

# CARDIOLINE

## Walk400h/Clickholter

### Operating manual



**CE**  
1936

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# CARDIOLINE

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Cardioline SpA  
Via Linz, 151  
38121 Trento  
Italy

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## 1. GENERAL INFORMATION

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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. Important additional information

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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 proceed to 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.

All trademarks mentioned in this document are property of their respective owners. Their protection is guaranteed.

No part of this manual may be reprinted, translated or reproduced without the manufacturer's written authorisation.

The code relating to this manual is provided below.

Language	Code
ENGLISH	36510214_EN

This manual refers to the software version 1.0.

## 2. SAFETY INFORMATION

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

1. the assembly operations, modifications or repairs are carried out by Cardioline SpA or by its Authorised Service Centre;
2. 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.
- No device modification is permitted.
- The device captures and displays the data that reflect 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.
- For the correct operation of the device and for the safety of the operators, patients and bystanders, the device and the accessories must be exclusively connected as outlined in this manual.
- The safety of the patient and operator is guaranteed if the accessories that may come into direct contact with the patient comply with standards IEC 60601-1 and IEC 60601-2-25. Only use spare parts and accessories supplied with the device and available from Cardioline SpA. Refer to paragraph 10.2 for a list of approved accessories.
- The enclosure of the device is classified as “CF-Type Applied Part” in compliance with par. 4.6 of IEC standard 60601-1. Applied part refers to the patient cable and the electrodes.
- Conductive parts of the patient cable, electrodes and associated connections, including the neutral conductor of the patient cable and electrode, must not come into contact with other conductive parts, including ground lead.
- The device has no specific protection from defibrillation discharges. Consequently, should a defibrillator need to be used, the device must be disconnected from the patient, for instance by removing the patient cable from the electrodes before defibrillation.

- This device is designed to be used only with the electrodes specified in this manual. Strictly follow the correct clinical procedures to prepare the skin before the application of the electrodes and monitor the patient in order to avoid any irritation, inflammation or other skin reactions. The electrodes are designed for short-term applications and must be promptly removed once the test is complete. Refer to paragraph 10.2 for a list of approved accessories.
- The ECG electrodes may cause skin irritation; check the skin for any irritations or inflammations.
- To prevent any infections, use the disposable components (e.g. the electrodes) only once. To ensure safety and use efficiency, do not use electrodes after their expiration date.
- The quality of the signal may be adversely affected by the use of other medical equipment such as defibrillators and ultrasound machines.
- The device is intended for external use and is not intended for direct cardiac application.
- 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.
- 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 enclosure of the device is not protected against ingress of liquids. Devices affected by liquid seepage must be cleaned as soon as possible and must be inspected by an authorised Service Centre.
- Do not clean the device or the patient cables 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 patient cable with ethylene oxide gas (EO). Refer to Section 9 for instructions on proper cleaning and disinfection.
- Do not leave the patient cable unattended if children are present as they might get accidentally strangled.
- Do not leave the electrodes unattended in the presence of children as they could cause suffocation if accidentally swallowed.
- The device is not intended to be used in a humid environment; never expose the device to extreme temperature and do not leave it in dusty, brackish or humid premises.
- The Walk400h device has been designed to be connected to a PC only if it has already been disconnected from the patient.
- Use of the protection bag is mandatory if the relative humidity of the environment is less than 50% (dry environment) to prevent the formation of electrostatic charges.



- The device can be used with the pouch or with the Walk400h waterproof case indicated in par. 10.2. The cases are not intended to come into direct contact with the body, therefore it is recommended to place them over a garment (for example a shirt).



### Attention

- The device and the patient cable should be cleaned before use. Check the connections for any damage or excessive wear before each use. Replace the patient cable should it present any damage or be excessively worn.
- Do not pull or stretch patient cables as this could result in mechanical and/or electrical failures. Patient cables should be stored after forming them into a loose loop.
- Electrodes and patient cable might loosen or detach during use, affecting signal quality. Instruct the patient on the operations to be performed in that case.
- 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/repared by qualified service personnel before being reused.
- The device does not require any calibration or special instrumentation for correct use and maintenance.
- When it is required to dispose of the device, its components and accessories (e.g.: batteries, cables, electrodes etc.) and/or packaging material, comply with local waste disposal regulations.
- The device uses standard batteries, that need to be replaced by the user. Disconnect the patient cable from the recorder, keeping the electrodes connected to the patient, before opening the battery compartment panel.
- In case of use of Lithium batteries they must comply with IEC 80086-4.
- In the event of prolonged inactivity, remove the batteries from the device.
- If the signal is quite noisy, the device could disable detection of the pacemaker pulses.

### Notes

- The movements of the patient may generate excessive noise and affect the quality of the signal and correct analysis of the device.
- An appropriate preparation of the patient is important in order to guarantee a proper application of the ECG electrodes and the correct operation of the device.
- There is no known safety hazard if other equipment, such as pacemakers or other stimulators, is used simultaneously with the device; however, disturbances to the signal may occur.
- If the electrodes are not properly connected to the patient, or one or more patient leads are damaged, the display will indicate a lead failure.
- As defined by the IEC 60601-1 and IEC 60601-2-47 safety standards, the device is classified as follows:
  - Equipment with IP protection rating (ME Internal power supply).

- CF-type applied parts.
- Ordinary equipment.
- Not suitable for use in the presence of flammable anaesthetics.
- Continuous operation
- The accuracy of signals recorded with the device complies with IEC standard 60601-2-47.
- Walk400h is capable of recording the activity of an implanted pacemaker, but may not always detect pacemaker spike less than 1 ms.
- The device belongs to Class IIa in compliance with Directive 93/42/EEC.
- The device has IP 4x protection rating against the ingress of solid particles and water. It is therefore protected against solid particles with diameter greater than 2.5 mm. The Walk400h Waterproof case (see par. 10.2) has a degree of protection against the intrusion of solid particles and the ingress of water equal to IP X2, therefore it protects the device from falling drops of water with a maximum inclination of 15 ° when used with the device itself. Without the Walk400h Waterproof case, the device has no protection against the penetration of liquids..
- The Walk400h Waterproof case is necessary for use in the home healthcare environment.
- The device's useful service life is 5 years.
- 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..... -25° C ÷ 70° C  
 Relative humidity..... 5% ÷ 95%  
 Atmospheric pressure..... 500 ÷1060 mbar

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

Ambient temperature..... 5° C ÷ 40° C  
 Relative humidity..... 50% ÷ 95% - without the bag  
 15% ÷ 95% - with the bag  
 Atmospheric pressure..... 500 ÷1060 mbar

**NOTE:** Use of the protection bag is mandatory if the relative humidity of the environment is less than 50% (dry environment) to prevent the formation of electrostatic charges.

## 2.1. Recommendations for the patient during the test

---

The device has been designed for performing outpatient ECG tests (Holter) normally lasting 24 or 48 hours. The Walk400h/Clickholter model is able to perform multiple recordings up to 7 days in total.

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 about the operations he is allowed to perform and the related risks.

