CARDIOLINE

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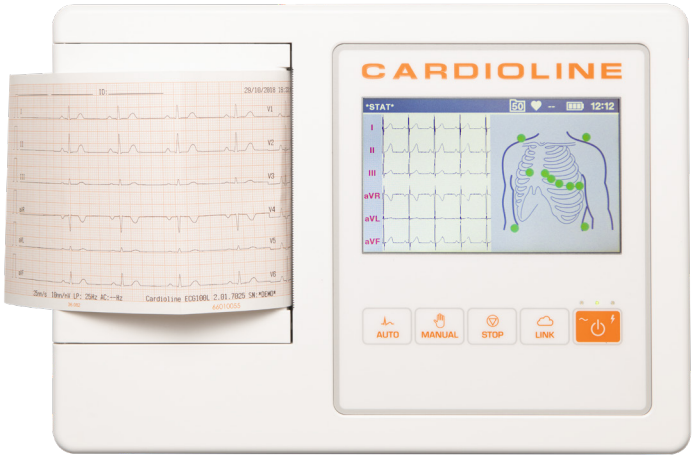
Location: Moldova

ECG 100L

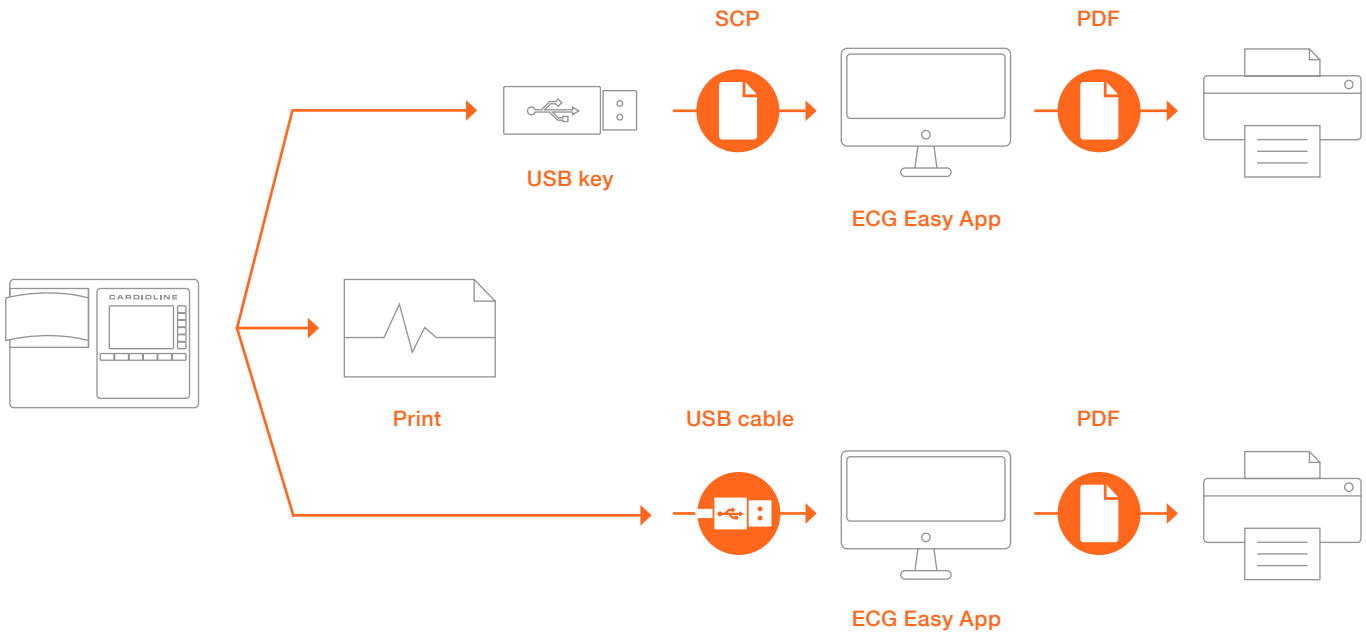
The portable 12 lead ECG for your medical practice

