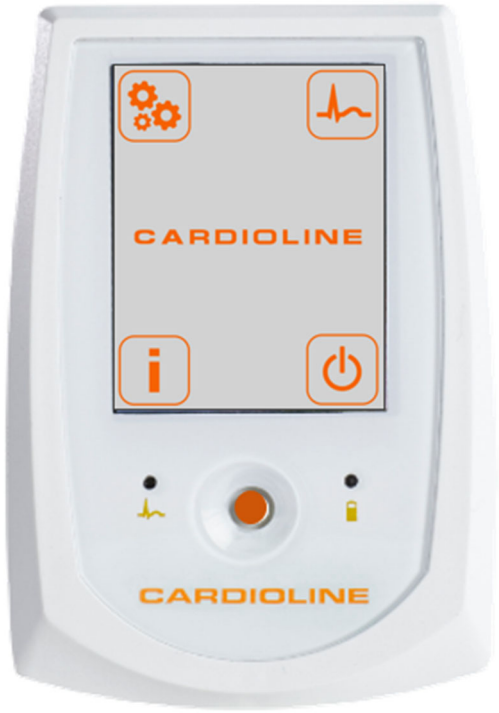
CARDIOLINE

PRODUCT SHEET: Walk400h



Description of product:

Walk400h is a new generation holter ECG recorder that allows you to record, with any patient cable configuration, up to 48 hours, with a sampling rate of up to 1000 samples/second and up to 7 days, with a sampling rate of 250 samples per second, for both adult and pediatric patients.

It is possible to choose the number of channels to be recorded using a 5, 7 or 10-wire cable. 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.

Walk400h 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 6 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 Webuploader software. 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.

The power supply with standard AA battery ensures that the recorder is easy to prepare.

General Information

Product name	Walk400h
Generic name	Walk400h
Product code	81018030
Manufacturer	Cardioline Spa
	Headquarters Via Linz, 151 38121 Trento Italia
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.
Year marketed	2018

Technical specifications	
ECG recording	
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 – 8 channels/12 leads (standard ECG assembly)
CMRR	> 85 dB
DC input impedance	> 60MOhm
A/D Converter Features	24 bit, 96000 samples/second/channel
Sampling rate for signal analysis and storage	User selected: 250 – 500 – 1000 samples/second/channel
Resolution A/D Converter	<1 µV/LSB
Signal resolution for analysis and storage	2.5uV
Dynamic range	+/- 400 mV
ECG Bandwidth	Performances equivalent to 0.05 - 300 Hz (at 1000 sps)
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 2nd ed.
Pacemaker detection	Hardware detection coupled with digital convolution filter Compliant with 60601-2-47 201.12.4.4.109

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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: 7 days Regardless of number of channels
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: ▪ Alkaline ▪ Lithium
Battery life	Alkaline battery (~2500 mAh): ▪ More than 48h of recording Lithium Battery (3000mAh, 1.5V): ▪ 7 days of recording
User interface	
Display	TFT 2.2” colour display displaying 6 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: 250-500-1000 Hz Maximum recording duration: 24hrs, 48hrs, 7 dd Dates and time Language
Patient data	ID Name Surname Date of birth Gender
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	5º C ÷ 40º C
Humidity	50% ÷ 95% - without the pouch 15% ÷ 95% - with the pouch
Pressure	500 ÷1060 mbar
Environmental storage specifications	
Temperature	-25º C ÷ 70º 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
Classification according to IEC 60601-1-2 – Electromagnetic compatibility	
Group	1
Class	B
Performance	
Standard	EN 60601-2-47

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Other classifications	
GMDN	12388 Recorders, Long-Term, ECG, Portable
CND	Z12050403 ECG HOLTER RECORDERS
RDM (Medical Device Catalogue)	1706791/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
63050101	IEC 10-wire patient cable
63090306	Walk400h USB connection cable
66030035C	Disposable button electrode 25 pcs
65090069	Pouch for Walk400h
66030038C	Fixing system for patient cable
63090732	Walk400h waterproof case (waterproof pouch IPX2)

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Cubeholter WS

General Information

Product name	Cubeholter WS
Generic name	Cubeholter WS
Product code	85039510
Manufacturer	Cardioline Spa Via Linz, 151 38121 Trento Italy

Description of Device

Cubeholter WS is a software system for importing, analysing and reporting Holter ECG traces, acquired by means of Walk400h and Clickholter recorders, with sampling rates from 250 to 1000 Hz and recording duration from 1 to 7 days.
Cubeholter WS creates a complete ECG Holter local work station where it is possible to prepare the Holter recorder, download the test, analyse it, review it and store it locally. It can be used with Cardioline connectivity software to manage a complex workflow, which allows you to receive and use work lists, receive tests remotely for reviewing, send PDF reports of the tests provided to Cardioline ECGWebApp.

