CARDIOLINE

# Walk Free

# User manual

CE 0633

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CARDIOLINE

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## Contents

# 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. Important additional 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 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.



The code relating to this manual is provided below.

| Language | Code |
|---|---|
| ENGLISH | 36519200 |

# 2. SAFETY INFORMATION

## 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 ambulant recordings, patients must be instructed to handle Walk Free beforehand. Patients who are unable to operate Walk Free after thorough training (change and application of electrodes, batteries, e.g. disabled or demented people) should be excluded from recording, unless they can rely on the support of third parties who can be assigned to the application in your usual living environment.
- 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 EN 60601-1 and EN 60601-1-11 and EN 60601-2-47. Only use spare parts and accessories supplied with the device.
- The enclosure of the device is classified as “BF-Type Applied Part” in compliance with par. 4.6 of EN standard 60601-1. Applied part refers to the electrodes.
- Conductive parts of the electrodes and associated connections must not come into contact with other conductive parts, including ground lead.
- 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 and long-term applications and must be promptly removed once the test is complete.
- The ECG electrodes may cause skin irritation; check the skin for any irritations or inflammations.
- Although the electrodes defined for Walk Free are very skin-compatible and comply with normative requirements (EN ISO 10993-1), allergic skin reactions (e.g. redness, inflammation or itching) can be caused by the adhesive layer of the electrodes in patients. Clarify possible skin allergies with the

patient. Contact the electrode manufacturer for more detailed information. Increased skin irritation is expected in patients treated with cortisone preparations.

- 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 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 and if all the devices involved are used according to their intended purpose.
- 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.
- Walk Free is shower-resistant, provided the battery cover is attached to the device.
- Nevertheless, it is recommended to remove Walk Free from the electrode (from the body) before showering. Do not spill liquids over the device.
- Protect the device from moisture, dust or dirt, especially when the battery compartment is open.
- Do not clean the device by submersing it 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 with ethylene oxide gas (EO). Refer to Section 8 for instructions on proper cleaning and disinfection.
- Do not leave the electrodes unattended in the presence of children as they could cause suffocation if accidentally swallowed.
- Never expose the device to extreme temperature and do not leave it in dusty brackish or humid premises.
- The Walk Free device has been designed to be connected to a PC only if it has already been disconnected from the patient.
- Make sure that if multiple Walk Free is used in parallel to different patients, the recorded data is correctly assigned to the respective patients.

## Attention

- The device should be cleaned before use. Check the connections for any damage or excessive wear before each use.
- Electrodes 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/repaired 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, electrodes etc.) and/or packaging material, comply with local waste disposal regulations and 2012/19/EU (WEEE).
- The device uses standard batteries, that need to be replaced by the user. Always disconnect the Patient before opening the battery compartment panel.
- Do not expose the device or batteries to direct solar radiation and avoid the direct proximity of heat sources (microwaves, heaters or ovens).
- In the event of prolonged inactivity (more than 8h), remove the batteries from the device.
- The device should not be operated in a potentially explosive environment.
- Walk Free must not be sterilised.
- Please refer to the instructions for cleaning and disinfection in Chapter 8.1 as well as the instructions for disposal in Chapter 11.

## Notes

- 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.
- Walk Free is suitable for use in children with a body weight less than 10 kg.
- For children use electrodes that are suitable for Holter/Long-Time ECG recordings on children.
- As defined by the EN 60601-1 and EN 60601-2-47 safety standards, the device is classified as follows:
    - Equipment with IP protection rating (ME Internal power supply).
    - BF-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 EN standard 60601-2-47.
- The device belongs to Class IIa in compliance with Directive 93/42/EEC and subsequent amendments.

- The device has IP 54B protection rating against the ingress of solid particles and water.
- 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**..... | -25º C ÷ 70º C |
| **Relative humidity**..... | 15% ÷ 90% (non-condensing) |
| **Atmospheric pressure**..... | 700 ÷1060 mbar |

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

| | |
|---|---|
| **Ambient temperature**..... | 5º C ÷ 40º C |
| **Relative humidity**..... | 15% ÷ 90% (non-condensing) |
| **Atmospheric pressure**..... | 700 ÷1060 mbar |

***NOTE**: Avoid sudden changes in temperature or humidity.*

## 2.1. Recommendations for users

When commissioning and operating the Walk Free Holter recorder system, please note the following information:

- Note the usage recommendations for applying the Walk Free recorder (Chapter7).
- Clean (save if necessary) and dry the area where the electrodes are placed carefully.
- Do not use electrodes whose packaging is open for more than 5 days (consider the manufacturer's recommendation).
- For planned long-term shots (>= 24h): Use only new batteries.
- Pay attention to the correct connection of the recorder to the electrodes.
- Place the electrodes carefully.
- Check the adhesive resistance of the electrodes several times a day.
- Check the contact of the recorder to the electrodes several times a day (by raising the recorder at the corners).
- When using radio-based phones (e.g. mobile phone/smart phone/tablet PC/DECT phone/radio), a distance from the Walk Free recorder of at least 30 cm should be respected. The devices must not be stored on the Walk Free recorder. This applies in principle to other electrically operated devices (e.g. hair dryer, shaver, computer, WLAN, etc.)

## 2.2. 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 Walk Free model is able to perform multiple recordings up to 9 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 adhesive resistance of the electrodes should be checked by the patients several times a day.
- The electrodes should be changed at least every 2 days, in hot weather or bad adhesive contact every 24 hours.
- The contact of the recorder to the electrodes should be checked regularly and several times a day (by carefully lifting the recorder at the contacts to the electrode).
- Direct contacts/impacts with/to the Walk Free should be avoided as far as possible.
- The patient should sleep as far as possible in supine position.
- The patient should avoid strong physical activity such as jogging or sports in general or strenuous physical work unless these activities are instructed by a doctor. This serves to improve the signal quality (e.g. avoiding shocks and shocks).
- If possible, no tight clothing should be worn in the chest area.