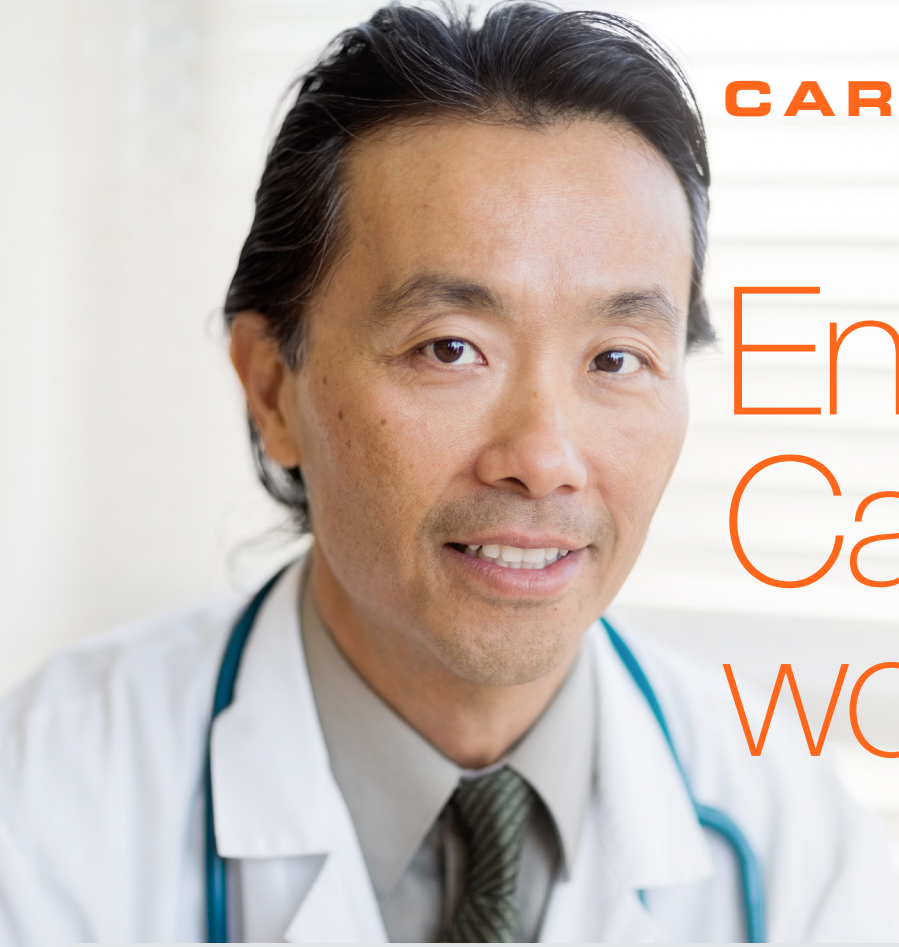


- The ECG 100L has been designed for total portability and ease of use, without compromising Cardioline's recognized quality standards.
- Particular attention has been dedicated to device usability, using a brilliant 5 inch color touch screen display, as well as dedicated keys for fast operation.
- User is guided through the ECG acquisition procedure step by step, from electrode placement, to quality checking, acquisition, printing and storage.
- Automatic, manual, Stat or rhythm ECGs can alternatively be acquired at the simple touch of a key.
- The new rhythm ECG function allows for rhythm analysis of 3 minutes of ECG, including HR trending and Variability.
- ECG files can be stored on the device or exported, through USB connection or memory stick to a specific ECG Management application for PCs, "ECG EasyApp", designed for easy but complete handling of patient ECGs.
- Glasgow algorithm for ECG interpretation is optionally available for pediatric and adult ECGs.