The software consists of the following main functions:

1) **Preparing the recorder and entering patient data.** By connecting the Holter recorder, it is possible to enter the patient's data and set the recording parameters.
2) **Downloading and storing recorded tests.** By connecting the Holter recorder, any recorded tests and patient data are downloaded to the computer in a local archive. Patient data can also be imported from GDT files.
3) **Test analysis and creation of specific parameters.** The software performs a series of automatic analyses on the downloaded test: recognition and removal of artefacts, heartbeat recognition, heart rate and Atrial Fibrillation analysis, template generation, strip configuration, recognition and classification of supra-and sub-ventricular arrhythmias, ST analysis, QT/QTc analysis, HRV analysis and pacemaker analysis.
4) **Holter test display and reviewing.** By using a display, it is possible to view the entire ECG Holter test and the results of the analyses referred to in the previous point, change its parameters and review it, creating the relevant PDF report.
5) **Exporting the PDF and GDT Holter report.** The Holter report can be exported in PDF and GDT format.

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Technical Specifications

Minimum Requirements for Work Stations

Operating System	Windows 7 or higher, 32 or 64 bit
Processor	Intel core i5 or higher
RAM	More than or equal to 8GB
Free space on Hard Disk	At least 2GB for the program plus the space for the archive
Screen	16:10 form factor @ 1600x1050, 22” or more (100% resizing) 16:9 form factor @ 1920x1080, 15.4” or more (>= 125% resizing) Maximum recommended resolution: 4096×2160 (4K)
USB	At least 1 USB port
Printer	Laser B/N or Colour
Safety Standard	IEC 60950-1

Tests archive

Archive type	Local database
Archive capacity	1,000 tests (recommended limit)
Functions	▪ View, delete and modify patient data and test parameters of archived recordings ▪ Prepare a recorder ▪ Import recordings from a recorder ▪ Delete recordings from a recorder
Compatible devices	▪ Walk400h ▪ Clickholter
Patient data	▪ Name; ▪ Surname; ▪ Patient ID; ▪ Date of birth; ▪ Gender; ▪ Pacemaker; ▪ Phone; ▪ E-mail; ▪ Therapy; ▪ Anamnesis ▪ Date of recording.
Test parameters	▪ Patient cable: 5, 7 or 10 wires; ▪ Recording duration: 24h, 48h or multiple days (multiday - up to a maximum of 7 days); ▪ Sampling rate: 250 Hz, 500 Hz or 1000 Hz.

Automatic analysis

Analysis windows	▪ RR Analysis ▪ Template analysis ▪ Arrhythmia analysis ▪ ST Analysis ▪ QT Analysis ▪ Strip Analysis ▪ HRV Analysis
Preview	▪ Allows to stop the analysis process to directly open and review the recorded exam in preview mode, and manually mark part of the tracing as artifacts if necessary, before restarting the automatic analysis;

Final report

Customisable final report:

- Header;
- Summary per page;
- Glossary: multiple editable glossary available for therapy, anamnesis, diary and signature fields;
- Templates: option to add textual parts also containing clinical parameters that can be entered through tags. The following tags available:
    - Test length, Beats, HR med, HR min, HR max, Atrial fibrillation, Bradycardia, Supraventricular tachycardia, Ventricular tachycardia, Pauses, Ventricular arrhythmias, Supraventricular arrhythmiasPrint reservations;
- Data:
    - Trend: RR/FC, Arrhythmias, ST, QT, HRV;
    - Tables: RR/FC, Complete or simplified Arrhythmias, ST, QT, HRV;
    - ECG: RRmax/RRmin, FCmax/FCmin (manually editable) Arrhythmia Strips, Templates, ST Analysis.