Attention

- The Walk Free is shower-resistant, provided the battery cover is attached to the device.
- Nevertheless, it is recommended to remove Walk Free from the electrode (from the body) before showering. Do not spill liquids over the device.
- Protect the device from moisture, dust or dirt, especially when the battery compartment is open.

### 2.2.1. Precautions for the patient, skin irritation

- The Walk Free is suitable for use on children under 10 kg.
- Although the electrodes defined for Walk Free are very skin-compatible and comply with the normative requirements (ISO 10993-1-5-10:2018), longer records may cause skin irritation (itching, redness).
- In these cases, stop the ECG record and contact your doctor immediately.

Increased skin irritation is expected in patients treated with cortisone preparations. You should also do very carefully here when gluing and removing the electrodes from the skin surface. For body care for long-term recordings, especially for applications >24 hours, the following instructions should be taken into account for daily personal care (both inpatient and outpatient).

### Cleaning without shower/bathroom

If possible, save the area around Walk Free from cleaning without a shower/bath if possible. For such cleaning, Walk Free does not need to be removed from the electrode.

### Showers

- The Walk Free is shower-resistant, provided the battery cover is attached to the device.
- Nevertheless, it is recommended to remove Walk Free from the electrode (from the body) before showering.
- When showering, the electrodes can remain on the body.
- After showering, dry the electrode carefully and wait a few minutes until the electrode is completely dried before reconnecting the Walk Free to the electrode.

### Bathing/swimming

- Remove Walk Free from the electrode (from the body) before bathing or swimming. Also remove the electrode from the body.
- After the bath, apply the Walk Free to the body again according to the instructions in Chapter 7.
- Dry the skin carefully before sticking the new electrode onto the body.
- Always glue a new electrode to the same place as the predecessor electrode.
- Instructions on removing/applying Walk Free from the electrode and changing the electrode can be found in Par. 0

## 2.3. Analysis Systems

The Walk Free:

- does not provide integrated analysis or diagnostic functions;
- does not include monitoring, detection, signaling or display of life-threatening arrhythmias or changes in morphology.

It is therefore not suitable for applications that require at least one of these functionalities.
All analysis functions can only be performed via appropriate compatible analysis system.
The recorded ECG data of the Walk Free are not suitable for the analysis of amplitude changes (e.g. change of amplitude in the ST segment).
The recorded ECG data must not be used for morphological ECG interpretation to derive diagnoses for amplitude-specific heart disease (e.g. ischemic heart disease, repolarization anomalies).

*ATTENTION*:
*Note that the computers used in the compatible analysis systems (Par. 9.1) must meet the normative requirements of EN 60601-1, or at least the normative requirements for information technology equipment, in order to ensure the readout of the recorded ECG data via the USB cable*
*Reading out the ECG recordings may only happen if the device has no connection to the patient (via the ECG electrode contacts).*

# 3. ELECTROMAGNETIC COMPATIBILITY (EMC)

The Walk Free is intended for operation in the electromagnetic environment of medical care facilities (Professional Healthcare) and in domestic environments. The customer or the user of Walk Free should ensure that the operation takes place in an electromagnetic environment that complies with the following requirements.

### Warnings

- The manufacturer shall guarantee compliance of the device with the EMC requirements only when the specified accessories are used. The use of other accessories may result in increased emission of electromagnetic interference or reduced strength against electromagnetic interference.
- Portable and mobile RF communication devices (including their accessories such as antenna cables and external antennas) should be at least 30 cm (12 inches) distance from all parts of the Walk Free including connected electrodes. Non-compliance can lead to a reduction in the performance characteristics of the device.
- The apparatus shall not be placed directly next to or stacked with other equipment. If such an arrangement is nevertheless necessary, the apparatus must be observed in order to verify its intended operation in this arrangement.

Magnetic and electric fields or ionizing radiation can influence the function of the device. Therefore, do not operate Walk Free near devices that produce large electromagnetic fields or ionizing radiation, such as RF chirurgic, X-ray, magnetic resonance therapy or diathermy devices.

Under the influence of increased electromagnetic interference, data recording can be temporarily disturbed or interrupted. This has no influence on the validity of the existing recorded data and its subsequent analysis.

In compliance with the EMC and electromagnetic environment guidelines listed in this user manual, no restriction of performance characteristics over the entire life of the medical device is to be expected.

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

The Walk Free is intended for use in the electromagnetic environment specified below. The customer or user of the Walk Free must ensure the device is used in such as environment.

| Interference meassurement | Compliance | Electromagnetic environment - Guide |
|---|---|---|
| HF emissions (CISPR 11) | Group 1 | The Walk Free uses RF energy exclusively for its internal function. Therefore, its RF emission is very low and it is unlikely that adjacent electronic devices will be disturbed. |
| HF emissions (CISPR 11) | Class B | Walk Free is suitable for use in all facilities, including those in the residential area and those directly connected to the public utility network, which also supplies buildings used for residential purposes. |
| Transmissions of harmonics (IEC 61000-3-2) | Not applicable (< 75 W) | |
| Transmissions of voltage fluctuations/flicker to IEC 61000-3-3 | Not applicable (< 75 W) | |

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

The Walk Free is intended for use in the electromagnetic environment specified below. The customer or user of the Walk Free must ensure the device is used in such as environment.