Technical Specifications

ECG channels	12-lead (I, II, III, aVR-L-F, V1-6)
Patient cable	Standard 15D, 10-wires
CMRR	>100dB
Input impedance	100MΩ
Sampling rate of the input stage	32000 samples/second/channel
ECG resolution	5µV/LSB; 500 s/s
Dynamic range	+/- 325 mV
Bandwidth	Performances equivalent to 0,05-150 Hz
Pacemaker detection	Hardware detection coupled with convolution digital filtering
Filters	Linear phase digital diagnostic high-pass filter (acc. to 60601-2-25 2nd ed.) 50/60 Hz AC interference adaptive digital filter Digital low pass filters at 25/40 Hz, for display and printing only
Defibrillation protection	AAMI/IEC standards
Front-end performance	ANSI/AAMI IEC 60601-2-25:2011
Acquisition mode	Automatic (12-leads), Manual (3/6-leads), Stat (12-leads), Rhythm (1/3-leads)
Configuration	Standard or Cabrera
Lead fail detection	Independent on all leads
ECG measurements	All leads, average, QT corrected, Sokolow-Lyon Index
ECG interpretation	Glasgow Analysis Program for Adults, Pediatric, STEMI
Export format	SCP-PDF
PC-ECG “Easy App”	Dedicated ECG Management application for PC





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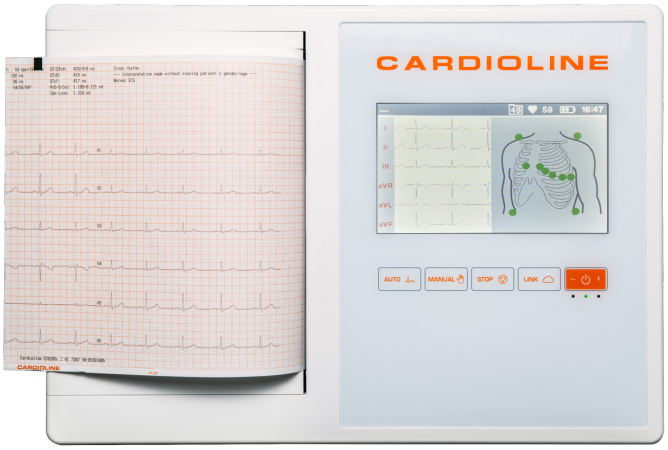
ECG200L

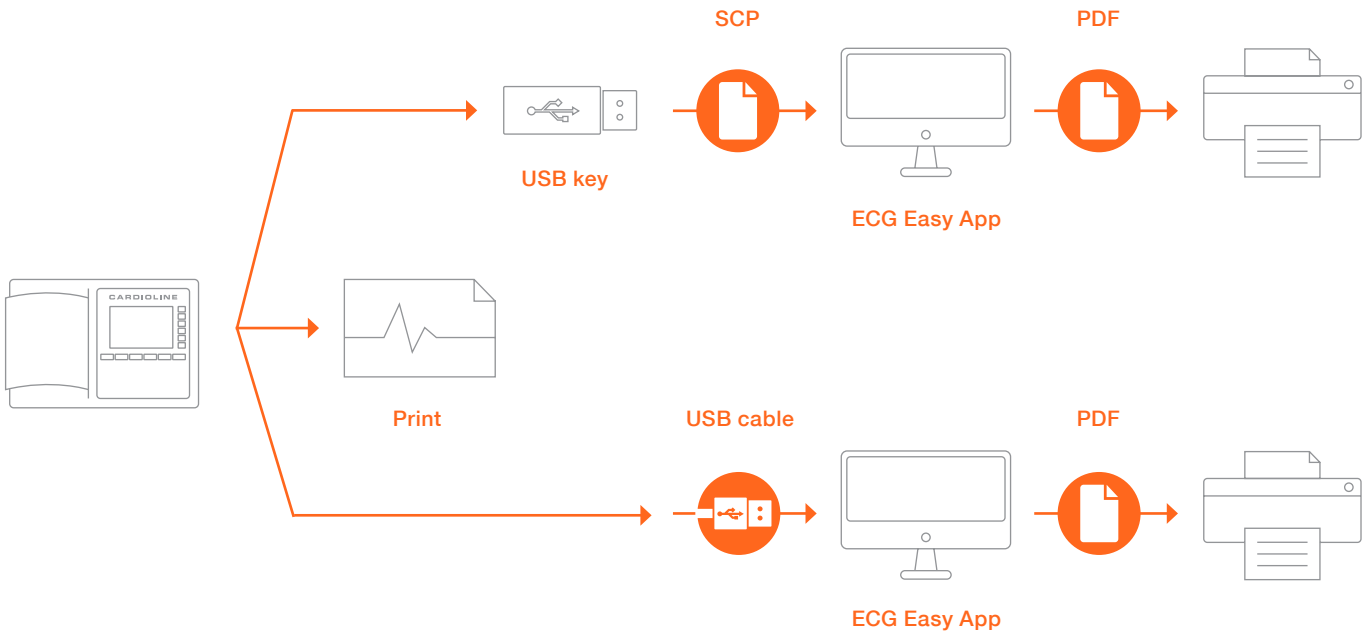
The full format 12 lead ECG for your medical practice