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

- The device must be worn for the whole duration of the test;
- If the device is used inside the bag, it should never be removed;
- The device is not protected against the ingress of liquids, unless it's used inside the Walk400h Waterproof case (see par. 10.2), thus it shouldn't be wet;;
- The device emits a beep to signal particular events, such as the depletion of the battery, in this case contact the referring physician or ambulatory for instructions;
- If the patient cable accidentally disconnects contact the referring physician or ambulatory for instructions;
- The device may be damaged in case of blows or falls, which might jeopardise its correct operation and completion of the scheduled tests;
- Inform the patient that patient cables and electrodes must be kept away from children, due to the risk of suffocation and strangulation

**NOTE:** *if the device is used according to the present manual and a new and adequate battery is used for each test, the patient doesn't have to replace the battery, as its duration is compliant with tests duration.*

### 3. ELECTROMAGNETIC COMPATIBILITY (EMC)

The device requires special precautions with regards to Electromagnetic Compatibility. The device must therefore be installed and started up in compliance with the information on Electromagnetic Compatibility contained in this manual.

Portable and mobile radio communication equipment may affect operation of the device.

The use of accessories, transducers or cables other than specified in paragraph 10.2 may increase emissions or decrease appliance immunity.



#### Warnings

- The device is intended to be used exclusively by professional healthcare personnel. The device can generate radio-electric interference and disturb operation of equipment in the vicinity. It could be therefore 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 placed close to or above other equipment. If necessary, check that the device works according to standard procedures.

Electromagnetic compatibility during the use of the device is required with the surrounding devices.

An electronic device can generate or receive electromagnetic interferences. 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. 3.4 for the recommended separation distance between the radio equipment and the device.

#### 3.1. Guidance and manufacturer's declaration – Electromagnetic emissions

The Walk400h/Clickholter system is intended for use in the electromagnetic environment specified below. The customer or user of the Walk400h/Clickholter must ensure the device is used in such as environment.

Emission test	Conformity	Electromagnetic environment – guidelines
Radio frequency emissions (RF) CISPR 11	Group 1	The Walk400h/Clickholter device only uses radiofrequency energy for its internal functions. Radiofrequency emissions are therefore very low and unlikely to interfere with electronic equipment in the vicinity.

Radio frequency emissions (RF) CISPR 11	Class B	The Walk400h/Clickholter device is suitable for use in all environments, including residential premises and those directly connected to the public mains voltage supplied for household use.
Harmonics emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

### 3.2. Guidance and manufacturer's declaration – Electromagnetic immunity


The Walk400h/Clickholter system is intended for use in the electromagnetic environment specified below. The customer or user of the Walk400h/Clickholter must ensure the device is used in such as environment.

Immunity test	Conformity	Compliance level	Electromagnetic Environmental Information
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact discharge +/- 8 kV air discharge	+/- 6 kV contact discharge +/- 8 kV air discharge	Floors should be wood, concrete or ceramic tile. If 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	Not applicable	The device works with internal battery.
Transient surge IEC 61000-4-5	+/- 1 kV from line to line +/- 2 kV from line to ground	Not applicable	The device works with internal battery.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% $U_T$ (>95% dip in $U_T$ ) for 0.5 cycles  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 works with internal battery and has been designed for continuing 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.

### 3.3. Guidance and manufacturer's declaration – Electromagnetic immunity

The Walk400h/Clickholter system is intended for use in the electromagnetic environment specified below. The customer or user of the Walk400h/Clickholter must ensure the device is used in such as 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	<p>Portable and mobile RF communication equipment should be used no closer than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance:</b></p> $d = \left[ \frac{3.5}{3V_{rms}} \right] \sqrt{P}$ $d = \left[ \frac{3.5}{3V/m} \right] \sqrt{P} \quad \text{From 80 MHz to 800 MHz}$ $d = \left[ \frac{7}{3V/m} \right] \sqrt{P} \quad \text{From 800 MHz to 2.5 GHz}$ <p>where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the specifications supplied by the transmitter's manufacturer and <math>d</math> is the recommended separation distance in metres (m).</p> <p>Field strengths of fixed RF transmitters, as determined by an electromagnetic site survey (a), should be less than the conformity level in each frequency range (b). Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
Radiated R IEC 61000-4-3	3 V/m From 80 MHz to 2.5 GHz	3 V/m	

**NOTE 1:** The highest frequency range is applied at 80 MHz and 800 MHz.

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

a) Field strengths from fixed transmitters, such as wireless telephony base stations (mobile or cordless phones) and land mobile radios, amateur radio, AM and FM radio transmitters and TV transmitters 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 where the Walk400h/Clickholter device is used exceeds the RF compatibility level above, the device should be monitored to ensure it operates normally. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Walk400h/Clickholter device.

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

### 3.4. Recommended separation distances between portable and mobile RF communications equipment and the Walk400h/Clickholter device

The Walk400h/Clickholter device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user may help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications (transmitters) and the Walk400h/Clickholter device, as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of the transmitter (W)	Separation distance according to the frequency of the transmitter (m)		
	from 150 MHz to 800 MHz	from 800 MHz to 2.5 GHz	from 800 MHz to 2.5 GHz
	$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	$d = \left[\frac{7}{E_1}\right]\sqrt{P}$
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 with maximum rated 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 specifications supplied by the transmitter's manufacturer.

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


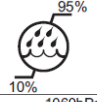





**NOTE 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by the absorption and reflection of structures, objects and people.

## 4. SYMBOLS AND LABEL

### 4.1. Explanation of the symbols

Symbol	Description
	Comply with the instructions in the operating manual – on the back of the device
	CE marking – compliance with the European Union directives
	Manufacturer
	Reference number (product code)
	Serial number
	Lot number
	Year of manufacture
	Type CF equipment
	Device suitable for recording on children weighing less than 10 kg
	Battery powered device
	Keep dry
<b>IP4x</b>	Degree of protection against the ingress of solid particles and water
	Refer to the user instructions
	Separate collection of electrical waste and electronic equipment
	Read the operating instructions – on the back of the device
	Storage and transport temperature limits



	Operating temperature limits
	Humidity fluctuation
	Pressure fluctuation
	Keep away from sunlight
	Do not reuse
	No latex
	No PVC

## 4.2. Device label

Walk400h



Clickholter



## 5. INTRODUCTION

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### 5.1. Purpose of the manual

---

This manual refers to devices Walk400h and Clickholter.

The manual represents a guide for execution of the following operations:

- Reasonable use of the device, of the function keys and of the menu sequences.
- Preparation of the device for use. (Section 6)
- Execution of a test. (Section 7).
- Recorder settings. (Section 8)
- Maintenance and troubleshooting (Section 9).

### 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.

It's responsibility of the physician, or of the authorized personnel that prepares the patient to inform the patient about how to use the device, the operations he is allowed to perform and the related risks (v. par. 2).

### 5.3. Intended use

---

Walk400h/Clickholter is an ECG Holter recorder intended for continuous ECG signal recording. The signal recorded in the devices' internal storage is intended to be transferred to a PC for analysis via a designated ECG Holter analysis software.

The ECG signal is recorded with a patient cable that may have 5, 7 or 10 wires (Walk400h only), according to the number of ECG channels to be recorded: 3 channels with 5 or 7-wire cables and 12 leads with 10-wire cable (Walk400h only). The recorded data are transferred to the PC through a USB connection.

A colour graphic display shows up to 6 channels during preparation of the recorded. This feature allows the physician to check signal quality before starting recording.

The device is indicated for use in a clinical setting: hospitals, clinics and outpatient facilities of any size. It is also suited for home use.