Manufacturer’s declaration on electromagnetic immunity

| Immunity tests | Test level IEC 60601-1-2:2014 | Conformity level | Electromagnetic environment - Guidelines |
|---|---|---|---|
| Electrostatic discharge (ESD) (IEC 61000-4-2) | ± 8 kV contact discharge ± 2 kV, ± 4 kV, ± 8 kV, ±15 kV air discharge | ± 8 kV contact discharge ± 2 kV, ± 4 kV, ± 8 kV, ±15 kV air discharge | Floors should be made of wood or concrete or with ceramic tiles. If the floor is fitted with synthetic material, the relative humidity shall be at least 30 %. |
| Magnetic field at frequencies of 50/60 Hz (IEC 61000-4-8) 150 Hz (EN 60601-2-47) | 30 A/m 50 Hz or 60 Hz | 30 A/m 50 Hz or 60 Hz | Magnetic fields at the mains frequency should correspond to the typical values found in a business or hospital environment. Walk Free does not contain magnetically sensitive components or circuit elements. |

| | | | |
|---|---|---|---|
| Conducted RF disturbances (IEC 61000-4-6)<br><br>Irradiated RF disturbances (IEC 61000-4-3) | 3 Veff<br>0,15 - 80 MHz<br>6Veff in ISM bands between 0,15 and 80 MHz<br>80% AM at 1 kHz<br><br>3 V/m<br>80 MHz – 2,7 GHz<br>80% AM at 1 kHz | Not applicable<br><br>3 V/m<br>80 MHz – 2,7 GHz<br>80% AM at 1 kHz | Portable and mobile radios should be used at no distance from Walk Free, including lines, than the recommended protection distance of 30 cm:<br><br>Support for the management of the EM environment and management of medical devices for EMC, including evaluation of the EM environment, investigation and reporting of EMI problems and location selection, is provided by the AAMI TIR 18 guideline.<br><br>  Disturbances are possible in the environment of devices carrying this image sign. |
| Near field of wireless RF communication devices | 385MHz – 5,7GHz<br>9-28V/m | 385MHz – 5,7GHz<br>9-28V/m | |
| Note 1: At 80 MHz and 800 MHz the higher frequency range applies.<br>Note 2: These guidelines may not be applicable in all cases. The propagation of electromagnetic quantities is influenced by absorptions and reflections of buildings, objects and humans.<br>Note 3: Table 9 of IEC 6100-2-1:2014 gives all test frequencies and immunity levels for wireless RF communication devices. Information is also provided to calculate the minimum protection distances depending on the power, frequency band and immunity level. | | | |

## Immunity in the near field of wireless RF communication devices (IEC 60601-1-2:2014, Table 9)

| Test Frequency | Band [1] | Service [1] | Modulation [2] | Maximum power | Distance | Immunity test level | Conformity level |
|---|---|---|---|---|---|---|---|
| MHz | MHz | | | W | meter | (V/m) | (V/m) |
| 385 | 380-390 | TETRA 400 | Puls modulation [2]<br>18 Hz | 1,8 | 0,3 | 27 | 27 |
| 450 | 430-470 | GMRS460,<br>FRS 460 | FM [3]<br>± 5 kHz deviation<br>1 kHz sinus | 2 | 0,3 | 28 | 28 |
| 710<br>745<br>780 | 704-787 | LTE Band 13,<br>17 | Puls modulation [2]<br>217 Hz | 0,2 | 0,3 | 9 | 9 |
| 810<br>870<br>930 | 800-960 | GSM 800/900,<br>TETRA 800,<br>iDEN 820,<br>CDMA 850,<br>LTE Band 5 | Puls modulation [2]<br>18 Hz | 2 | 0,3 | 28 | 28 |

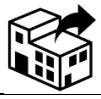
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 1720<br>1845<br>1970 | 1700-1900 | GSM 1800;<br>CDMA 1900;<br>GSM 1900;<br>DECT;<br>LTE Band 1, 3,<br>4, 25; UMTS | Puls modulation [2]<br>217 Hz | 2 | 0,3 | 28 | 28 |
| 2450 | 2400-2570 | Bluetooth, WLAN<br>802.11 b/g/n,<br>RFID 2450,<br>LTE Band 7 | Puls modulation [2]<br>217 Hz | 2 | 0,3 | 28 | 28 |
| 5240<br>5500<br>5785 | 5100-5800 | WLAN 802.11a/n | Puls modulation [2]<br>217 Hz | 0,2 | 0,3 | 9 | 9 |

Note: In order to achieve the immunity test level, the distance between the transmitting antenna and the Walk Free can be shortened to 1 m if necessary. The test distance of 1 m is permitted in accordance with IEC 61000-4-3.

[1] For some services only the uplink frequencies are included.
[2] The carrier is modulated with a rectangular signal with a touch ratio of 50 %.
[3] Alternatively to frequency modulation, a 50 % pulse modulation at 18 Hz can be used. Since this does not correspond to the current modulation; this would be the worst case.

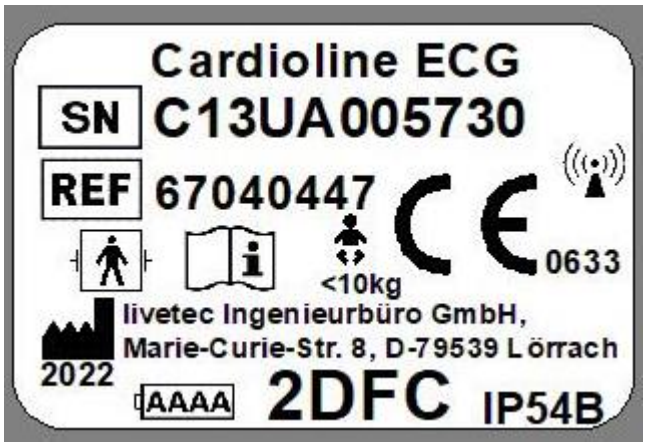
# 4. SYMBOLS AND LABEL

## 4.1. Explanation of the symbols

| Symbol | Description |
|---|---|
| CE 0633 | CE marking. The device complies with the requirements of the European Council Directive 93/42/EEC for medical equipment followed by Notified Body 0633. |
|  | Manufacturer information. |
|  JJJJ | Date of production. Indication of the year in which the device was manufactured. |
|  | Distributor information. |
| IP54B | IP degree of protection against water. |
|  | Classification of the application part according to IEC 60601-1. Defibrillation-protected application part of type BF. |
|  | Special waste that may not be disposed of in normal household waste. Must be disposed of in an environmentally friendly manner in accordance with local rules. |
|  | Instructions for use. |
|  | Device includes radio transmitter (Bluetooth module). |
| SN | Serial number. |
| AAAA | Battery operation.<br>Size of battery AAAA. |
|  < 10 kg | Suitable for ECG recordings in children with a body weight of less than 10 kg. |

| | |
|---|---|
|  | Temperature range Storage and transport. |
|  | Area relative humidity storage and transport. |
|  | Ambient air pressure Storage and transport. |
|  | Keep it dry. |
|  | Avoid direct sunlight. |
|  | Top. |
|  | Recycling. |

## 4.2. Device label



# 5. INTRODUCTION

## 5.1. Purpose of the manual

This manual refers to devices Walk Free.
The manual represents a guide for execution of the following operations:

- Reasonable use of the device and use of the function keys.
- Preparation of the device for use (Section 6)
- Execution of a test (Section 7).
- Maintenance and troubleshooting (Section 8).

