and the Walk 200b Waterproof case, mentioned in paragraph 8.2, are not intended to come into direct contact with the body. It is therefore recommended to place them over a piece of clothing (e.g. a T shirt).

6.4. Starting measurements

Once all these steps have been completed, the monitor can be started. First, a manual measurement must be carried out by pressing the START key.
This measurement is used to determine whether the recorder is working correctly.
If errors occur, check once more that the procedure followed in setting up and fitting the equipment was correct. Should this not solve the problem, repeat the setting-up procedure.
Only after a successful manual measurement the patient can be allowed to leave with the equipment.

6.5. Interrupting measurements

During a measurement, any key can be used to interrupt the measurement.
The display then shows “-STOP-” and beeps 5 times.
The process is also saved in the table of measurements under “Interruption”.

6.6. Download of the recordings

At the end of the measurement the recordings can be downloaded from the recorder using one of the compatible Cardioline software (Cubeabpm, webuploader or Device Web Manager). Please refer to the user manual of these software for more instructions.

7. MAINTENANCE AND TROUBLESHOOTING

7.1. Principal sources of error

The following may cause faulty measurements or undesired results:

- Arm movement by the patient during the measurement
- Switching off the device (e.g. at night)
- Incorrect cuff size fitted
- Slipping of the cuff in use
- Absence of successful manual measurement at the surgery
- Failure to take medication
- Incorrect protocol set by the user
- Batteries not fully or correctly charged, or worn out
- Defect in the charging unit

In case of failed measurement, Walk200b will automatically start an additional measurement after 3 minutes from the previous failed one.

7.2. Cleaning of the recorder

Cleaning operations must be performed by medical staff.
Don't sterilize the device.
To clean and disinfect the equipment surface, use a sterilizing detergent solution as generally used in hospitals, with low alcohol content. The unit surface may be cleaned with a wet tissue, but the liquid must never infiltrate the equipment.
Wash the electrodes with water and/or use only cool sterilization.
NOTE: *remove the battery before the cleaning.*

7.3. Cleaning of cuffs

Cleaning operations must be performed by medical staff.
The cuffs are reusable for an unlimited period of time.
Before washing, remove the air cushion. Take care not to kink the air cushion in the covering cloth after replacement. Wash the covering cloth with warm water(~30°C) using a mild washing powder (do not spin).
Do not use fabric softeners or other aids (disinfectant rinses or textile deodorants), these solutions may leave residues and damage the materials.
The cuff sleeve is not suitable for drying in a tumble dryer.

Wash the bladder only with warm water, adding a mild cleaning solution if necessary and wipe off. Take care to ensure that no water enters the tube opening.
When using other disinfectants not recommended by IEM, the user is responsible for proving harmless application. Never use disinfectants that leave a residue on the product or which are unsuitable for use in contact with skin.

7.4. Display maintenance

Keep the display dry avoiding the formation of condensation. Failure to respect these strategies may result in the loss of liquid crystals. To clean the display surface, use a soft cloth. The use of cloths that are too rough may scratch it. Do not use solvent-based chemical products.
Warning: if the display panel breaks, do not swallow the liquid that comes out. In case of contact with the skin or clothing, immediately wash them using plenty of soap and water.
Abnormalities in the display of fonts may be caused by heavy pressure during use. Normal functioning will be re-established.

7.5. Periodic checks

Cuffs and tubes control when necessary and at least once a year.
General check of the functionality of the instrument and of the leakage current: when necessary or at least every 2 years. Check the calibration every other year.

Check the printout carefully for:

- Correctly entered times and intervals in accordance with the protocol
- Times of day/night changeovers
- Correctness of standard values (nocturnal reduction)
- Battery voltage

7.5.1. Checking the battery voltage:

The fully charged batteries are installed in the monitor directly from the charging unit. The battery voltage is shown in the LCD display of the Walk200b monitor shortly after switching on the device, for approx. 3 sec. This voltage should be at least 2.75 V to guarantee measurement over 24 hours.

7.5.2 Calibration

The device has been calibrated by the manufacturer; a label inside the battery compartment shows the calibration's expiry date.
It is recommended to check the calibration regularly - at least once every other year. The calibration may be verified by Cardioline or by any authorised service centre.

Calibration expiry label

7.6. How to change the batteries

The batteries, 2 AA ultra alkaline or rechargeable NiMh (at least 1500mAh), should be substituted if the special indicator on the display shows a charge of less than 2,75%.
Rechargeable batteries are subject to aging. In case the rechargeable batteries are damaged or is no longer possible to make measurements for the 24 hours with it, they must be replaced immediately. Ni-Mh rechargeable batteries last longer if they are discharged completely before a new recharging. Batteries run depending on the temperature. It is suggested to leave the rechargeable batteries into its charger until they need to be used.

WARNING: Before removing or inserting the batteries from the recorder ensure that the same is turned off and that the patient is disconnected.

- *Open the battery compartment door.*
- *Insert the batteries placing their polarities in the correct position.*
- *Close the battery compartment door.*

WARNING: The insertion of batteries with incorrect polarities means that the device will not work.
WARNING: do not dispose of the substituted batteries in the environment.
WARNING: do not use battery types that are different from each other in terms of technology and specifications.
WARNING: remove the batteries from the unit if it will be out of use for a long time.
NOTE: Removal of the batteries does not mean the loss of data.