Tracings display format

- Interval displayed;
- Leads displayed;
- Tracing format: 1 (compacted display - only in the RR window), 3, 12;
- Amplitude: 1, 5, 10, 20, 40 mm/mV;
- Speed: 5, 10, 25, 50, 100 mm/s.
- Signal filtering (display): ON (25 Hz), OFF

Parameters for analysis

Criteria:

- SVS: Number of consecutive beats to classify an Arrhythmia as Supraventricular.
- SVT: Number of consecutive beats to classify an Arrhythmia as Supraventricular Tachycardia.
- BRA: Number of consecutive beats to classify an Arrhythmia as Bradycardia.
- PAU: Minimum RR value to classify an Arrhythmia as a Pause.
- BRA: Maximum frequency value to classify an Arrhythmia as Bradycardia.
- SVT: Minimum frequency value to classify an Arrhythmia as Supraventricular Tachycardia.
- AIVR: Minimum frequency value to classify an Arrhythmia as Accelerated Idioventricular Rhythm.
- VT: Minimum frequency value to classify an Arrhythmia as Ventricular Tachycardia.
- Pacemaker Analysis: on/off.
- Type of pacemaker: atrial, ventricular, atria-ventricular, unknown.
- Pacemaker operating frequency: between 40 and 110 bpm.

Thresholds:

- Normal premature: Negative variation of RR as a percentage of the average value to classify a normal beat as premature.
- Atypical premature: Negative variation of RR as a percentage of the average value to classify an atypical beat as premature.
- Rhythmic (%): RR variation in percentage with respect to the average value to classify a normal beat as normal even in terms of rhythm.
- Delayed: Positive variation of RR as a percentage of the average value to classify a beat as delayed.

Classified heartbeats

- Normal heartbeat;
- Ventricular heartbeat;
- Supraventricular heartbeat;
- Artefacts;
- Induced heartbeat (if pacemaker analysis is active).

Arrhythmia detection

- Atrial fibrillation;
- Bradycardia
- Tachycardia
- Supraventricular couplets

- Supraventricular save
- Idioventricular rhythm (accelerated)
- Supraventricular tachycardia
- Ventricular couplets
- Ventricular triplet
- Ventricular tachycardia
- Bigeminy
- Trigeminy
- Pause
- Junctional rhythms
- Capture fault (if pacemaker analysis is active);
- Sensitivity fault: oversensing (if the pacemaker analysis is active);
- Sensitivity fault: undersensing (if the pacemaker analysis is active).
- Possibility to manually add Bundle Branch block, Ventricular R on T, Interpolated, Fusion events.

Actions on the tracings

- Measurements by means of callipers (duration and amplitude);
- Entering, removing, and editing beats and arrhythmias:
  - Enter/edit an arrhythmia;
  - Enter, edit or remove a heartbeat;
  - Report the presence of atrial fibrillation in an ECG section;
  - Remove an atrial fibrillation;
  - Edit heartbeat classification;
  - Cancel the last operation performed.

RR Window

Display parameters

- Interval displayed;
- Display type: trend or table;
- Duration of the interval to be analysed: complete, 12h, 6h;
- Events displayed Arrhythmias shown: Atrial fibrillation (AFIB), Artefacts, Induced heartbeat intervals (pacemaker), Sleep and Wake time zones, or all;
- View RR-HR diagram and ECG waveform, or only ECG in full windows
- 12, 6, 3 channels view, or 1 channel compacted view

Actions on data and on the tracings

- Adding or Excluding an arrhythmia;
- Adding, modifying or removing a beat;
- Navigation on the tracings with mouse and keyboard;
- Zoom and drag of the tracings;
- Automatic scrolling of the tracings;
- Measuring duration, HR and amplitude;

Parameters for analysis

RR:

- Threshold correlation: Template creation threshold. Increasing the threshold increases the accuracy (beats of the same template more similar to each other) in the creation of templates by increasing the number of templates;
- Min QRS amplitude.
- Mains filter: 50 or 60 Hz

Noise recognition:

- Noise algorithm: To activate/deactivate the noise recognition algorithm and the dynamic lead selection for beat recognition.
- Channel 1 and Channel 2: Channels used for beat recognition (if Noise algorithm is deactivated).