## 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 (Par. 2).

## 5.3. Intended use

Walk Free is an ECG Holter recorder intended for continuous measurement and digital storage of ECG signals during the patient's daily activities as part of a long-term/Holter ECG. The recorded data are used to diagnose cardiac arrhythmias.
The recorded data, store in the internal memory of the device, is downloaded from Walk Free to a PC in a medical facility and evaluated with a suitable Holter-EKG analysis software. The recorded data are transferred to the PC through a USB connection. A doctor evaluates the normal and abnormal ECG data for further therapeutic measures.
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 must not be used on the open heart.
- 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

The Walk Free is a medical device for long-term Holter ECG data recording with the following features:

- No cables necessary.
- High wearing comfort for the patient.
- Low effort for cleaning and disinfection.
- Easy application or removal of the adhesive electrode(s) via three pushbuttons.
- Continuous recording of three ECG signals up to 9 days without changing the battery.
- Recording of usual 24h – 48h Holter ECGs.
- Support for event marking by the patient (e.g. in case of symptoms or medication).
- Secure and simple data download via the integrated USB interface.
- Bluetooth interface for patient-specific initialisation of the device.
- Support of standardized ECG data formats such as MIT, ISHNE, EDF+.

By using decentralised single-use electrodes in conjunction with state-of-the-art hardware and software technology, Walk Free enables permanent recording of long-term ECGs well over 24h with very high signal quality and at the same time maximum patient comfort.
By eliminating previously common cables and due to the integrated intelligence, Walk Free requires almost no operation steps and thus enables (especially for ambulant applications with elderly patients) ECG recordings without affecting patients in their usual living environment and quality of life.
For the first time, this enables practicable, efficient, and safe “round the clock” long-term ECG recordings.
By simply changing the single-use electrodes, Walk Free can be used as a long-term recorder for ECG recordings up to 9 days.

### Advantages for the cardiologist

- Simplest configuration, commissioning and application.
- Secure recordings by cable-free technology; also over long periods of time (no loose cables, no loose adhesive electrodes, and no bad electrode contacts).
- Modular concept enables ECG recordings over theoretically unlimited periods of time.
- High signal quality by eliminating the cables and derivation of the vectors on the smallest area (low-artefact, low-interference ECG recordings).
- Low patient instruction effort for ambulant recordings.

### Benefits for the patient

- No impairment of quality of life and habits. After a short wearing period, you don't notice the Walk Free anymore.
- Simplest operation/handling by patients even during longer recording periods (only necessary to change the electrodes).

The device includes:

1. Recorder module (Walk Free).

   It includes the electronics for measuring and storing the 3 ECG leads.


2. Batteries AAAA size.

   It is a disposable part and must be changed after each examination.


*example*

3. Decentralised single electrodes.

   Using three decentralised single-use ECG adhesive electrodes the recorder module measures and calculates the leads. The electrodes are also a disposable part.

*example*

4. PC initialisation software (Device Web Manager) provided via a link where download it.

5. PC micro USB cable

6. Battery cover


7. Operating manual.

### 5.4.1. General overview

Front view:


*Device with electrodes*

Rear view:


*Device without electrodes*

## 5.4.2. Control and display elements

### Control elements

The Walk Free does not include any control elements.

### Display elements

The Walk Free includes 3 LEDs for displaying device/battery and error status as follows:

| | |
|---|---|
|  | Green LED: Display of the current Device State and additional signal control channel 3. |
|  | Yellow LED: Display of Battery State and additional signal control channel 2. |
|  | Red LED: Display of Error State and additional signal control channel 1. |

### State „Self-test“

In this state, Walk Free performs an internal self-test, during which all important functions of the device are tested.

| | |
|---|---|
|  | All 3 LED’s flash every 2s for the duration of 1s. |

*NOTE: This state is automatically activated after attaching the battery to the recorder module of the Walk Free.*

### State „Ready for initialisation“

In this state, Walk Free is ready for initialisation by Device Web Manager software. This state is displayed as follows:

| | |
|---|---|
|  | Green LED flashes every 2s twice for the duration of 200ms . |
|  | Optional: If the red LED is switched on (permanently) during this state, this means that there is still an ECG recording on the Walk Free recorder, which has not yet been read out and evaluated. |

*NOTE: This condition is automatically activated after the battery has been installed on the recorder module of the Walk Free and after self-testing has been carried out.*

### State „Initialisation"

In this state an initialisation by the Device Web Manager software takes place. This state is displayed as follows:

| | |
|---|---|
|  | Green LED flashes every 2s for the duration of 1s. |

*NOTE: This state is achieved as soon as the initialisation software Device Web Manager is connected to the Walk Free and an initialisation takes place.*

### State „Signal Control/ECG display"

In this state an amplitude modulated (with brightness modulated) display of the 3 ECGs via the 3 LEDs of the Walk Free takes place as follows:

| | |
|---|---|
|  | Display channel 1 (derivation I) |
|  | Display channel 2 (derivation II) |
|  | Display channel 3 (derivative III) |

*NOTE: In this modulated display, the R-spike as well as the T-wave of the ECG is visible.*

*NOTE: This state is automatically activated after initialisation and start of ECG recording.*
*However, this state can be activated as desired during the ECG recording by a "double click" with medium force on the Walk Free.*
*This state is active for approx. 120s after activation. Then the Walk Free switches to the state "ECG recording".*

### State „ECG recording"

In this state an ECG measurement and recording takes place. Patient contact is available.