7.7. Troubleshooting table

Problem	Cause	Solution
After replacing batteries, the clock still	The internal buffer battery is exhausted.	The date and time can be set after each change of batteries.

shows 00.00 and the date 01.01.xxxx	The biennial calibration has not been performed. The buffer battery is changed at the metrological check.	Send the device for calibration to your dealer or directly to Cardioline SpA
The measurement data can no longer be called up or displayed.	An error has occurred during saving of patient data.	Delete the patient concerned (menu bar) and re-enter.
The connection from the Walk200b to the PC is faulty.	1. The incorrect COM interface is set. 2. Walk200b is not in transfer mode (the time is shown on the display).	1. Set the correct interface in the utilities program 2. Switch the Walk200b off and then on again, without removing the connector cable.
The patient ID number is missing.	The monitor is not initialised, the patient ID number has not been transmitted during preparation for a 24-hour monitoring session.	The patient ID number can still be transferred after the measurement. The data obtained will not be affected.
No measurements were carried out during the night phase.	1. The batteries were drained prematurely. 2. The patient switched off the Walk200b	1. The rechargeable batteries may be defective (please contact your dealer). 2. Alert the patient to the urgency of obtaining a complete 24-hour recording
The message bt does not appear on the display.	You are not in transfer mode	Press and hold Event button again, till to see bt on the screen.
No automatic measurements are performed.	1. No manual measurement was performed after putting on the equipment. 2. Incorrect protocol set	1. After putting on the equipment a successful measurement must always be performed manually 2. Set protocol 1 or 2
The measurement interval is not as you expected.	1. Incorrect protocol set 2. No manual measurement was performed after putting on the equipment.	1. The programmed protocol is not the protocol set in the Walk200b. Check the protocol manually 2. Perform a manual measurement to activate the set protocol.
Err 1	1. The patient has severe arrhythmia 2. The arm was moved during the measurement 3. Not enough valid heartbeats detected	1. Monitor not applicable 2. Keep the arm still during measurement 3. Re-fit the cuff
Err 2	1. The arm was moved during the measurement 2. Cuff not fitted correctly on the arm	1. Keep the arm still during measurement 2. Check the fit of the cuff and monitor
Err 3	1.Blood pressure outside measurement range 2. Severe arm movement 3. Problems with pneumatics	1. If this message continues, the monitor is not suitable for the patient 2. Keep the arm still during measurement

		3. If this error continues, send the unit to dealer or directly to Cardioline SpA
Err 5 bAtt	1. Battery voltage too low 2. Betteries defective 3. Battery contacts are corroded	1. Replace the batteries 2. The battery voltage is correct but during cuff inflation bAtt is shown on display. Replace the batteries 3. Clean the battery contacts with a cotton cloth and some alcohol
Err 6 + Possible continuous alarm until a key is pressed	1. Air tube blocked 2. Blood pressure cuff is not correctly connected 3. Leak in cuff or connecting tube	1. Check the cuff for a blockage or kink in the tube. If there is a kink in the cuff tube, release the tube. Otherwise send the equipment for repair without delay to Cardioline SpA 2. Connect the cuff with the device 3. If necessary, replace the cuff or connecting tube
Err 7	The recorder memory is full (maximum 300 measurements and events may be stored)	Delete data from the monitor, but make sure that the data has been saved
Err 8	Measurement interrupted by pressing a key	
Err 9 + Possible continuous alarm until a key is pressed	1. Pressure remains in the cuff 2. Zero-point adjustment could not be performed successfully	1. Wait for the cuff to deflate completely 2. Send the unit without delay to your dealer or directly to Cardioline SpA for checking
Err 10 + continuous alarm until a key is pressed	1.Serious fault due to pressure build-up outside the measurement process (pump has switched on illegally) 2. these error messages all indicate a serious error in the program code	Send the unit without delay to your dealer or directly to Cardioline SpA for checking and repair
Walk200b takes measurements every two minutes	Protocol 9 has been set in the Walk200b	Set protocol 1 or 2
The required protocol cannot be set by pressing key combinations	Measurements from the last patient are still in the memory	
The monitor cannot be switched on	1. The batteries were installed incorrectly 2. The battery voltage is too low 3. Display difettive	1. insert both batteries again and check for correct polarity 2. Replace the batteries 3. Send the unit without delay to your dealer or directly to Cardioline SpA
A fault occurs during the first measurement	The cuff does not fit the upper arm of the patient	Using the tape measure supplied, measure the arm circumference and compare it with the printing on the cuff