- The ECG 200L has been designed to provide simple and fast 12 lead resting ECG acquisition for the private practice.
- Particular attention has been dedicated to device usability using a brilliant 7 inches color touch screen display, as well as dedicated keys for fast operation.
- User is guided through ECG acquisition step by step, from electrode placement, to quality checking, acquisition, printing and storage.
- Automatic, manual, Stat or rhythm ECGs can alternatively be acquired at the simple touch of a key.
- The new Rhythm ECG function allows for rhythm analysis of 3 minutes of ECG, including HR trending and Variability.
- ECG files can be stored on the device or exported, through USB connection to a PC or a memory stick.
- Glasgow algorithm for interpretation is available for pediatric and adult ECGs.
- A specific ECG Management application for PC's, "ECG EasyApp," is designed to allow for easy but complete handling of patient ECGs.

Technical Specifications

ECG channels	12-lead (I, II, III, aVR-L-F, V1-6)
Patient cable	Standard 15D, 10-wires
CMRR	>100dB
Input impedance	100MΩ
Sampling rate of the input stage	32000 samples/second/channel
ECG resolution	5µV/LSB; 500 s/s
Dynamic range	+/- 325 mV
Bandwidth	Performance equivalent to 0,05-150 Hz
Pacemaker detection	Hardware detection coupled with convolution digital filtering
Filters	Linear phase digital diagnostic high-pass filter (acc. to 60601-2-25 2nd ed.) 50/60 Hz AC interference adaptive digital filter Digital low pass filters at 25/40 Hz, for display and printing only
Defibrillation protection	AAMI/IEC standards
Front-end performance	ANSI/AAMI IEC 60601-2-25:2011
Acquisition mode	Automatic (12-leads), Manual (3/6-leads), Stat (12-leads), Rhythm (1/3-leads)
Configuration	Standard or Cabrera
Lead fail detection	Independent on all leads
ECG measurements	All leads, average, QT corrected, Sokolow-Lyon Index
ECG interpretation	Glasgow Analysis Program for Adult, Pediatric, STEMI
Export format	SCP-PDF
PC-ECG “Easy App”	Dedicated ECG Management application for PC



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Cubeholter WS

General Information

Product name	Cubeholter WS
Generic name	Cubeholter WS
Product code	85039510
Manufacturer	Cardioline Spa Head Office and Production facility: 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, pattern generation, 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 ▪ Event analysis ▪ ST Analysis ▪ QT 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;
- Template: configurable multiple result template, to automatically add fixed text with variable tags based on the exam outcome. The available tags are as follow:
    - Datelenght, Beats, HR med, HR min, HR max, Afib, Bradycardia, SVT, VT, Pause, VEvents, SVCEvents.
- Print reservations;
- Data:
    - Trend: RR/HR, Events, ST, QT, HRV;
    - Tables: RR/HR, Events, ST, QT, HRV;
    - ECG: RRmax/RRmin, HRmax/HRmin (manually editable), Event 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 event as Supraventricular.
- SVT: Number of consecutive beats to classify an event as Supraventricular Tachycardia.
- BRA: Number of consecutive beats to classify an event as Bradycardia.
- PAU: Minimum RR value to classify an event as a Pause.
- BRA: Maximum frequency value to classify an event as Bradycardia.
- SVT: Minimum frequency value to classify an event as Supraventricular Tachycardia.
- AIVR: Minimum frequency value to classify an event as Accelerated Idioventricular Rhythm.
- VT: Minimum frequency value to classify an event 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;
- Artefacts;
- Induced heartbeat (if pacemaker analysis is active).