| | |
|---|---|
|  | Green LED flashes every 2s for the duration of 200ms. |

### State „Pause"

In this state the ECG measurement and recording is interrupted because there is no patient contact:

| | |
|---|---|
|  | Green LED flashes every second for the duration of 200ms. |

*NOTE: In this state, instead of an ECG's, a zero line or a pseudo QRS complex is recorded at 60 bpm. This state automatically changes to the state "ECG recording" as soon as the patient contact is detected again.*

### State „End“

This state indicates the end of a recording. This state is achieved e.g. after a serious error or after a detection of an empty battery.

| | |
|---|---|
| | All LED’s off |

### State „Battery State“

The battery State is displayed at Walk Free as follows:

| | |
|---|---|
|  | State EOS-1: Residual battery life >= 12 h.<br>Yellow LED flashes every 2s for a duration of 200ms. |
|  | State EOS-2: Residual battery life >= 6 h.<br>Yellow LED flashes every second for the duration of 200ms. |

### State „Error State“

A serious error leading to the interruption of the recording is displayed at Walk Free as follows:

| | |
|---|---|
|  | Red LED is permanent ON.<br>Troubleshooting See Walk Free Instructions for use (Par. 8.5). |

# 6. PREPARATION FOR USE

## 6.1. Switching on the recorder

To switch on the recorder insert 1 AAAA type battery in the battery compartment on the front of the recorder as described in par. 8.3.

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

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

When a battery is inserted all 3 LEDs of the Walk Free have to light up cyclically (state self-test). After self-testing the Walk Free switches to the state „Ready for initialization" and waits for contact with the patient. After applying the recorder to the patient and recognizing contact to the patient, the Walk Free switches to „Initialization" and awaits initialization of the ECG recording (par. 7.4).

## 6.2. Installation of Device Web Manager initialization software

To install the Device Web Manager software refer to the specific User Manual (par. 5.1).

# 7. EXECUTION OF THE EXAMINATION

## 7.1. General procedure

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

1. Prepare and connect the patient (as described in Par. 7.2 and 7.3)
2. Prepare and start recording.
    a. initialisation and start of ECG recordings (as described in Par. Errore. L'origine riferimento non è stata trovata.);
    b. instruct the patient (as described in Par. 7.5).
3. Definition of manual event markers (as described in Par. 7.6).
4. Cyclical function control (as described in Par. 7.7).
5. Stop ECG recording and analysis of ECG recording (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. 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: In patients who use Body Lotion, the skin must be cleaned or degreased particularly carefully.*

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

## 7.3. 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.

Apply the Walk Free recorder and connect the electrodes as follows:

1. Attach 3 individual electrodes to the Walk Free recorder according to the following image.


2. Remove the protective foils on the undersides of the electrodes.
3. Apply the Walk Free recorder to the patient by sticking the electrodes and recorders to the patient's skin in accordance with the recommendations of par. 7.3.2 and press with medium force on the recorder and on the outer contours of the electrodes.
4. Try to place the electrode(s) in such a way that as little curved skin surface as possible must be balanced.
5. The use of decentralized electrodes reduces artefacts (e.g. for more corpulent patients) and can be better placed on complex skin surfaces.
6. Make sure that all 3 contacts of the electrode and the recorder module are connected. Check this by slightly lifting the recorder module at each electrode contact. A good positioning should also prevent a "raising" of the electrodes during movements.
7. If possible, avoid placing the electrodes directly on muscle tissue.
8. Avoid mechanical stress on the electrodes.

### 7.3.1. Suitable electrode types

For the use of the Walk Free Holter recorder systems it is recommended to use the following types of electrode:

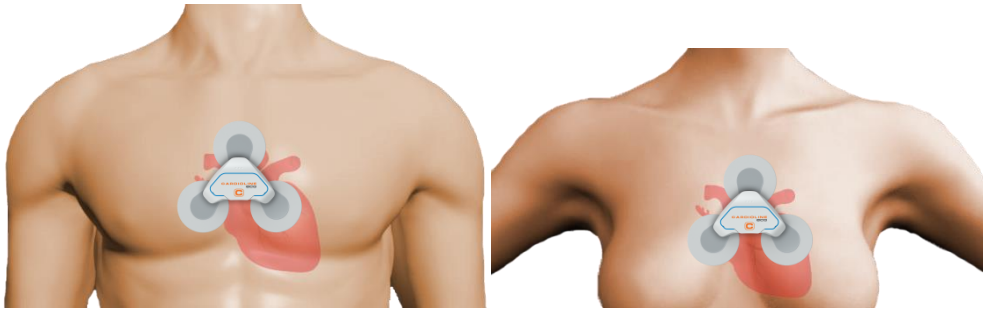
- AMBU decentralized electrodes, type „Blue Sensor L“, “Blue Sensor VL”or “Blue Sensor VLC” (for sensitive skin), for children „Blue Sensor P“, available from the distributor of the Walk Free Holter recorder systems or from specialist retailers.

*WARNING: Always note the “durability date” of the electrodes according to the technical data and the information on the packaging of the electrodes.*
*WARNING: In case of open packs: Use the single-use electrodes within a maximum of 5 days (please pay attention to the manufacturer’s information).*
*WARNING: When choosing the electrodes, pay attention to the suitability of the electrodes for Holter and long-term ECG recordings, especially with regard to skin compatibility or suitability for use in children under 10 kg.*

