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CARDIOLINE

DISTRIBUTOR

PRODUCT SHEET: Walk Free

Description of product:

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



- Cable free to support a high level of patient comfort and enhanced Signal quality, reducing artefact and maximising accurate waveform “beat” detection, in support of maximising accurate automatic Algorithm analysis.
- High wearing comfort for the patient.
- Ease of cleaning and disinfection, due to the device design and the absence of cables, delivers a high level of infection control, and reduces the Holter Recorder Maintenance, delivering customer reduced life-time costs benefit versus the traditional cable solution.
- Easy application or removal of the adhesive electrodes via three pushbuttons.
- Continuous recording of three ECG signals up to 9 days without changing the battery.
- Recording of usual 24h – 48h Holter ECGs.
- User-friendly Patient Event activation (e.g., in case of symptoms or medications) supporting ease of use for patients of all ages and mobility.
- Secure and simple data download via the integrated USB interface.
- Bluetooth interface for patient-specific initialisation of the device.
- Support of multiple standardized ECG data formats such as MIT, ISHNE, EDF+. Promoting reporting flexibility and additional output data types for standard Research requirements.

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.

Three LEDs provide indications on battery.

The recorder comes with a compact design in terms of weight and dimensions to ensure that the appliance is comfortable to wear.



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The recorded data may be downloaded and analysed via the Cardioline Cubeholter software or downloaded and sent to a remote computer via the Cardioline Device Web Manager and Cubeholter WS softwares. With Device Web manager it is also possible to prepare the recorder, by transferring patient data onto it and the type of recording to be performed.

The power supply with standard AAAA battery ensures that the recorder is easy to prepare. The AAAA battery supplies the power for recordings up to 9 days long with three LED's providing the operator with indicators for battery strength and device recording status.

General Information	
Product name	Walk Free
Generic name	Walk Free
Product code	67040447
Manufacturer	livetec Ingenieurbuero GmbH
	Headquarters Marie-Curie-Str. 8 79539 Loerrach Germany
Intended use	<p>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.</p> <p>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.</p> <ul style="list-style-type: none"> ▪ 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.
Year marketed	2021



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Technical specifications	
ECG recording	
ECG leads	3 leads
Sampling rate	250 S/s
Resolution ADC	16 bits
Amplitude resolution	2.5 μ V
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
Data format	Cardioline, MIT, ISHNE, EDF+
Interfaces to the readout device	SB interface (USB – 2.0) Read data rates: approx. 15 MBytes/s Write data rates: approx. 10 MBytes/s
Bluetooth interface	Bluetooth 4.0 Frequency band:2400.0-2483.5 MHz Type of modulation: JRCK (PI/4DQPSK, 8DPSK) Maximum radiated power:4 dBm (BT Class 2)
Compatible devices/software	Cardioline Cubeholter, Device Web Manager
Electrical features	
Power supply	1 Alkaline battery, 1.5 V, AAAA size (Mini, LR61/E96) Alkaline
Operating time	Up to 9 days/24h per day with one battery.
User interface	
LED	3 LED (Green, Yellow, Red) for displaying battery status
Specifications	
Dimensions	approx. 71.5 x 46 x 14.7 mm
Weight	approx. 30g
Protection against accidental entry of water or substances	IP 54B
Environmental operating specifications	
Temperature	5 $^{\circ}$ C ÷ 40 $^{\circ}$ C
Relative humidity	15 % to 90 % (non-condensing)
Air pressure	700 ÷ 1060 hPa
Environmental storage specifications	
Temperature	-25 $^{\circ}$ C ÷ 70 $^{\circ}$ C



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Relative humidity	15 % to 90 % (non-condensing)
Air pressure	700 ÷ 1060 hPa

Regulations and Safety	
Classification according to MDD 93/42/EEC	
Class	Class IIa
Rational	Rule 10 annex IX Directive 93/42/EEC and its amendments
Notified Body	CERT Berlin (0633)

Classification according to IEC 60601-1 – Electrical safety	
Protection against electrical shock	IP (Internal power supply)
Applied parts	CF type
Protection against accidental entry of water or substances	IP 4X IP 42 with Walk400h waterproof case
Sterilisation methods	NA (not intended to be sterilised)
Suitability for use in oxygen-rich environments	No
Operation mode	Continuous operation
Performance	
Standard	EN 60601-2-47
Other classifications	
GMDN	12388 UMDNS Recorders, Long-Term, ECG, Portable
CND	Z12050403 ECG HOLTER RECORDERS
Applicable standards	
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
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



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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

Standard accessories	
Disposable Holter/Stress Test snap electrodes	25 pcs
USB connection cable	1 pc
Alkaline battery AAAA LR06 1,5 volt	2 pcs
Battery cover (spare parts)	2 pcs
Warranty	24 months
Important information/User Manual	1 pc.

Accessories	
L-00-S	Disposable Holter ECG snap electrodes, 25 pcs.
63050145	Alkaline battery AAAA LR06 1,5 volt conf. 8 pcs.

Connectivity applications	
81019622	Device Web Manager