

# CARDIOLINE

## PRODUCT SHEET: Clickholter



### Description of product:

Clickholter is a new generation holter ECG recorder that allows you to record 3 ECG channels with a 5 or 7 wires patient cable and up to 7 days, with a sampling rate of up to 500 samples per second, for both adult and pediatric patients.

Clickholter is available in two configurations: BASE and PLUS.

BASE configuration provides up to 48 hours at 250 samples per second recording.

PLUS configuration adds the capability to extend the recording duration to 7 days and the sampling rate to 500 samples/second (up to 48hrs).

The device automatically recognises the inserted cable and consequently selects the type of recording. Through the software it is also possible to select the sampling rate to be used by the device while recording.

Clickholter offers the operator the option to record a 20s voice message during the preparation of the exam.

The user interface is simple and intuitive. A TFT 2.2" colour display shows up to 3 traces simultaneously, allowing the physician to check good signal quality before starting recording. A 4-way joystick plus pressure allows you to easily navigate the menu and configure the device. Two LEDs, a green one and a blue one, provide indications on battery and device status, while a buzzer signals any errors.

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

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 or Webuploader software. Data are transferred via a USB cable.

With Device Web Manager or Webuploader 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 AA battery ensures that the recorder is easy to prepare.

### GENERAL INFORMATION

Product name	Clickholter
Generic name	Clickholter
Product code	81018031
Manufacturer	Cardioline S.p.A.
	<b>Headquarters</b> Via Linz, 151 38121 Trento Italia

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Intended use	<p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <ul style="list-style-type: none"> <li>▪ The device is indicated for continuously recording the ECG signal.</li> <li>▪ The device is not indicated for use as physiological monitoring of vital signs.</li> <li>▪ The device is not intended as the only means for determining the diagnosis.</li> <li>▪ The device is indicated for use on adult and paediatric patients.</li> </ul> <p>The device is indicated for use by a physician or trained personnel acting on behalf of an authorised physician.</p>
Year marketed	2018

## TECHNICAL SPECIFICATIONS

ECG recording	
ECG leads	Up to 3 leads
Patient Cable	5-wire cable – 3 single-pole channels 7-wire cable – 3 double-pole channels
CMRR	> 85 dB
DC input impedance	> 60MΩ
A/D Converter Features	24 bit, 96000 samples/second/channel
Sampling rate for signal analysis and storage	User selected: 250 – 500 samples/second/channel
Resolution of A/D Converter	<1 µV/LSB
Signal resolution for analysis and storage	2.5µV
Dynamic range	+/- 400 mV
Sampling rate for signal analysis and storage	User selected: 250 – 500 samples/second/channel
ECG Bandwidth	Performances equivalent to 0.05 – 150 Hz (at 500 sps) – PLUS Configuration Performances equivalent to 0.05 – 75 Hz (at 250 sps) – BASE Configuration

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Filters	Linear phase digital diagnostic high-pass filter (compliant with IEC 60601-2-25 2nd ed.)
Front-end performance	ANSI/AAMI EN 60601-2-47 2 <sup>nd</sup> Ed.
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	250 samples/second/channel: up to 48 hours (PLUS and BASE) 500 samples/second/channel: up to 48 hours (PLUS) 250 samples/second/channel: 7 days (PLUS)
Internal memory	16 GB SD card Capacity above 100 3-channel recordings, 24 hours at 250 sps
Data transfer	USB 2.0
Compatible devices	Cardioline Cubeholter, Webuploader
Electrical features	
Power supply	1 standard AA battery: <ul style="list-style-type: none"> <li>Alkaline</li> <li>Lithium</li> </ul>
Battery life	Alkaline battery (~2500 mAh): <ul style="list-style-type: none"> <li>More than 48h of recording</li> </ul> Lithium Battery (3000mAh, 1.5V): <ul style="list-style-type: none"> <li>7 days of recording</li> </ul>
User interface	
Display	TFT 2.2" colour display displaying 3 traces Resolution: 240 x 320 px
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
Configurable settings	Recording type: 250-500 Hz (PLUS) Maximum recording duration: 24hrs, 48hrs, 7 days (PLUS) Dates and time Language
Patient data	ID Name Surname Date of birth Gender

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Specifications	
Dimensions	96 x 65 x 20 mm
Weight	100g with battery (80g without battery)
Protection against accidental entry of water or substances	IP 4X IP 42 with Walk400h waterproof case
Packaging	15x21x5 cm, 1 Kg
Environmental operating specifications	
Temperature	5° C ÷ 40° C
Humidity	50% ÷ 95% - without the pouch 15% ÷ 95% - with the pouch
Pressure	500 ÷ 1060 mbar
Environmental storage specifications	
Temperature	-25° C ÷ 70° C
Humidity	5% ÷ 95%
Pressure	500 ÷ 1060 mbar

## 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	TUV (1936)
Classification according to FDA	
Number 510K	Unavailable
Classification	Unavailable
Product Code:	Unavailable
Review Panel:	Unavailable
Regulation Number:	Unavailable
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

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Classification according to IEC 60601-1-2 – Electromagnetic compatibility	
Group	1
Class	B
Performance	
Standard	EN 60601-2-47
Other classifications	
GMDN	12388 Recorders, Long-Term, ECG, Portable
CND	Z12050403 ECG HOLTER RECORDERS
RDM (Medical Device Catalogue)	1754483/R
Applicable standards	
EN ISO 15223-1	Medical devices - Symbols to be used with labels, labels and information on medical devices to be supplied - Part 1: General requirements
EN 1041	Information supplied by the manufacturer of medical devices
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971	Medical devices - Application of risk management to medical devices
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 62304	Medical device software - Software life cycle processes
EN 60601-1-6	Medical electrical equipment - Part 1: General safety requirements - Collateral standard: Usability
EN 60601-1-11	Electromedical devices - General requirements for basic safety and essential performance - Collateral standard: Requirements for electromedical devices and electromedical systems used in a domestic environment.
EN 62366	Medical devices - Application of usability engineering to medical devices
EN 60601-2-47	Medical electrical equipment - Part 2-47: Particular requirements for basic safety and essential performance of ambulatory electrocardiographic systems.

PRODUCT AND ACCESSORY CODES	
Accessories	
63050099	IEC 5-wire patient cable
63050100	IEC 7-wire patient cable

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63090306	Clickholter USB connection cable
VL-00-S	Disposable snap electrodes, 25 pcs
9983015	Disposable snap electrodes, 50 pcs
SGFO3642	Disposable snap electrodes, 100 pcs (only for Telemedicine)
65090069	Pouch for Clickholter
66030038C	Fixing system for patient cable
63090732	Walk400h waterproof case (waterproof pouch IPX2)