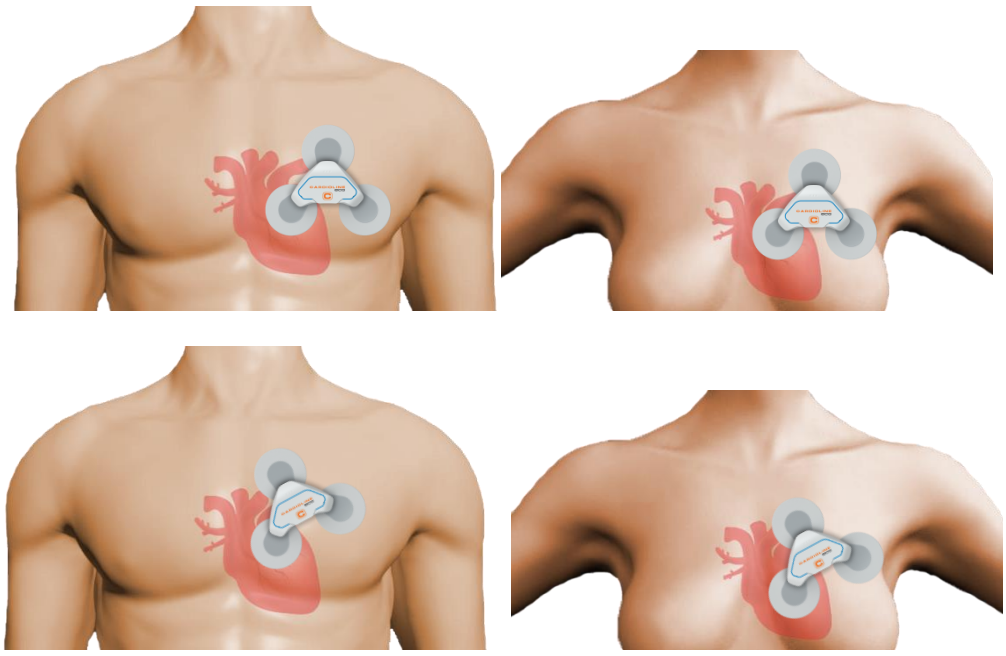
### 7.3.2. Positioning of the electrodes

The electrodes used can be positioned as follows:

- Recommended position: Middle rib cage

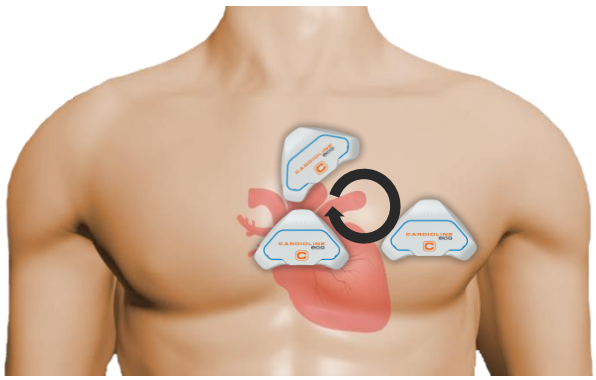


- Alternative position



***NOTE**: Make sure that the electrodes are not positioned too high; the lower electrode(s) should be positioned as close as possible to the horizontal heart axis.*
***NOTE**: When placed on the left chest: Make sure that the electrodes are not positioned too far to the left, the right electrode poles should be placed as close as possible to sternum.*

- Prepositioning without adhesive electrode(s)



***NOTE**: The positioning closer to the atrium increases the P-wave.*

## 7.4. Initialisation and start of ECG recording

The ECG recording should be initialised and started as follows:

- Initialisation via Device Web Manager (with USB connection), (par. 7.4.1).

In order for the ECG recording to be initialised, Walk Free must be in the state "Ready for initialisation" or state “Signal control/ECG display”.
You can see the state "Ready for initialisation" by the fact that the green LED on Walk Free flashes 2 times in a row every 2 seconds. This condition is activated automatically after the Walk Free has been applied to the patient.
They recognise the state of "signal control/ECG display" by the fact that all 3 LEDs on the Walk Free flash at the rhythm of the heart rate. This state can be activated at any time by double-clicking on the housing of the Walk Free recorder. Complete information are in par. 5.4.2.

### 7.4.1. Initialization with Device Web Manager

To initialise the Walk Free using the Device Web Manager refer to the specific User Manual (par. 6.1.1 and par. 6.1.2).

## 7.5. 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.

## 7.6. Definition of manual event markers

The Walk Free offers the possibility that the patient can define manual event markers at any time, for example if he feels “uncomfortable” or if he suspects arrhythmias (with appropriate symptoms). Event markers can be defined by the patient as follows:

- Double click/double stroke on the housing of the Walk Free.
- After the definition of a manual event marker, the Walk Free switches to the status **“signal control/ECG display”**.

In this state an amplitude modulated (thus brightness modulated) display of the 3 ECG derivatives via the LEDs of the Walk Free takes place.

***NOTE:*** *To make sure that a manual event marker has been detected by Walk Free, repeat the double click on the case until the state* ***“signal control/ECG display”*** *is displayed and all 3 LEDs (red, yellow green) on Walk Free flash at heart rhythm.*

## 7.7. Cyclical function control

During an ECG intake, a cyclical functional check should be carried out as follows. Note the following hints:

| | |
|---|---|
|  | ▪ A cyclic flashing of the green LED in a rhythm of 1 or 2 seconds indicates a correct function of the Walk Free. |
|  | ▪ The light of the red LED indicates an error.<br>▪ In this case, change the battery and reapply the Walk Free.<br>▪ Stop the ECG recording and notify the service if the red LED still lights up afterwards. |
|  | ▪ The yellow LED indicates the discharge state of the battery.<br>▪ Change the battery at the latest when the yellow LED flashes in the 1s rhythm. |

If the Walk Free is temporarily removed from the electrode (e.g. during body cleansing or when changing the electrode), this is recognised by the Walk Free and the device changes to the State “Pause”. In this state, instead of an ECG’s a zero line or a pseudo QRS complex at 60 bpm is recorded.

After the re-attachment of the Walk Free on the electrode (after detection of the patient contact), the device proceeds independently with the ECG signal recording and storage (state “ECG recording”).

The states “ECG recording” and “Pause" are displayed by Walk Free via the green State — LED

The complete description of the state displays is in par. 5.4.2.

## 7.8. Stop ECG recording and analysis of ECG recording

### 7.8.1. Stop ECG recording

To finish the ECG recording, simply remove the Walk Free from the electrodes and remove the battery from the recorder module as described in par. 8.3.

### 7.8.2. Read out the ECG recording/import into the Analysis Software

Connect the Walk Free recorder to the computer on which the analysis software is installedvia the supplied USB cable.