Template Window

Display parameters

- Interval displayed;
- Template type: normal, ventricular, supraventricular or induced
- Averaged leads view: configurable channel 1 and/or channel 2 and/or channel 3,

	compact or expanded view; ▪ 3, 6 or 12 channel ECG waveform.
Actions on data	▪ Joining two templates; ▪ Modification of template type; ▪ Removal of a template or beat in the selected template

Arrhythmia Window

Display parameters	▪ Interval displayed; ▪ Display type: trend, table or strips; ▪ Averaged leads view (in strips view): configurable channel 1 and/or channel 2 and/or channel 3, compact or expanded view; ▪ Duration of the interval to be analysed: complete, 12h, 6h; ▪ Arrhythmias shown: SVEB, DEL, SVCPT, SVS, SVT, NOR, APB, AAB, BRA, AR, AT, ASVT, AFLU, AFIB, VEB, ESC, CPT, VTRIP, VRUN, IVR, AIVR, VTRI, VRUN, VT, BYG, TRI1, TRI2, VFLU, VFIB, QUAD, JPB, JR, AJR, PAU, other arrhythmias manuals BBB, RonT, Interpolated and Fusion; ▪ Sorting options: Beats, Duration, MaxHR, MinHR, Time.

ST Window

Display parameters	▪ Interval displayed; ▪ Display type: trend, table or strips; ▪ Leads to be displayed: channel 1 and/or channel 2 and/or channel 3; ▪ Duration of the interval to be analysed: complete, 12h, 6h; ▪ ST length: 60, 80 ms; ▪ ST episodes (in strip display): ST+, ST-.
Actions on data	▪ Editing markers: QRSOnSet, j and ToffSET ▪ Add ST+/ST- episodes; ▪ Removing an episode.
Parameters for analysis	Criteria: ▪ Max: Maximum duration to classify a variation of the ST as an ST episode. ▪ Min: Minimum duration to classify a variation of the ST as an ST episode. Thresholds: ▪ J point elevation: J point elevation to classify a variation of the ST as an ST episode. ▪ J point depression: J point depression to classify a variation of the ST as an ST episode.

QT Window

Display parameters	▪ Interval displayed; ▪ Display type: trend or table; ▪ First trend to be displayed (only in trend display): RR, QT, QTc Bazett, QTc Fredericia, QTc Hodges; ▪ Second trend to be displayed (only in trend display): RR, QT, QTc Bazett, QTc Fredericia, QTc Hodges; ▪ Duration of the interval to be analysed: complete, 12h, 6h.
Actions on data	▪ Marker of fiducial points: QRSOnSet, j and ToffSET ▪ Add ST+/ST- episodes; ▪ Removing an episode.

HRV window

Display parameters	▪ Displayed interval; ▪ Display type: trend or table ▪ First trend to be displayed (only in trend display): RR, FC, RMSSD, SDNN; ▪ Second trend to be displayed (only in trend display): RR, FC, RMSSD, SDNN; ▪ Duration of the interval to be analysed: complete, 12h, 6h.

Actions on data	▪ Selection of an interval on trends and calculation of the relative HRV parameters

Strips window

Display parameters	▪ Strip Types (automatic or selected by the user)
Types of automatic strips	▪ Maximum heart rate and/or ▪ Templates ▪ Arrhythmia ▪ ST Analysis
Automatic strips configuration	▪ Gain: 1, 5,10 20, 40 mm / mv ▪ 3-lead printing format: 1 or 3. ▪ 12-lead printing format: 1,3, 6 or 12.
Strips selectable by the user	▪ ECG - selected from the Rhythm Section ▪ ECG long - selected from the RR Window ▪ Template - selected from the Template Window ▪ Arrhythmia - selected from the Arrhythmia Window ▪ ST - selected from the ST Window ▪ HRV - selected from the HRV Window
Strip Management	▪ Strip enabling/disabling for insertion in the report ▪ Strip deletion ▪ Edit label and printing format ▪ Strip printing

Connectivity

Reception of worklists	Optional (via Cardioline WebUploader software)
Transfer of recordings for remote reviewing	Optional (via Cardioline WebUploader and WebReceiver software)
Transmission of PDF reports to Cardioline ECGWebApp	Optional (via Cardioline WebUploader software)

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

Classification	in the works
Product Code:	in the works
Review Panel:	in the works
Regulation Number:	in the works

Classification according to IEC 62304 – Software

Class of risk	B

Performance

Standard	EN 60601-2-47:2012

Other classifications	
GMDN	36827 Electrocardiograph, Holter analyser
CND	Z12050482 - INSTRUMENTATION FOR HOLTER SYSTEMS FOR CARDIAC PARAMETERS - SOFTWARE ACCESSORY COMPONENTS
RDM (Medical Device Catalogue)	1719714