Code 1	Walk200b Bluetooth interface has not started up correctly. Possible hardware error.	Send the unit without delay to your dealer or directly to Cardioline SpA
Code 2	Walk200b Bluetooth interface could not be configured correctly. (Communication problem between Walk200b and Bluetooth module)	Try again. If the error continues, send the unit to your dealer or directly to Cardioline SpA for checking
Code 3	The status of Walk200b Bluetooth interface could not be ascertained (Communication problem between Walk200b and Bluetooth module)	Try again. If the error continues, send the unit to your dealer or directly to Cardioline SpA for checking
Code 4	Walk200b Bluetooth interface is not yet paired with the Bluetooth dongle	Follow the steps described in “cube installation guide” (see § “Device configuration”)
Code 5	Walk200b Bluetooth interface could not connect to the computer’s Bluetooth dongle.	Try again. If the error continues, send the unit to your dealer or directly to Cardioline SpA for checking

8. TECHNICAL SPECIFICATIONS

Pressure measurement range.....	Systolic: 60 to 290 mmHg Dyastolic: 30 to 195 mmHg
Accuracy.....	± 3 mmHg in the range indicated
Static pressure range	0 to 300 mmHg
Pulse range	30 to 240 beats per minutes
Method.....	oscillometric
Measurement intervals	5, 10, 15, 20, 25, 30, 40, 50, 60, 90 and 120 minutes
Monitoring protocol.....	2 modifiable interval groups
Storage capacity.....	300 measurements or 48 hours
Battery capacity	> 300 measurements
Interfaces.....	Bluetooth (Class 1 / 100 m) and USB
Power supply	2 Ni-MH batteries each 1,2 V, 1500 mAh min and max 2450 mAh (AA) or 2 alkaline 1,5 V batteries(AA, Mignon)
Dimensions	128 x 75 x 30 mm
Weight.....	approx 240 g including batteries
Altitude.....	Up to 3000 meter above sea level

8.1. Harmonised standards applied

STANDARD	DESCRIPTION
EN 15223-1	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
EN 1041	Information supplied by the manufacturer of medical devices
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971	Medical devices - Application of risk management to medical devices

STANDARD	DESCRIPTION
EN 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6	Medical electrical equipment - Part 1: General safety requirements - Collateral standard: Usability
EN 60601-1-11	Electromedical devices - General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
IEC 80601-2-30	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
EN 62304	Medical device software - Software life cycle processes
EN 62366	Medical devices - Application of usability engineering to medical devices

8.2. Accessories

CODE	DESCRIPTION
01020009	Large cuff for Walk200b
01020008	Standard cuff for Walk200b
01020007	Small cuff for Walk200b
01020006	Extra small cuff for Walk200b
01020010	Extralarge cuff for Walk200b
69400074	Under-cuff band
65090070	Pouch
63090733	Walk200b waterproof case (waterproof bag)

9. WARRANTY

Cardioline SpA guarantees this equipment to be free of defects in material and workmanship for 24 months from date of purchase of the device and for 3 months for spare parts and accessories. The date of purchase shall be proven by a document, issued upon delivery, which shall be submitted in the case of any claim under the warranty.
The warranty provides for free-of-charge repairing or replacement of the equipment parts with manufacturing or material defects. The possible replacement of the equipment is at the manufacturer's discretion. Extended warranty after repairing is not available.
This warranty does not cover defects resulting from:

- tampering, third party negligence, including servicing or maintenance by unauthorised personnel;
- failure to comply with the usage instructions, improper use or use of the equipment different than that for which it was intended;
- improper operation of the power supplies;
- damages caused by fires, explosions or natural disasters;
- use of non-original consumable parts;
- transportation carried out without any precautionary measures;
- use of software programs not associated with the primary function of the machine;
- other circumstances not attributable to manufacturing defects.

Unless otherwise specified, the removable parts, the accessories and the parts which are subject to normal wear are excluded under the warranty; for example: patient cables, batteries, connection cables, electrodes, glass parts, computer supports, ink cartridges, etc.
Cardioline Spa declines all liability for any damage which may be caused, directly or indirectly, to persons or property as a consequence of non-compliance with all the prescriptions specified in the manual, especially warnings regarding installation, safety, use and maintenance of the equipment, as well as non-operation of the equipment.
In the event of repair and/or replacement of the equipment or its spare parts, take the equipment to the nearest Cardioline Spa authorised service centre or send it to Cardioline S.p.A. All costs of material and labour will be free of charge and transport costs shall be at the customer's expense.
After 24 months from the date of purchase of the equipment and 3 months from the date of purchase of the accessories and spare parts, the warranty becomes void and service will be provided charging for the parts replaced and labour costs according to the current rates.
Any derogation from the present warranty conditions shall be valid only if expressly approved by Cardioline SpA.

10. DISPOSAL

Pursuant to Italian Legislative Decree no. 49 dated 14 March 2014 "Implementation of Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE)", the crossed-out "wheeled bin" symbol on the medical device indicates that, at the end of its service life, the product must be collected separately from other wastes. Therefore, when disposing of the product at the end of its service life, the user is required to contact the supplier or the manufacturer.
Suitable differentiated collection to allow for the subsequent recycling of the decommissioned device, with environmentally-compatible treatment and disposal, helps to prevent any negative effects on the environment and health and to promote the recycling of the materials from which the device is made.
The illegal disposal of the product by the user entails the application of administrative sanctions envisioned by Italian Legislative Decree no. 22/1997 (Art. 50 and subsequent to the Italian Legislative Decree no. 22/1997).

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