- The device is indicated for continuously recording the ECG signal.
- The device is not indicated for use as physiological monitoring of vital signs.
- The device is not intended as the only means for determining the diagnosis.
- The device is indicated for use on adult and paediatric patients.
- The device is indicated for use by a physician or trained personnel acting on behalf of an authorised physician.

## 5.4. Description of the device

Walk400h is a Holter recorder that makes it possible to capture 3 or 12 leads for 24 or 48 hours at 250/500/1000 samples per second or up to 7 days at 250 samples per second.

Clickholter is a Holter recorder that makes it possible to capture 3 leads for 24 or 48 hours at 250/500/1000 samples per second or up to 7 days at 250 samples per second.

Clickholter is available in two configurations: BASE and PLUS.

Walk400h and Clickholter differ for the following features:

	Clickholter BASE	Clickholter PLUS	Walk400h
<b>PATIENT CABLES</b>	5 wires / 3 channels 7 wires / 3 channels	5 wires / 3 channels 7 wires / 3 channels	5 wires / 3 channels 7 wires / 3 channels 10 wires / 12 leads
<b>RECORDING DURATION</b>	24h/48h	24h/48h/7days	24h/48h/7days
<b>SAMPLING RATE</b>	250 s/s	250 s/s 500 s/s (only 24h and 48h)	250 s/s 500 s/s, 1000 s/s (only 24h and 48h)
<b>ACCELEROMETER</b>	No	No	Yes

Selection of the number of channels to be recorded takes place simply by using a 5, 7 or 10 wire cable (only Walk400h). The device automatically recognises the inserted cable and consequently selects the type of recording. Through the recorder's software it is also possible to select the sampling rate to be used by the device while recording.

The Walk400h model is fitted with an accelerometer providing indications on the patient's activity and position: lying down, walking, running, standing still.

A TFT 2.2" colour display shows up to 6 traces simultaneously, allowing the physician to check good signal quality before starting recording. A navigation joystick with 4 direction buttons and one central button allows the menu to be used conveniently and data to be entered. Two LEDs, a green one and a blue one, provide indications on battery and device status, while a buzzer signals any errors or recorder status warnings.

The recorded data may be downloaded and analysed by any compatible Holter analysis software. Data are transferred via a USB cable. Data are transferred via a USB cable.

With webuploader it is also possible to prepare the recorder, by transferring patient data onto it and the type of recording to be performed.

Walk400h / Clickholter can complete a recording on a single battery.

A new and properly stored high quality alkaline AA battery (approx 2500mAh capacity) is sufficient to complete a 48 hour recording.

A new and properly stored AA lithium battery (3000 mAh or higher, 1.5V) is adequate for recording up to 7 days.

In all other cases, Walk400h / Clickholter give the possibility to replace the batteries without interrupting the recording.

**WARNING:** In case of use of Lithium batteries they must comply with IEC 80086-4.

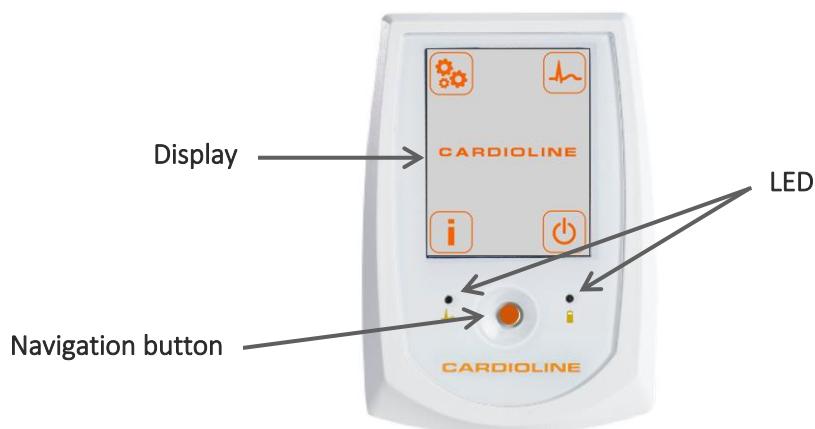
The device includes:

1. Patient cable with 5, 7 or 10 wires (Walk400honly).
2. Bag.
3. 1 battery (AA 1.5V).
4. Disposable button electrodes (25 pcs.).
5. USB PC connection cable.
6. Operating manual.

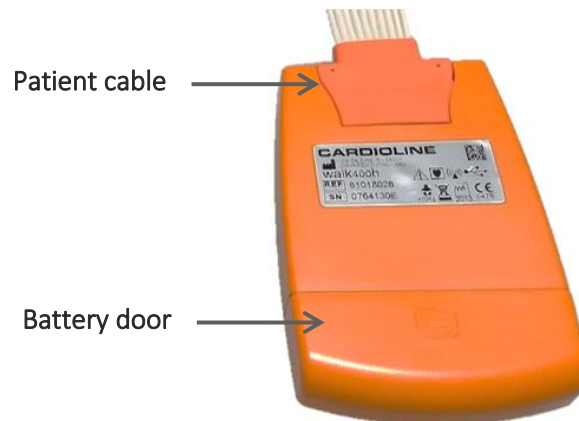
### 5.4.1. General overview

---

Front view:



Rear view:



### 5.4.2. Navigation button

The device is fitted with a navigation button that can be pressed or moved in 4 directions (like a joystick). In this manual, the various functions of the button are referred to using the following terminology:

- **ENTER:** press the button.
- **LEFT:** push the button to the left.
- **RIGHT:** push the button to the right.
- **UP:** push the button up.
- **DOWN:** push the button down.

#### Operation with display on

With display on, the button may be used to navigate the menu as described in the following chapters.

#### Operation with display off

With display off, the possible functions of the button are described in the following table.











Function	Description
DISPLAY SWITCHING ON	When any button is pressed for 1 second the display switches on, unless a test is in progress.
INTERRUPTION OF AN ONGOING TEST	Press DOWN for 4 seconds to interrupt the recording in progress
ENTERING AN EVENT-MARKER DURING A TEST	Press the central button during a recording to activate the "Event Marker" function.






### 5.4.3. Display

The LCD display at the front of the recorder shows useful information for the doctor and the patient on measuring data, monitoring settings and any system errors.

### 5.4.4. LED

The combination of the LEDs illustrated in the following table has the following meanings.

Status LED	Battery LED	Status
		<b>OFF</b> Recorder OFF – no battery or battery completely down
		<b>SYSTEM START-UP</b> Switching on the system and loading the system's firmware. This operation has variable duration between 4 and 10 seconds. Do not remove the batteries during this stage.
		<b>DISPLAY ON</b> Recorder on with display on and operative menu keys, batteries charged.
		<b>RECORDING</b> Recorder on and test in progress.
		<b>USB</b> If recorder on and connected to the PC through USB cable. The display shows the USB icon.

-  LED OFF.
-   LED permanently on, in the colour shown.
-   Flashing LED, in the colour shown.

### 5.4.5. Audible warning

The device is fitted with a buzzer that sends warning messages or in some cases, alarm messages to the user. The table sums up the possible functions of the audible warning.