Detection of arrhythmic events

- Atrial fibrillation;
- Bradycardia
- Tachycardia
- Supraventricular couplets
- Supraventricular save
- Idioventricular rhythm (accelerated)

- Supraventricular tachycardia
- Ventricular couplets
- 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 events:
  - Enter/edit an event;
  - 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: 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 event;
- 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, induced, link to supraventricular events;
- 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
Event 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; ▪ Events displayed: SVEB, DEL, SVS, SVT, NOR, APB, AAB, BRA, AR, AT, ASVT, AFLU, AFIB, VEB, ESC, CPT, IVR, AIVR, VT, BYG, TRI1, TRI2, VFLU, VFIB, QUAD, JPB, JR, AJR, PAU, more manual events 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
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

Compatible Devices

Leaflet

USB protection key

USB connection cable

CD ROM with Cubeholter software

Software back-up USB key

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ECG100L

General Information

Product Name	ECG100L
General Name	ECG100L
Product Code	80508097
Manufacturer	Cardioline Spa Registered Office and Factory: Via Linz, 151 38121 Trento Italy Sales Office: Via F.lli Bronzetti, 8 20129 Milan Italy
Device Description	The device is a 12-lead, fully diagnostic PORTABLE electrocardiograph which displays, acquires, prints and stores ECG tracings, for adults and children, together with its measurements.. ECG100L is characterized by a useful 5" colour touchscreen display, from which all operations can be easily performed. A smart user interface guides the user through the different steps necessary to acquire the electrocardiogram. Various messages on the screen visually inform the user of the ongoing operations and warn him in case of errors (for example in case of lead fail). The device is equipped with USB to export the ECG stored in the device memory. The device can be supplied with the optional 12-lead Glasgow resting ECG interpretation algorithm, with specific criteria by age, sex and race. If this option is enabled, the algorithm provides full ECG interpretation in short or extended form, including infant, pediatric and acute ST elevation myocardial infarction detection. For further information on the resting ECG interpretation algorithm, see the Guidance for the physician on the application on adults and children (see accessories list). The device is battery or mains operated. The printing formats supported include: standard or Cabrera 3, 3+1, 3+3 or 6 channels in automatic mode and 3, 6 or 12 printout channels in continuous mode, as well as printout of the rhythm strip. It is possible to export the exams on a key or USB to a PC software application named ECGEasyApp.

Technical Specifications

ECG Acquisition

ECG channels	12-lead (I, II, III, aVR-L-F, V1-6)
Patient Cable	Standard 15D connector, 10 wires patient cable
CMRR	> 100dB
Input impedance	100MΩ
A to D converter	16 bit, 32000 samples/second/channel
Sampling rate of the input stage	32000 samples/second/channel
Sampling rate for signal analysis	500 samples/second/channel

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A/D conversion	16 bit
Output Data Resolution	5 µV/LSB
Dynamic Range	+/- 325 mV
Bandwidth	Performances equivalent to 0,05-150 Hz
Pacemaker detection	Hardware detection coupled with convolution digital filtering
Defibrillation Protection	AAMI/IEC standards
Front-end performance	ANSI/AAMI IEC 60601-2-25:2011
Acquisition Mode	Automatic (12 leads), Manual (3/6 leads), Stat (12 leads), Rhythm (1 Lead for 3 minutes or 3 Leads for 1 minute)
Lead Configuration	Standard, Cabrera
Processing	
Pace detection	Hardware detection in compliance with the requirements 60601-2-25
Lead fail detection	Independent on all leads
Heart Rate Meter	30 - 300 bpm
Filters	Linear phase digital diagnostic high-pass filter (according to 60601-2-25 2nd ed.) 50/60 Hz AC interference adaptive digital filter Digital low pass filters at 25/40 Hz, for display and printing only
ECG Measurements	All leads, average, corrected HR Average RR PR Interval QRS duration QT interval and QTc interval, with Hodges, Bazzet and Fridericia's formula max R[V5]or[V6] and S[V1] Sokolow-Lyon Index P, R, T axis.
ECG Interpretation	Glasgow Analysis Program for Adults, Pediatric, STEMI (optional)
ECG Interpr. Data input	Sex, age
Storage	50 ECG
Available languages	Brazilian, Czech, Croatian, French, English, Italian, Polish, Portuguese, Romanian, Russian (with Russian keyboard), Serbian, Spanish, German, Turkish, Hungarian, Brazilian, Dutch
Autotest	The device performs an auto-test of its internal electronic functions at every start up.
Processing Options	
Interpretation	Glasgow Analysis Program for Adults, Pediatric, STEMI
Supported export formats	
SCP	Standard
PDF	Through a dedicated application for files management on Personal Computer
Connectivity	
USB	Standard
Display	
Display Type	5" TFT Backlit Color LCD with Resistive Touch Panel
Display resolution	800x480