Applicable Standards	
EN 1041	Information supplied by the manufacturer of medical devices
EN ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
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 60601-2-47	Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and 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

Compatible Devices	
81018030	Walk400h – v. 1.0 and onward
81018026	Walk400h (old model) – v. 1.0 and onward
81018031	Clickholter – v. 1.0 and onward
81018009	Clickholter (old model) – v. 1.0 and onward
810195xx	ECGWebApp v. 2.20 and onward

Certificato di conformità CE

EC Certificate of Conformity

TÜVRheinland®

Sistema completo di garanzia di qualità secondo direttiva 93/42/CEE allegato II escluso punto 4

EC Directive 93/42/EEC Annex II, excluded clause 4 Full Quality Assurance System Medical Devices

Certificato n°: **HD 60146561**

Registration No:

Fabbricante: **Cardioline S.p.a.**

Manufacturer:

Sede legale: **Via Linz, 151**

Registered Headquarter: **38121 Trento (TN) - Italia**

Sede operativa: **Via Linz, 151**

Operational Headquarter: **38121 Trento (TN) - Italia**

Scopo: **Dispositivi di monitoraggio di parametri fisiologici vitali /**

Scope: *Monitoring devices of vital physiological parameters*

Software / *Software*

(Vedere allegato tecnico al presente Certificato per tipologie, modelli e codici)

(*See the attachment for typologies, models and codes designation)*

L'organismo notificato dichiara che il Sistema di qualità stabilito ed applicato dalla società sopra specificata soddisfa i requisiti dell'allegato II, articolo 3 della suddetta direttiva. Questa approvazione è soggetta a sorveglianza periodica, così come definita nell'allegato II, articolo 5 della suddetta direttiva e può essere utilizzata congiuntamente alla dichiarazione di conformità redatta dal fabbricante. / The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5, of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

L'organismo notificato/ ***Notified Body***

Data di emissione/*Issue date*: **15/04/2020**

Data di ultima modifica/*Last revision date:* **15/04/2020**

Data di scadenza/*Expiry date:* **26/05/2024**

Paolo Caglio

TÜV Rheinland Italia S.r.l. Certification Body

TÜV Rheinland Italia S.r.l. - Via Mattei, 3 - 20010 - Pogliano Milanese (MI)

Autorizzata dal Ministero della Salute e dal Ministero dello Sviluppo Economico

Accredited by Ministry of Health and by Ministry of Economic Development

Organismo notificato con il numero 1936 presso la Commissione Europea

Notified under No. 1936 to the EC Commission

CE La marcatura CE può essere apposta esclusivamente se vengono soddisfatti i requisiti di tutte le direttive CE applicabili CE

The CE marking may be used if all relevant and effective EC Directives are complied with

Allegato tecnico al Certificato n° HD 60146561

Attachment to the certificate:

TÜVRheinland®

Fabbricante/*Manufacturer:* **Cardioline S.p.a.**

Scopo/*Scope:* **Dispositivi di monitoraggio di parametri fisiologici vitali /** *Monitoring devices of vital physiological parameters*

Tipologia/ *Typology:* **Holter abpm /** *Abpm Holter*

Modello/ *Model:*

Walk200b, bp one +

Tipologia/ *Typology:* **Holter ECG /** *ECG Holter*

Modello/ *Model:*

Clickholter; Walk400h, click holter+

Tipologia/ *Typology:* **Unità di acquisizione ECG /** *ECG Acquisition Units*

Modello/ *Model:*

HD+ ; CLICKECG-HD

Tipologia/ *Typology:* **Elettrocardiografi /** *Electrocardiograph*

Modello/ *Model:*

ECGxxx (z) (+)

Legenda/ *Key.*

- **xxx : dimensione stampante** / *printer size*
- **(z): interfaccia** / *interface*
- **(+) : connettività internet** / *internet connection*

L'organismo notificato
Notified Body

TÜV Rheinland Italia S.r.l. TÜVRheinland Certification Body

Data di ultima modifica: **15/04/2020**
Last revision date:

Tipologia/ *Typology:* **Sistemi elettrocardiografi /** *Electrocardiographic systems*

Modello/ *Model*

touchECG System

Codice/Code

KTCH$XXYZ-@

Legenda/ *Key:*

- **$= sistema operativo** / *Operating system (Windows or Android)*
- **XX=tipo di computer** / *kind of computer,*
- **Y= tipologia di carrello** / *kind of cart,*
- **Z= altri accessori** / *other accessories,*
- **@=Elettrodi, cavi paziente, caratterizzazioni estetiche** / *Electrodes, patient cable and esthetical customizations*