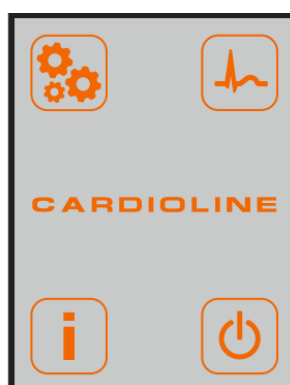
Event	Signal
From STANDBY to DISPLAY	1 ACOUSTIC SIGNAL
From DISPLAY to STANDBY	1 ACOUSTIC SIGNAL
From DISPLAY to RECORDING	1 ACOUSTIC SIGNAL

Event	Signal
From RECORDING to STANDBY	1 ACOUSTIC SIGNAL
From STANDBY to USB mode	1 ACOUSTIC SIGNAL
From USB mode to STANDBY	1 ACOUSTIC SIGNAL
Start voice recording	1 LONG ACOUSTIC SIGNAL
End voice recording	1 LONG ACOUSTIC SIGNAL
Battery low alarm during a RECORDING	1 ACOUSTIC SIGNAL every 4 seconds
Out of memory during a RECORDING	3 LONG ACOUSTIC SIGNALS followed by 1 ACOUSTIC SIGNAL before automatic shutdown
Entering an "Event MARKER during a RECORDING	1 ACOUSTIC SIGNAL
Saturation condition greater than 3 minutes	1 LONG ACOUSTIC SIGNAL

## 5.5. Navigation in the Menu

### 5.5.1. Start Page

After switching on, the device shows the **Start Page**.



*Start Page*

From these pages it is possible to access the main device functions, listed in the following table.

### Start Page Functions

Function	Description
INFORMATION	Shows information on the device
START RECORDING	Start a new Holter recording
SETTINGS	Lets you access the Options Menu for system settings
STANDBY	Puts the device in standby

#### Buttons:

- UP, DOWN, RIGHT, LEFT: to move on the icons;
- ENTER: to confirm the selection.

### 5.5.2. Information Page

---

The Information page shows:

- Firmware version
- Serial Number of the recorder
- Connected patient cable: 5 wires, 7 wires, 10 wires or no connected cable;
- Estimate of available storage: number of complete recordings that may be stored;
- Number of recordings in the memory;
- Date and time.

#### Buttons:

- LEFT: to go back to the Start Page.



## 6. PREPARATION FOR USE

---

### 6.1. Switching on the recorder

---

To switch on the recorder insert 1 AA type, 1.5 Volt battery in the battery compartment on the back of the recorder and press the Knob.

**WARNING:** insert the battery paying attention to positioning it correctly, as shown in the diagram stamped in the battery compartment.

**WARNING:** always disconnect the patient before opening the battery compartment cover.

**WARNING:** remove the battery from the unit in the event of prolonged inactivity.

**WARNING:** In case of use of Lithium batteries they must comply with IEC 80086-4.

**NOTE:** if the display switches on but the message "SD Card not recognized. Connect the device to PC. See user manual for details" is shown proceed as described in par. 9.3.

When a battery is inserted, the recorder starts a test phase, after which, if a recording was in progress, the recording is retrieved and restarted, otherwise the device starts up and the Start Page is displayed.

If the device is connected through the USB cable to a PC, the display shows the USB icon until operations are completed and the device is disconnected.

### 6.2. Commissioning

---

Upon commissioning ensure the recorder's default settings are adequate.

To do so, access the settings page as described in Par. 8.

Ensure the following fields are set with the correct settings:

- Language
- Date and time

Should they need to be modified proceed as described in Par. 8.

The device stores the settings and, unless there are specific needs, they do not need to be edited when the recorder is started up again.

### 6.3. Switching off the recorder

---

To set the device in standby mode again, go to the Start menu, select the power off button and push it down. To completely power off the device remove the battery from its housing.

## 7. EXECUTION OF THE EXAMINATION

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### 7.1. General procedure

---

The operations required to perform a Holter test are described below.

1. Choose the number of channels (Walk400h only) and the cable to be used.
2. Prepare and connect the patient (as described in Par. 7.3 and 7.4)
3. Prepare and start recording (as described in Par. 7.5).
  - a. Choose the type of test (Duration and sampling rate) (as described in Par. 7.5.1);
  - b. Optionally, insert a 20s voice message to help patient identification (as described in Par. 7.5.2);
  - c. Check the quality of the traces on the display and make sure there are no error messages (as described in par. 7.5.3).
  - d. Start recording (as described in Par.7.5.4).
4. Position the recorder on the patient (as described in Par. 7.7).
5. Instruct the patient (as described in Par. 7.8).

**NOTE:** *Strictly adhere to instructions on preparing the patient, one of the most crucial stages for successful recording.*

### 7.2. Selection of the number of channels

---

The recorder acquires simultaneously the ECG signal from 3 to 12 channels (Walk400h only) according to configuration, installed options and patient cable used:

- 5-wire cable: 3-channel recording
- 7-wire cable: 5-channel recording
- 10-wire cable: 12-channel recording (Walk400h only).

### 7.3. Preparing the patient's skin

---

Before connecting the electrodes, ensure the patient has fully understood the procedure and knows exactly what the test they are doing consists of, that they have been correctly instructed on the required behaviour throughout the recording and are ready for any actions to be taken in special cases and to perform everyday activities.

- Privacy is very important to allow the patient to be relaxed.

- Reassure the patient that the procedure is painless, and that they will only feel the electrodes on the skin.

It is important that the patient's skin be accurately cleaned. There is a natural electrical resistance on the surface of the skin, generated by various sources such as hair, sebum, and dry or dead skin. Skin preparation is required to minimise the negative effects caused by excessive skin-electrode impedance and to optimise the ECG signal quality.

To prepare the skin:

- If necessary, shave the skin area where the electrode must be applied.
- Wash the area with hot soapy water.
- Dry the skin vigorously with an abrasive pad, such as a gauze, to remove dead skin cells and fat, and to increase blood flow in the capillaries.

**NOTE:** Pay attention not to cause abrasions, discomfort or bruises on the skin of elderly or fragile patients.

## 7.4. Connecting the patient

---

It is important to position the electrodes properly in order to acquire a good electrocardiographic signal. Lower impedance, in fact, provides better waveform, reducing noise, and good quality electrodes should be used for the same reason.

Connect the electrodes as follows:

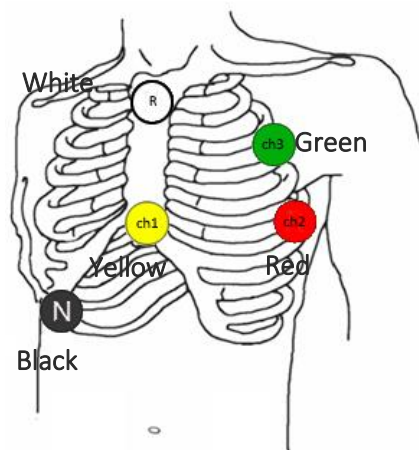
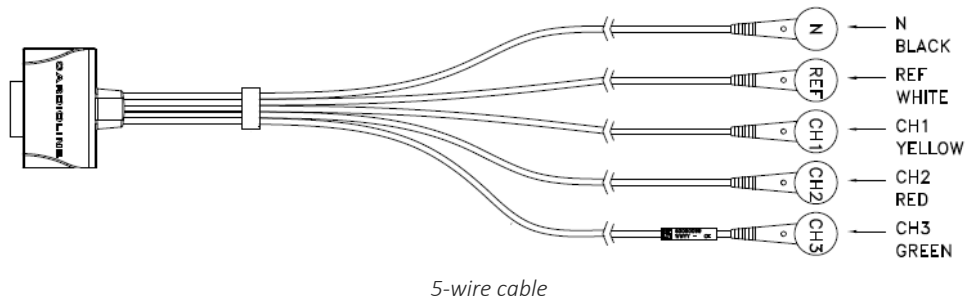
1. Remove the protective film on the back of the electrodes and apply them in the desired points. Electrode placement is a clinical choice at the discretion of the physician who intends to perform the test on the patient. The following paragraphs show examples of electrode placement based on the selected type of cable.
2. Check proper adhesion of the electrodes, by gently tugging them. If the electrode moves freely, replace it. If the electrode does not move easily, a good electrical contact is ensured.
3. Connect the patient cable terminals to the electrodes.
4. Apply a strip of sticking plaster on the electrode head (it is recommended to form a small loop with the end of the connection cable and to fasten it under the adhesive strip).
5. Connect the patient cable to the connector on the upper side of the device.