Display data	3/6/12 leads realtime
Display formats	6x2, 6x1, 3x1
Keyboard	
Keyboard Type	Touchscreen plus functional dedicated keys
Dedicated Keys	AUTO, MANUAL, STOP, LINK
Printer	
Technology	108 mm Thermal printhead
Resolution	8 dots/mm
Paper Type	thermal paper roll 100mm x 20m
Sensitivity/Gain	5, 10, 20 mm/mV
Auto print speed	5, 10, 25, 50 mm/s
Auto print	3, 3+1, 6 channels; Standard or Cabrera
Manual print speed	5, 10, 25, 50 mm/s
Manual Print	3/6/12 channels; Standard o Cabrera
Rhythm Print	1 minute 3 leads; 3 minutes 1 lead HR Trend HR statistics
Printing formats	6x2, 6+6, 3x4, 3x4+1, 3x4+3
Calibration signal	Yes, 1 mV
Lead marker	Yes, before each lead trace
USB External Peripherals	
External data storage	USB memory stick (for data export)
Electrical Characteristics	
Power source	External power supply or internal rechargeable battery
Power supply	Medical grade - Mod. AFM60US18 - XP Power Limited
Input Voltage power supply	100-240 Vac
Input Current power supply	1.5-0.9 A
Input frequency power supply	50/60 Hz
Rated Output power supply	60 W, 18 V, 3.34 A
Protection Class power supply	I
Degree of Protection power supply	IP20
Battery Type	NiMH
Battery Duration	more than 500 ECGs – more than 6h
Battery Charging Time	4 hours to 85% full capacity
Physical Characteristics	
Dimensions	270x190x60 mm
Weight	1,48 Kg
Shipping container	360x360x250 mm - 4Kg

Operating Environmental Specifications	
Temperature	+10°C - +40°C
Humidity	50% - 90%
Pressure	700hPa - 1060hPa

Storage Environmental Specifications	
Temperature	5°C - +40°C
Humidity	20% - 90%
Pressure	700hPa - 1060hPa

Regulatory and Safety

Classification according MDD 93/42/CEE	
Class	Class IIa
Rationale	rule 10 annex IX 93/42/EEC Directive and its amendments
Notified body	TUV (1936)

Classification according to FDA regulation	
Classification:	In progress
Product Code:	In progress
Review Panel:	In progress
Regulation Number:	In progress

Classification according to IEC 60601-1 - Electrical Safety	
Protection against electric shock:	IP (internal power ME) - class I on the external AC/DC
Applied parts:	type CF – defibrillation-proof
Protection against harmful ingress of water or particular matter:	IPX0
Method(s) of sterilization:	NA (not intended to be sterilized)
Suitability for use in an oxygen rich environment:	No
Mode of operation:	continuous operation

Classification according to IEC 60601-1-2 - Electro Magnetic Compatibility	
Group	1
Class	B

Performances	
Standard	EN 60601-2-25:2011

Other classifications	
GMDN	110407 - Electrocardiographs, Multichannel, Interpretive
CND	Z12050302 - ELETTROCARDIOGRAFI PER DIAGNOSI AVANZATA
RDM (Registration number in Italy)	1614799