Then import the ECG recording from the Walk Free recorder into the analysis system used and analyze the ECG recording according to the instructions in the respective user manual of the analysis system used.

*ATTENTION: Make sure that the software of the analysis system is configured correctly so that the Walk Free Recorder is recognized by the analysis system and it can work correctly with the Walk Free Recorder.*
*Follow the instructions in the user manual of the evaluation system used.*
*ECG recordings are only permitted to be read out if the device has no connection to the patient (via the ECG electrode contacts).*

# 8. MAINTENANCE AND TROUBLESHOOTING

## 8.1. Cleaning and disinfection

Clean and disinfect Walk Free after each application to a patient. Ensure sufficient ventilation. Do not sterilise the device with steam, ethylene oxide, ultrasound or gamma rays.
The surface of the device must be cleaned with a damp cloth. Do not immerse the Walk Free in water and other liquids. Under no circumstances should liquid enter the recorder. Do not use abrasive cleaning agents to clean the device.
Walk Free must not be cleaned with organic solvents such as petrol, alcohols or ethers in order to avoid material fatigue, discoloration or breakage.

### Cleaning

- moisten a soft cloth with soap solution or aqueous alcohol solution (70 % ethanol/30 % water);
- clean the Walk Free.

### Desinfect

- Moisten a soft cloth with an aqueous alcohol solution (70 % ethanol, 30 % water) or a plastic-suitable cleaning solution, better cleaning cloths or tissues, for sensitive medical devices.
- Wipe the Walk Free.

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

## 8.2. Change of electrode

The electrodes defined for the use of the Walk Free are suitable for ECG recordings over several days and have very good adhesive and contact properties. However, it is recommended to change the electrodes after 2 days at the latest, at warm and hot temperatures every 24 hours.

Proceed as follows:

- Remove the Walk Free /electrode from the patient's body and separate the Walk Free from the electrodes.
- Clean the body surface according to the instructions on paragraph 7.2.
- Also remove any adhesive residues of the predecessor electrode.
- Dry the skin before applying the new electrode.
- Use new electrodes and first apply the electrode(s) to the Walk Free recorder according to the following images:



- Remove the protective foils on the undersides of the electrodes.

- Then attach the Walk Free recorder with the electrodes to the patient's skin.
- Press with medium force on the recorder and on the outer contours of the electrode.

*NOTE:*
*Do not disconnect the Walk Free from the battery while changing the electrode.*
*Always glue a new electrode to the same place as the predecessor electrode.*

*ATTENTION:*
*Always note the "durability date" of the electrodes according to the technical data and the information on the packaging of the electrodes.*
*In case of open packs: Use the electrodes within a maximum of 5 days (compliance with manufacturer's recommendation).*
*Please refer to the instructions for cortisone preparations in Chapter 2.1.*

## 8.3. Battery change

Although the Walk Free battery allows up to 9 days to record (for new or fully charged batteries), it may be necessary to change the battery for long-term recordings.

Proceed as follows:

- Remove the battery cover from the recorder.

- Then insert a new battery into the battery compartment as follows:
    - Note the polarity and insert the battery as shown in the picture.
    - The three control LEDs at the top of the recorder are starting to flash.


    - Carefully close the battery compartment with the lid.


- Apply the recorder module back to the electrodes after changing the battery or use new electrodes).

*NOTE:*
*After inserting the battery into the recorder, all 3 LED's of the Walk Free have to light up cyclically for a few seconds (**Status "Self-test"**).*
*After a battery change, the Walk Free continues the ECG recording on its own.*

*ATTENTION*
*Monitor the battery status display at Walk Free regularly during an ECG recording (especially for long-term recordings).*
*Change the battery as soon as the battery status indicator shows the status **"EOS-2"** (yellow LED flashes in seconds).*
*At the start of a recording, definitely use a new battery.*

## 8.4. Self-testing, internal surveillance and protection measures

*ATTENTION:*
*In order to ensure the good maintenance and the safety of the device the manufacturer recommends the following tests for the operator, which he can also carry out himself as long as they have suitable tools and skills. If you need further support for testing, please contact Cardioline.*

- *Visual inspection: Housing damage.*
- *Functional tests:*
  - *no error indicator by red LED after booting;*
  - *signal control according to instructions for use (par. 7.7 and 7.8);*
  - *recording of test signals, reading out data and checking signal quality for interference.*

*The check interval should be 36 months.*

### 8.4.1. Self-testing

The Walk Free has the following internal monitoring and protection measures:

- Self-test after switching on
- Self-test during operation

#### Self-test after switching on

After switching on (after inserting the battery), Walk Free independently carries out an extensive functional test, during which all functions of the device necessary for operation are tested. During this test, the following functions of Walk Free will be tested:

- Test of the internal microcontroller (RAM, Flash, Timer and Function).
- Test of internal supply voltages.
- ECG amplifier test (configuration and function test).
- ECG memory test (read/write test, size and free memory).
- Battery inserted test (capacity check).
- Test of the USB and Bluetooth interface (write/read test).

#### Self-test during operation

During operation, Walk Free additionally checks the following functions cyclically:

- Test of internal supply voltages.
- ECG memory test (read/write test, size and free memory).

- Test of the connected battery (capacity check).

*NOTE: If a result of a self-test is negative, the ECG recording is not started and the Walk Free goes into the "error" state. This condition is displayed via the permanently activated red LED for a duration of approx. 1h (par. 5.4.2). Then the Walk Free switches itself "OFF".*

### 8.4.2. Internal monitoring and safeguard measures

The Walk Free includes the following internal protective measures:

- Defibrillation resistance according to EN 60601-1 (recovery time ≤ 5 s).
- Stress resistance/test voltages to applied part according to EN 60601-1.
- Leakage currents to the applied part according to EN 60601-1.

### 8.4.3. Electrode monitoring

The Walk Free checks the electrode/skin contact cyclically during the ECG recording as follows:

- If an electrode impedance limit is exceeded, a zero line or a pseudo QRS complex with a frequency of 60 bpm shall be recorded for the duration of exceeding this limit (State pause, par. 5.4.2).
- If the limit value is lower, the ECG recording will be continued again.