**WARNING:** proper operation of the recorder is only assured if the electrodes recommended by Cardioline are used.

**NOTE:** to prevent damaging the patient cable, grab it by the plug when inserted and removed from the connector and avoid tugging at the wires.

### 7.4.1. 5-wire cable

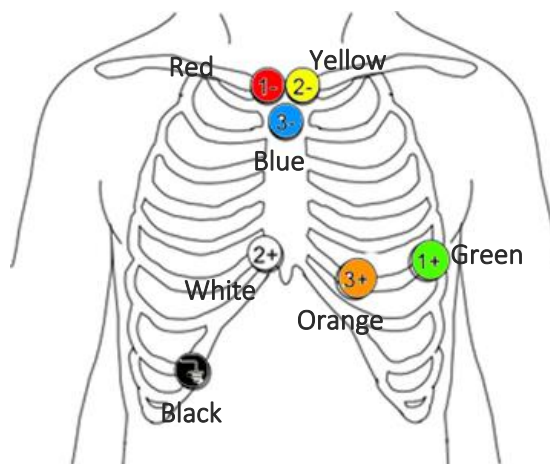
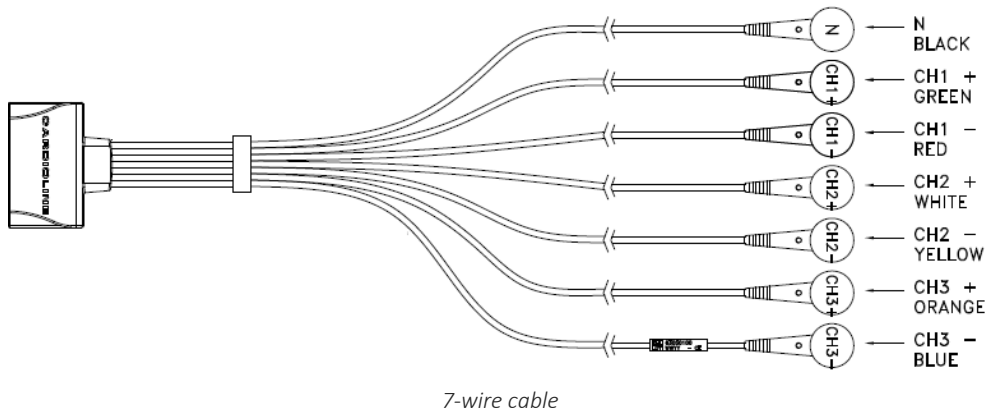
The picture and table show how to use and install this cable.










Electrode			Position
Ch1		Yellow	Fifth intercostal space at the left end of the sternum
Ch2		Red	Sixth intercostal space at the axillary line
Ch3		Green	Second left intercostal space at the midclavicular line.
REF		White	On the sternum, close to clavicles
N		Black	On the lower rib, on the left side of the chest.

### 7.4.2. 7-wire cable

The picture and table show how to use and install this cable.



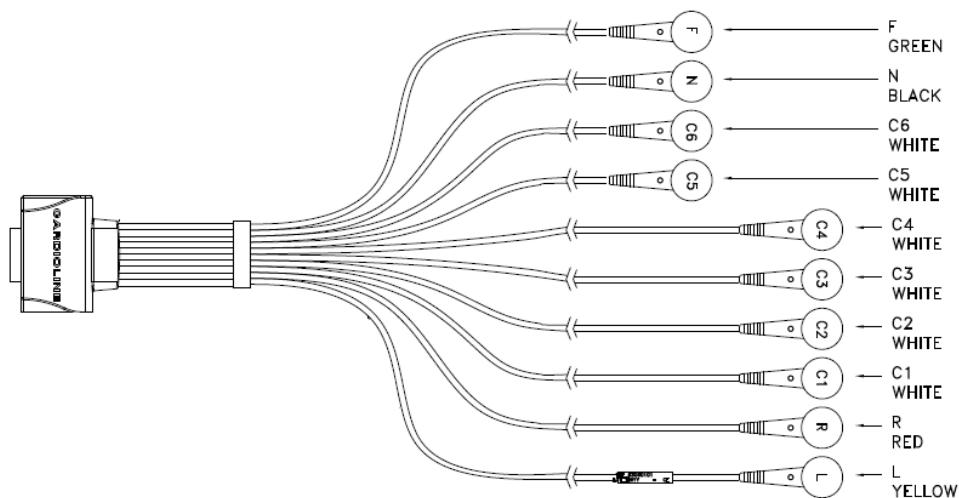
IEC electrode			Position
Ch1+		Green	Sixth intercostal space at the axillary line
Ch1-		Red	On the right clavicle, next to the sternum.
Ch2+		White	Fifth intercostal space at the left end of the sternum.

Ch2-		Yellow	On the left clavicle, next to the sternum.
Ch3+		Orange	Sixth left intercostal space at the midclavicular line.
Ch3-		Blue	On the sternum, close to clavicles
N		Black	On the lower rib, on the left side of the chest.

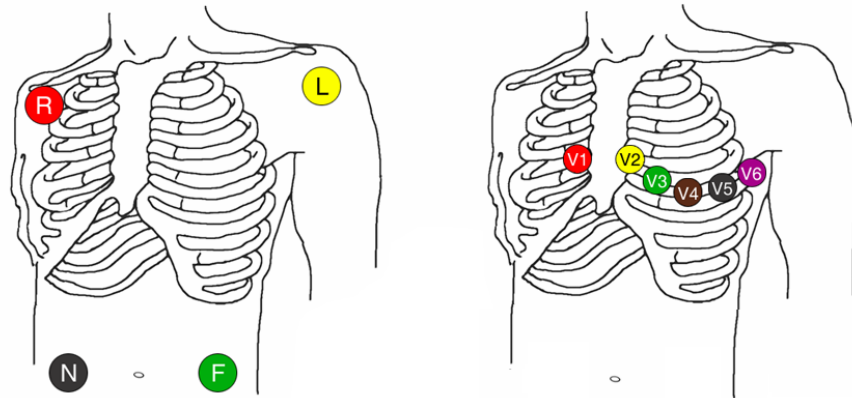
### 7.4.3. 10-wire cable (Walk400h only)

This type of cable follows the standard convention for 12-channel electrocardiography.











The only difference being that peripheral electrodes must be placed on the trunk in a position close to the respective limbs, as pictured below.