Applicable Standards

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 1041	Information supplied by the manufacturer of medical devices
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
EN ISO 14971	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
EN 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2	Medical electrical equipment - Part 1-2: 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 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 62366	Medical devices - Application of usability engineering to medical devices
EN 60601-2-25	Medical electrical equipment - Part 2-25: Particular requirements for the safety of electrocardiographs

Product codes and accessories

Accessories

63030105	Set of 4 Peripheral ECG electrodes clamp Ag/AgCl
63030106	Set of 4 peripheral ECG electric clamp Ag/AgCl
63030107	Set of 4 peripheral ECG electric clamp pediatric Ag/AgCl
63030163	Set of 6 chest ECG electric suction type Ag/AgCl
63050025	ECG patient cable IEC, 10 lead, plug 4 mm
63050068	ECG patient cable AHA, 10 lead, plug 4 mm
63050108	ECG patient cable IEC, 10 lead, snap 180cm
63050109	ECG patient cable AHA, 10 lead, snap
63050032	ECG patient cable IEC-10 CLIP 4 mt
66030031C	Disposable electrodes ECG, snap, 50 pcs
66030040C	Disposable electrodes ECG, tab, 100 pcs; pack of 10
66030036C	Disposable electrodes ECF neonatal, 25 pcs
66030037C	Disposable electrodes ECG banana, 60 pcs
63090236	Set of 10 snap adapters for 4 mm plug
66020008	Adapters for tab and button electrodes for 4 mm plug, 10 pcs
66010055C	Paper Roll 100mm x 20m (ECG100L); 5 pcs
67010223	Carrying case “Cardioline ECG 100”
63090712	ECG100+/S/L trolley II Edition

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ECG200L

General Information

Product Name	ECG200L
General Name	ECG200L
Product Code	80608070
Manufacturer	Cardioline Spa Registered Office and Factory: Via Linz, 151 38121 Trento Italy Sales Office: Via F.lli Bronzetti, 8 20129 Milan Italy
Device Description	The device is a 12-lead, fully diagnostic electrocardiograph which displays, acquires, prints and stores ECG tracings, for adults and children, together with its measurements.. ECG200L is characterized by a useful 7" colour touchscreen display, from which all operations can be easily performed. A smart user interface guides the user through the different steps necessary to acquire the electrocardiogram. Various messages on the screen visually inform the user of the ongoing operations and warn him in case of errors (for example in case of lead fail). The device is equipped with USB to export the ECG stored in the device memory. The device can be supplied with the optional 12-lead Glasgow resting ECG interpretation algorithm, with specific criteria by age, sex and race. If this option is enabled, the algorithm provides full ECG interpretation in short or extended form, including infant, pediatric and acute ST elevation myocardial infarction detection. For further information on the resting ECG interpretation algorithm, see the Guidance for the physician on the application on adults and children (see accessories list). The device is battery or mains operated. The printing formats supported include: standard or Cabrera 3, 3+1, 3+3, 6 or 12 channels in automatic mode and 3, 6 or 12 printout channels in continuous mode, as well as printout of the rhythm strip. It is possible to export the exams on a key or USB to a PC software application named ECGEasyApp.

Technical Specifications

ECG Acquisition

ECG channels	12-lead (I, II, III, aVR-L-F, V1-6)
Patient Cable	Standard 15D connector, 10 wires patient cable
CMRR	> 100dB
Input impedance	100MΩ
A to D converter	16 bit, 32000 samples/second/channel
Sampling rate of the input stage	32000 samples/second/channel
Sampling rate for signal analysis	500 samples/second/channel