Tipologia/ *Typology:* **Sistema per l'analisi di sforzo cardiavascolari/** *Cardiovascular stress test system*

Modello/ *Model*

Cubestress System

Codice/Code

KSSXYYZWJ-@

Legenda/ *Key*

- **X=tipologia di sistema** / *system type,*
- **YY=tipo di computer** / *kind of computer,*
- **Z= tipologia di carrello** / *kind of cart,*
- **W= tipologia di stampante** / *kind of printer,*
- **J= accessori** / *other accessories,*
- **@=Caratterizzazioni estetiche** / *esthetical customizations*

L'organismo notificato
Notified Body

TÜV Rheinland Italia S.r.l. TÜVRheinland® Certification Body

Data di ultima modifica: **15/04/2020**
Last revision date:

Scopo/*Scope:* **Software /** *Software*

Tipologia/ *Typology:* **Software elettrocardiografico /** *Electrocardiographic software*

Modello/ *Model*

touchECG rel. 3.xy Ed: z

Codice/Code

81019579 – for Windows
81019582 – for Android

Tipologia/ *Typology:* **Sistemi software di importazione, analisi, refertazione e archiviazione esami Holter ECG /** *Software systems for importing, analyzing, reporting and archiving Holter ECG exams*

Modello/ *Model*

Cubeholter WS Rel. 3.xy Ed: z

Codice/Code

85039510

Modello/ *Model*

Cubeholter Web Rel. 3.xy Ed: z

Codice/Code

85039520

Legenda/ *Key*

x= versioni minori / minor changes
y= correzioni / bug fix release

Se xy=00, è idenfiticato con 0 / If xy = 00, it's identified as 0

z: contenuto della configurazione / content of the distribution media

L'organismo notificato
Notified Body

TÜV Rheinland Italia S.r.l. TÜVRheinland Certification Body

Data di ultima modifica: **15/04/2020**
Last revision date:

Tipologia/ *Typology:* **Software di archiviazione, misurazione e refertazione esami /**
Software for exams archiving, measurement and review

Modello/ *Model:*

ECGWebApp Rel. 2.xy Ed: z

Codice/Code:

81019560

Tipologia/ *Typology:* **Sistemi software di monitoraggio /** *Monitoring systems software*

Modello/ *Model:*

CUBE SUITE; Cubeabpm; Cubestress Lite; Cubestress Rel. 1.4 .x.y Ed: z

Modello/ *Model:*

Cubestress Rel. 4.xy Ed: z

Codice/Code:

85050100

Legenda/ *Key:*

x= versioni minori / minor changes
y= correzioni / bug fix release

Se xy=00, è idenfiticato con 0 / If xy = 00, it's identified as 0

z: contenuto della configurazione / content of the distribution media

L'organismo notificato
Notified Body

Data di ultima modifica: **15/04/2020**
Last revision date:

CERTIFICATE

The Certification Body TÜV Rheinland Italia S.r.l.

certifies, in accordance with the TÜV Rheinland Group procedures, that the Company

Cardioline S.p.a.

Via Linz, 151

IT - 38121 Trento (TN)

has established and applies a quality management system
for the following scope:

Design, manufacturing, trading, installation and servicing of systems and electrical medical devices and software for cardiology.

Through an Audit, Report No. 7968894070LM18, proof has been furnished that the quality management system fulfils the requirements of the standard

UNI CEI EN ISO 13485:2016

Please refer to the Quality Manual for the details about
the exclusions with respect to the requirements of the standard.

Certificate Registration No. **39 05 0631503**.

This Certificate is valid from 2021-04-25 to 2024-04-24.

The reference date for all the next audits is (day-month): 12-06.

Milan, 2021-04-25. First Certification: 2012-06-13

The certification responsible: Elena Re
TÜV Rheinland Italia S.r.l., Via E. Mattei, 3 - I - 20005 Pogliano Milanese (MI)

This certificate does not represent proof that the statutory requirements of the Directives 93/42/EEC, 90/385/EEC or 98/79/EC have been fulfilled.

ACCREDIA
SGQ N° 083 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

TÜVRheinland CERTIFIED
Management System
EN ISO 13485:2016
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