10-wire cable (Walk400h only)



Electrode placement

IEC electrode			Position
C1		Red	Fourth intercostal space to the right of the sternum.
C2		Yellow	Fourth intercostal space to the left of the sternum.
C3		Green	Midway position between electrodes V2/C2 and V4/C4.
C4		Brown	Fifth intercostal space at midclavicular line.
C5		Black	Between electrodes V4 and V6.
C6		Violet	Level with electrode V4 at left midaxillary line.
L		Yellow	On the deltoid muscle.
R		Red	On the deltoid muscle.
F		Green	On the thigh.
N		Black	On the thigh.



## 7.5. Preparation and start of recording without PC

---

It is possible to start recording even without connecting the recorder to a PC via the USB cable. After switching on the recorder, As described in Par. 6.1, and after connecting the patient, as described in the previous paragraphs, select **START RECORDING** from the Start Page. The recorder displays the Start recording page, which shows:

- Duration of the recording (24 hours / 48 hours / 7 days (Walk400h only)) and sampling rate set;
- Information on the patient (if preloaded, see paragraph 7.6);

If no patient cable is connected upon switch-on, the recorder displays the following message:

Attention! Cable not found – Check connections –

In this condition, the only permitted action is going back to the previous menu. Then connect the patient cable you wish to use and start the test again.

Buttons:

- **RIGHT**: to open the next page;
- **CLICK**: to open the page to select recording duration and sampling rate (disabled if the data have been preloaded as described in paragraph 7.6);
- **LEFT**: to go back to the previous page.

The wizard then starts up and the user is shown the sequence of instructions set out in the following paragraphs.

If no connected patient cable is found or the connected cable does not match the one required by the configured protocol, an error message is displayed.

### 7.5.1. Selection of test type

---

There is the option of choosing the type of test to be performed based on duration of the test one wishes to perform and recorder model.

The page to select test duration is accessed by pressing ENTER in the STATUS window.



*Selection of test type page*

The device can record the following types of test, according to set-up and installed options:

1. **24hr test:** 3 or 12 channels (Walk400h only) for 24 hours
2. **48hr test:** 3 or 12 channels (Walk400h only) for 48 hours
3. **Several days:** this mode lets you perform a test with 3/12 channels at 250 Hz for over 48 hours. The test consists of one or more segments the duration of which is undefined, and not necessarily continuous over time. The recorder's batteries may be replaced between segments; before starting the test, the recorder indicates the maximum available duration based on available storage in the device. The several days test mode has a maximum duration of 7 days. Furthermore, avoid prolonged lack (about 7 days) of the batteries during the test as this would cause de-programming of the built-in clock. In either case, the test is automatically closed by the recorder after restart.

After selecting the type of test, the device performs a memory check to ensure there is sufficient space for the selected recording. If unsuccessful, an error message is displayed and the process is cancelled. In the case of 7-day recording, the message is only displayed if the space is less than required by a 48-hour recording.

#### Buttons:

- **UP/DOWN:** to scroll the list
- **RIGHT or ENTER:** to confirm the type of test and switch to the next page;
- **LEFT:** to go back to the previous page and cancel the selection.

*NOTE: One test only may be prepared during the preparation stage.*

### 7.5.2. Voice recording

---



*Voice recording page*

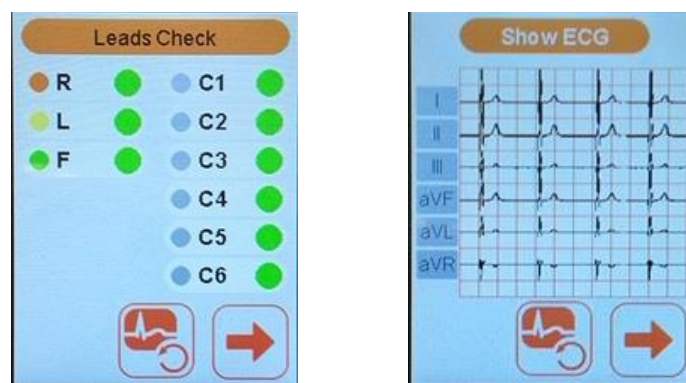
Press ENTER to record a voice message. After 20 seconds the recorder switches to the next phase.

This feature allows the operator to record an audio file containing personal information and any other notes, when the test is downloaded the recorded audio can be played back so as to enter the information in the analysis software.

#### Buttons:

- **ENTER:** to start recording;
- **RIGHT:** to save the recording and go to the next page;
- **LEFT:** to go back to the previous page and delete the recording.

### 7.5.3. Display traces and saturation



*Display saturation and traces*

The device shows a page indicating channel saturation and one or more pages (according to the cable used) displaying traces in real time.

In real time display the number of channels per page depends on the type of patient cable:

- 10-wire cable (Walk400h only): 2 pages, 6 channels each
  - First page I, II, III, aVR, aVL, aVF
  - Second page: C1, C2, C3, C4, C5, C6
- 5 or 7-wire cable, 1 page, 3 channels:
  - First page: C1, C2, C3
  - Second page: none

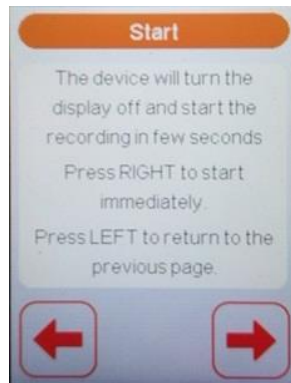
#### Buttons:

- **ENTER:** to scroll through the saturation check and trace display pages;
- **RIGHT:** to go to the next page.

#### 7.5.4. End of preparation and start of recording

---

The recorder shows a message to confirm start of recording by the user.



*Start of recording confirmation page*

Buttons:

- **RIGHT or ENTER:** to confirm start of recording;
- **LEFT:** to cancel the start up and go back to the previous page.

Recording is nevertheless started after 30 seconds.

Entry into the RECORDING phase is signalled as follows:

1. the display switches off;
2. the BLUE status LED starts blinking (test in progress);
3. the GREEN battery LED switches off.

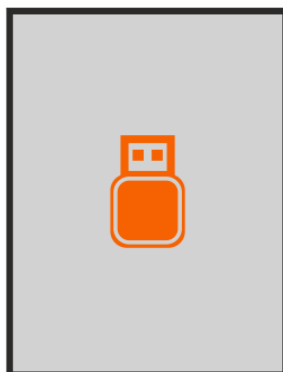
#### 7.6. Recorder preparation via a PC

---

This preparation method makes it possible to preload the personal information and the type of recording (cable, duration and sampling rate) before starting a recording making use of the connection with the PC via USB, using the Cardioline webuploader software.

To perform recorder preparation proceed as follows:

1. Connect the device to the PC using the USB cable supplied;
2. The recorder displays a screen with a USB drive icon and the PC alerts to a connected USB drive



USB connection page

3. Use the webuploader software to enter the personal information and recording data (please refer to the manual of the Cardioline webuploader software for a detailed explanation).
4. Disconnect the device after ejecting the USB drive through the safe removal procedure (this operation assures the information is written correctly in the recorder's memory).
5. Proceed with fitting the recorder onto the patient as described in the previous paragraphs and start the test as described in paragraph 7.5

**NOTE:** in this case it is not possible to modify the type of recording and the recorder shows an error message if the patient cable does not match the one configured in this phase.

**NOTE:** the software in the PC must be adequately configured and installed to assure proper operation. For more details refer to the appropriate user manual.