### 8.4.4. Cyclical function control by the user

Walk Free supports functional control by the user (doctor or patient). The function control can be performed by the user in the following ways:

- by checking the status indications (par. 7.7);
- by activating the signal control (par.7.8).

## 8.5. Troubleshooting table

Although Walk Free has extensive self-testing and monitoring functions, dysfunctions can occur occasionally. Please note the following information:

| Problem | Cause | Solution |
|---|---|---|
| No LED lights up after inserting the battery. | - Battery failure (empty battery)<br>- Error recorder module | - Remove the battery and insert it again. |

| | | |
|---|---|---|
| | - Battery inserted wrongly | - Insert the battery with a plus pole in the housing recess of the battery compartment.<br>- Using new battery<br>- Contact service. |
| Red error LED lights up after inserting the battery. | - Self-testing errors<br>- Battery failure<br>- Signal memory defective or insufficient free space | - Remove the battery and insert it again.<br>- Using new battery<br>- Empty signal memory<br>- Contact service. |
| Walk Free cannot be initialised after application to the patient | - No patient contact<br>- Error recorder module<br>- Bluetooth module not available on PC/tablet, not activated or defective | - Read user manual.<br>- Check patient contact, reactivate signal control.<br>- Check Bluetooth interface on PC/tablet.<br>- Contact service. |
| No status display during recording (Green LED permanent OFF). | - Battery empty<br>- Error recorder module | - Read ECG.<br>- Change the battery.<br>- Contact service. |
| Red error LED glows while recording. | - Error recorder module<br>- Signal memory defective or insufficient free space<br>- Battery empty<br>- Other error Self-testing | - Read ECG.<br>- Using new battery<br>- Contact service. |
| No Bluetooth connection to Walk Free. | - Bluetooth module on PC, tablet not available, not activated or broken<br>- Error recorder module | - Read ECG.<br>- Change the battery.<br>- Check Bluetooth interface on PC/tablet.<br>- Contact service. |
| ECG recording cannot be read. | - Walk Free not connected to Cubeholter<br>- Error recorder module | - USB connector check Walk Free (USB cable).<br>- Contact service. |

# 9. TECHNICAL SPECIFICATIONS

| | |
|---|---|
| Number of ECG channels | 3 |
| Sampling rate | 250 S/s |
| Resolution ADC | 16 bits |
| Amplitude resolution | 2,5 µV |
| Measuring range | 100 mV |
| Frequency response | 0,1 (0.05) – 70 Hz |
| Electrode monitoring | Yes, about impedance measurement |
| Accuracy of parameters | According to EN 60601-2-47: Outpatient electrocardiographic systems |
| Supply | Over interchangeable batteries |
| Data format | Cardioline, MIT, ISHNE, EDF+ |
| Dimensions | approx. 71.5 x 46 x 14.7 mm |
| Weight | approx. 30g |
| Environmental conditions: Operation | Temperature:+ 5 °C – + 40 °C<br>Relative humidity: 15 % to 90 % (non-condensing)<br>Air pressure:700-1060 hPa |
| Environmental conditions: Storage/transport (without battery) | Temperature:— 25 °C – + 70 °C<br>Relative humidity:15 % to 90 % (non-condensing)<br>Air pressure:700-1060 hPa |
| Housings | Plastic/ABS |
| Interfaces to the readout device | USB interface (USB – 2.0)<br>Read data rates: approx. 15 MBytes/s<br>Write data rates: approx. 10 MBytes/s |
| Bluetooth interface | Bluetooth 4.0<br>Frequency band:2400.0-2483.5 MHz<br>Type of modulation: JRCK (PI/4DQPSK, 8DPSK)<br>Maximum radiated power:4 dBm (BT Class 2) |
| Battery type | 1 x Alkaline battery, 1.5 V, AAAA size (Mini, LR61/E96) |
| Operating time | up to 9 days/24h per day with one battery<br>permanent measurements are also possible when changing the batteries |
| Compatible devices | Cardioline Cubeholter |

## 9.1. Compatible analysis system

The Walk Free is supported by the following ECG analysis software Cardioline Cubeholter for the import, analysis and reporting of ECGs recorded.

| Analysis software | From version | Features |
|---|---|---|
| Cubeholter analysis software | 3.5 | Import, analysis and reporting |

Since the Walk Free supports standardized ECG data formats such as MIT, ISHNE, EDF+, the Walk Free can be operated with analysis systems that support these data formats.
Please contact the Walk Free sales department if you have any questions about the compatibility and use of the Walk Free with certain evaluation systems.

*ATTENTION:*
*Please note that the computers used in the compatible analysis systems meet as far as possible the normative requirements of EN 60601-1 or at least the normative requirements for information technology equipment in order to ensure the readout of the recorded ECG data via the USB interface.*

*NOTE: for the installation and use of Cardioline Cubeholter refer to the specific user manual.*

## 9.2. Classification and standards

| CLASSIFICATION |
|---|
| Application part type BF according to EN 60601-1. |
| Portable device with internal power supply. |
| Moisture protection degree: IP54B (in case of closed battery compartment protection against dust deposits inside and protected against splash water), IP2X without battery cover (contact protection). |
| Defibrillation resistance according to EN 60601-1. |

| PRODUCT LIFE CYCLE |
|---|
| 5 years |

| STANDARD | DESCRIPTION |
|---|---|
| 93/42/EEC | Medical Devices Directive |
| 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 |

| STANDARD | DESCRIPTION |
|---|---|
| EN 1041 | Information supplied by the manufacturer of medical devices |
| 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 62366 | Medical devices - Application of usability engineering to medical devices |

# 10. 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;
- 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.

# 11. DISPOSAL

Walk Free and all components including electrodes and batteries must be disposed of in accordance with national regulations and local waste disposal regulation of each country (e.g. WEEE Directive 2012/19/EU for Europe). We offer you to return the device for disposal to your specialist dealer, distributor or the manufacturer.

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CARDIOLINE