## 7.7. Placement of the recorder on the patient

---

After starting the recording the recorder must be fixed to the patient's body. The device may be placed directly in contact with the patient's body using a gauze or, should one wish to do so, the device may be placed in its bag, which is attached to the patient's body.

**NOTE:** the device can be supplied with a bag (see list of accessories in this manual) which can be used to protect the recorder and to fix it to the patient. Use of the case is not mandatory.

**NOTE:** Use of the protection bag is mandatory if the relative humidity of the environment is less than 50% (dry environment) to prevent the formation of electrostatic charges.

**NOTE:** The bag and the Walk400h Waterproof case, indicated in par. 10.2, they are not intended to come into direct contact with the body, therefore it is recommended to place them above a garment (for example a shirt).

## 7.8. Instructing the patient

---

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 about the operations he is allowed to perform and the related risks. Refer to par. 2 for further details.

## 7.9. During test recording

---

The RECORDING mode is indicated by the BLUE status LED blinking.

During this stage the device records the ECG signals and accelerometer signals in its memory for the time set in the preparation stage.

### 7.9.1. Use of an Event Marker

---

It's possible to enter time markers during the recording by pressing ENTER.

The patient may intentionally enter an event by pressing ENTER during the recording. In this manner, a symptom or special activity can be signalled. It is also possible for the patient to signal when the recorder is temporarily disconnected by entering an event at the beginning and end of the period.

The recorder is also able to recognize and record autonomously events associated to signal saturation or lead fail and pacemaker impulses.

### 7.9.2. Accidental disconnection of the batteries

---

Should the batteries be accidentally disconnected during the recording, the recording session is interrupted but not closed. If the batteries are inserted again, the recorder shows the "Resume recording" window. Use the right button to resume the interrupted recording, then the display switches off and the recording resumes according to the preset mode as described in Par.7.9.5.

If the batteries are not put back in, when the device is connected to the PC with the USB cable the test is closed and downloaded.

**WARNING:** *to be able to continue a interrupted test the batteries must be put back in within the maximum time for the recording; otherwise the test is closed automatically the next time the device starts up.*

### 7.9.3. Accidental disconnection of the patient cable

---

If the patient cable is accidentally disconnected during the recording, the device records the event as "disconnected leads" but the recording continues. Therefore, just reconnect the cable with no other operations required.

However, if a different type of cable from the previous one is connected, the recorder records it as an error and interrupts the recording.

### 7.9.4. Low battery

---

If the batteries go below the safety threshold during the recording, the recorder sends an acoustic signal to the patient every 4 seconds.

At this point, the patient, having been appropriately instructed, must replace the batteries. When the batteries have been replaced, the recorder switches on and a warning window reading “Restart recording” appears on the screen. Press the key on the right to restart the recording: the display switches off and recording resumes according to the preset mode as described in Par.7.9.5.

If the key on the right is not pressed, recording will resume automatically after 30 seconds

**ATTENTION:** *the detection of the battery status is not operational if lithium batteries are used.*

### 7.9.5. Resume a recording

---

From the Start page it is possible to resume an interrupted recording, not yet completed, for instance following battery replacement.



*Resume recording message*

Buttons:

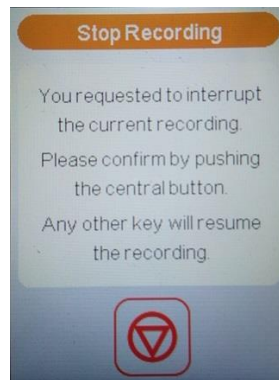
- **RIGHT:** confirm and go to the trace check page.

### 7.10. End of recording

---

End of recording may occur for the following reasons:

1. the programmed recording time has elapsed
2. the device is connected to the PC using the USB cable
3. the manual stop command is given by pressing and holding the DOWN button for 4 seconds, the display switches on and shows a confirmation message of interrupted recording. Press the ENTER button to confirm the interruption, press any other button and the display switches off and recording is resumed.



Confirm interruption

**WARNING:** It may happen that due to the low battery, after the manual stop command the screen of the device does not turn on as expected, and the device turns off autonomously. To restart the recording, insert a new battery, or connect the device to the computer to download the exam.

When recording ends the device signals it with an acoustic signal, capture is interrupted and the device goes back into normal operating mode, ready for a new test or to download the one just performed. When the display is switched on again, the INFO window shows the presence of a stored test through the counter of filed tests.

## 7.11. Test transfer to the PC

The tests contained in the recorder's memory to be downloaded into a PC for subsequent analysis and reviewing.

In addition to patient data and information on the test, the download also includes the type of recorder used and events occurred during the recording (main marker, saturation, pacemaker, audio recording, acceleration file).

To transfer the data, the recorder must be connected to the PC with the USB cable and the recorder must be switched on (par. 6). The recorder goes automatically into USB mode and the following screen is displayed.



USB connection page

**NOTE:** It is recommended to transfer data immediately after treatment to ensure security of patient data.



Data transfer is managed directly by the software installed in the PC. Please refer to the user manual of the analysis software for further details and instructions.

Upon completion of the data transfer the recorder's memory may be automatically cleared or not, based on the settings of the software installed on the PC.

## 8. RECORDER SETTINGS

### 8.1. Settings

To configure the recorder, select the item Settings from the Start page.



Settings Page

Buttons:

- **UP, DOWN:** to go to the various items;
- **LEFT:** to go back to the Start Page;
- **ENTER:** to select the field and open the page to enter a new setting.

The following table lists the settings.

Field	Function	Possible values
<b>Language</b>	Language used.	Italian – English – German – French – Spanish – Portuguese – Czech – Turkish – Russian – Polish – Romanian – Serbian – Hungarian – Croatian
<b>Recording duration</b>	Indicates the default duration of recordings	24 hours / 48 hours / 7 days
<b>Sampling rate</b>	Sampling rate used for recording <i>NOTE: if recording duration is set at 7 days it is possible to set frequency at 250 Hz only, other settings are not permitted.</i>	250 / 500 / 1000 Hz (1000Hz only for Walk400h)

Field	Function	Possible values
Date format	Format for the date	DMY (dd/mm/yyyy) MDY (mm/dd/yyyy) YMD (yyyy/mm/dd)
Date and time	Current date and time	

### 8.1.1. Set a new figure

---

A page is displayed that shows available figures for each setting. To make a new setting just select one of the available figures using the central button.

The selected figure is highlighted.

#### Buttons:

- **UP, DOWN:** to go to the various figures;
- **LEFT:** to go back to the previous page without saving changes;
- **ENTER:** to select the field and go back to the previous page after saving the new setting.

## 9. MAINTENANCE AND TROUBLESHOOTING

### 9.1. Cleaning and disinfection

Clean the device after each use.

Do not sterilise the device and the patient cable.

To clean and disinfect the surface of the device and cables, use detergent solutions with low alcohol content, generally used in hospitals.

The surface of the device must be cleaned with a damp cloth. Do not allow any liquid to penetrate the device.

The allowed cleaning solutions are:

- Ethyl Alcohol solution 90%
- Methyl Alcohol solution 90%
- Isopropyl Alcohol solution 90% - only for plastic parts and not for display/keyboard area
- Hydrogen Peroxide solution 10v
- Hydrogen Peroxide solution 36v
- Sodium Hypochlorite solution 2%

No sterilisation of the electrodes is required as disposable electrodes SOLELY must be used with button connection for outpatient ECG (Holter).

**NOTE:** remove the battery before cleaning the device.

**NOTE:** cleaning and disinfection of the device should not be performed by the patient.

### 9.2. Regular checks

Check of patient cables: according to need, but at least once a year using an ECG simulator.

General operation tests of the device and check of current leakage: according to need, but at least every 2 years.

### 9.3. Troubleshooting table

Problem	Cause	Solution
The green LED of battery status blinks and the display does not switch on	The inserted battery is not sufficiently charged to be able to start a new test.	Replace with a new alkaline or lithium battery.

The display switches on but no screen is displayed	The inserted battery is not sufficiently charged to be able to start a new test.	Replace with a new alkaline or lithium battery.
The display switches on but the message "SD Card not recognized. Connect the device to PC. See user manual for details" is shown	The device is not able to recognize the SD card.	Connect the device to a computer with the USB cable. If the SD card is not accessible, try to format the SD card using FAT32, according to Windows instructions. Disconnect the device from the PC and switch it on. If the problem persists contact Cardioline service.
The display does not switch on	<ol style="list-style-type: none"> <li>1. The batteries were not installed correctly</li> <li>2. Battery voltage is too low</li> <li>3. Faulty display</li> </ol>	<ol style="list-style-type: none"> <li>1. Insert both batteries again and check correct polarity</li> <li>2. Replace the batteries</li> <li>3. Hand the unit to your dealer or directly to Cardioline.</li> </ol>
Noise and artefacts on ECG signal	Electrode – skin contact is not optimal	<ol style="list-style-type: none"> <li>1. Ensure all electrodes are properly attached to the patient and to the cable</li> <li>2. Ensure the electrodes have not expired.</li> </ol>
The device connected to the PC is not detected and the display does not switch on	The device is off.	Press the central button to switch the device on.
The device (on) connected to the PC is not detected	The battery is exhausted	Remove the battery and repeat the operation
The device (on) connected to the PC is detected but the memory is not accessible	<ol style="list-style-type: none"> <li>1. Internal memory is corrupted</li> <li>2. Internal memory is damaged</li> </ol>	<ol style="list-style-type: none"> <li>1. Try formatting the PC memory (select filesystem FAT32)</li> <li>2. Hand the unit to your dealer or directly to Cardioline.</li> </ol>
The device does not respond to HIRES programming (webuploader)	The Hires configuration is not supported by the device and is converted into 7dd/250Hz	Do not use webuploader if you wish to capture a high resolution trace (500 or 1000 Hz)

## 10. TECHNICAL SPECIFICATIONS

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ECG leads	Up to 12 leads
Patient Cable	5-wire cable – 3 single-pole channels 7-wire cable – 3 double-pole channels 10-wire cable (Walk400h only) – 8 channels/12 leads (standard ECG assembly)
CMRR	>85 dB
DC input impedance	> 60MΩ
A/D converter	24 bit, 96000 samples/second/channel
Resolution	<1 μV/LSB
Dynamic range	+/- 400 mV
Sampling rate for signal analysis and storage	User selected: 250 – 500 – 1000 (Walk400h only) samples/second/channel
Bandwidth	0.67 - 300 Hz (bandwidth at 1000 samples/second)

**NOTE:** cf. Paul Kligfield et al, *Recommendations for the Standardization and Interpretation of the Electrocardiogram Part I, Circulation. 2007;115:1306-1324*: “To reduce artifactual distortion of the ST segment, the 1990 AHA document recommended that the low-frequency cutoff be 0.05 Hz for routine filters but that this requirement could be relaxed to 0.67 Hz or below for linear digital filters with zero phase distortion. The ANSI/AAMI recommendations of 1991, affirmed in 2001, endorsed these relaxed limits for low-frequency cutoff for standard 12-lead ECGs, subject to maximum allowable errors for individual determinants of overall input signal reproduction. These standards continue to be recommended”.

Signal resolution for analysis and storage	2.5μV
Front-end performance	ANSI/AAMI IEC 60601-2-47
Pacemaker detection	Hardware detection coupled with digital convolution filter Compliant with 60601-2-47 201.12.4.4.109
Defibrillation protection	Not present
Patient cable recognition	Automatic identification of patient cable used

Lead-fail detection	Independent for all leads
Maximum recording duration	500/1000 samples/second/channel: 48 hours 250 samples/second/channel: up to 7 days  Regardless of number of channels
Patient's activity recording	Indication of patient's activity: walking, running, stopping.
Internal memory	16 GB SD card Capacity equal to at least 100 recordings 3-channels, 24 hours at 250 s/s
Data transfer	USB 2.0
Compatible devices	Cardioline cubeholter, webuploader
Power supply	1 standard AA battery: <ul style="list-style-type: none"><li>▪ Alkaline</li><li>▪ Lithium (compliant with IEC 80086-4)</li></ul>
Battery life	Alkaline battery (~2500 mAh): <ul style="list-style-type: none"><li>▪ More than 48 hr recording</li></ul> Lithium battery (3000mAh, 1.5V): <ul style="list-style-type: none"><li>▪ 7 days recording</li></ul>
Display	TFT 2.2" colour display displaying 6 traces Resolution: 240 x 320
Buttons	1 multifunction button (4 direction buttons + 1 central button)
LED	Green battery status indication LED Blue device status indication LED
Buzzer	A buzzer to signal errors
Voice recorder	Voice recorder for any comments while preparing the patient
Event marker	Enter events by means of the central button
Configurable settings	Recording type: 250-500-1000 (Walk400h only) Hz Maximum recording duration: 24hrs, 48hrs, 7 dd Dates and time Language
Patient data	ID Name Surname Date of birth Gender
Dimensions	50 x 50 x 8 mm

Weight	100 g with battery (80 g without battery)
Protection against accidental ingress of water or substances	Device: IP 4x – Walk400h waterproof case : IP x2
Packaging	15x21x5 cm, 1 Kg

## 10.1. Harmonised standards applied

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STANDARD	DESCRIPTION
EN ISO 15223-1	Medical devices - Symbols to use in labels of the medical device, in the labelling and in the information which must 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
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	Medical electrical equipment 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
EN 60601-2-47	Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
EN 62304	Medical device software - Software life cycle processes
EN 62366	Medical devices - Application of usability engineering to medical devices



## 10.2. Accessories

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CODE	DESCRIPTION
63050099	IEC 5-wire patient cable
63050100	IEC 7-wire patient cable
63050101	IEC 10-wire patient cable
63090306	USB connection cable
VL-00-S	Disposable button electrodes, 25 pcs
9983015	Disposable button electrodes, 50 pcs
SGFO3642	Disposable button electrodes, 100 pcs (only for Telemedicine)
65090069	Bag for Walk400h / Clickholter
66030038C	Disposable button electrode, 25 pcs
63090732	Walk400h waterproof case (waterproof pouch IPX2)
P-00-S	Pediatric disposable button electrode, 50 pcs.

## 11. WARRANTY

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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;
- damage 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. Material and labour are free of charge whereas transport risks and costs shall be borne by the customer.

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.

## 12. DISPOSAL

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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 waste. 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 (Article 50 and subsequent of Italian Legislative Decree no. 22/1997).





Cardioline S.p.A.  
Headquarters  
Via Linz, 151  
38121 Trento  
Italia  
T. +39 0461 96821

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**CARDIOLINE**