CARDIOLINE

A/D conversion	16 bit
Output Data Resolution	5 µV/LSB
Dynamic Range	+/- 325 mV
Bandwidth	Performances equivalent to 0,05-150 Hz
Pacemaker detection	Hardware detection coupled with convolution digital filtering
Defibrillation Protection	AAMI/IEC standards
Front-end performance	ANSI/AAMI IEC 60601-2-25:2011
Acquisition Mode	Automatic (12 leads), Manual (3/6/12 leads), STAT (12 leads), Rhythm (1 Lead for 3 minutes or 3 Leads for 1 minute)
Lead Configuration	Standard, Cabrera
Processing	
Pace detection	Hardware detection in compliance with the requirements 60601-2-25
Lead fail detection	Independent on all leads
Heart Rate Meter	30 - 300 bpm
Filters	Linear phase digital diagnostic high-pass filter (according to 60601-2-25 2nd ed.) 50/60 Hz AC interference adaptive digital filter Digital low pass filters at 25/40 Hz, for display and printing only
ECG Measurements	All leads, average, corrected HR Average RR PR Interval QRS duration QT interval and QTc interval, with Hodges, Bazzet and Fridericia's formula max R[V5]or[V6] and S[V1] Sokolow-Lyon Index P, R, T axis.
ECG Interpretation	Glasgow Analysis Program for Adults, Pediatric, STEMI
ECG Interpr. Data input	Sex, age
Storage	50 ECG
Available languages	Brazilian, Czech, Croatian, Dutch, French, English, Italian, Polish, Portuguese, Romanian, Russian (with Russian keyboard), Serbian, Spanish, German, Turkish, Hungarian
Autotest	The device performs an auto-test of its internal electronic functions at every start up.
Processing Options	
Interpretation	Glasgow Analysis Program for Adults, Pediatric, STEMI (optional)
Supported export formats	
SCP	Standard
PDF	Through a dedicated application for files management on Personal Computer
Connectivity	
USB	Standard
Display	
Display Type	7" TFT Backlit Color LCD with Capacitive Touch Panel
Display resolution	800x480

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Display data	3/6/12 leads real-time
Display formats	12x1, 6x2, 6x1, 3x1
Keyboard	
Keyboard Type	Touchscreen plus functional dedicated keys
Dedicated Keys	AUTO, MANUAL, STOP, LINK
Printer	
Technology	216 mm Thermal printhead
Resolution	8 dots/mm
Paper type	Thermal paper: roll 210x3000 mm – z-fold A4 295x210mm – letter 280x216mm
Sensitivity/Gain	5, 10, 20 mm/mV
Auto print speed	5, 10, 25, 50 mm/s
Auto print	3, 3+1, 6 channels; Standard or Cabrera
Manual print speed	5, 10, 25, 50 mm/s
Manual Print	3/6/12 channels; Standard o Cabrera
Rhythm Print	1 minute 3 leads; 3 minutes 1 lead HR Trend HR statistics
Printing formats	12x1, 6x2, 6+6, 3x4, 3x4+1, 3x4+3
Calibration signal	Yes, 1 mV
Lead marker	Yes, before each lead trace
USB External Peripherals	
External data storage	USB memory stick (for data export)
Electrical Characteristics	
Power source	Internal power supply and internal rechargeable battery
Input Voltage	100-240 Vac
Input Current	1.5-0.75 A
Input frequency	50/60 Hz
Rated Output	60 W, 18 V, 3.34 A
Protection Class	I
Battery Type	NiMH
Battery Duration	more than 500 ECGs – more than 6h
Battery Charging Time	4 hours to 85% full capacity
Physical Characteristics	
Dimensions	413x295x80 mm
Weight	4,17 Kg
Shipping container	580X470X280 mm – 7Kg
Operating Environmental Specifications	
Temperature	+10°C - +40°C

Humidity	50% - 90%
Pressure	700hPa - 1060hPa

Storage Environmental Specifications

Temperature	5°C - +40°C
Humidity	20% - 90%
Pressure	700hPa - 1060hPa

Regulatory and Safety

Classification according MDD 93/42/CEE

Class	Class IIa
Rationale	rule 10 annex IX 93/42/EEC Directive and its amendments
Notified body	TUV (1936)

Classification according to FDA regulation

Classification:	In progress
Product Code:	In progress
Review Panel:	In progress
Regulation Number:	In progress

Classification according to IEC 60601-1 - Electrical Safety

Protection against electric shock:	Internal power - class I
Applied parts:	type CF – defibrillation-proof
Protection against harmful ingress of water or particular matter:	IPX0
Method(s) of sterilization:	NA (not intended to be sterilized)
Suitability for use in an oxygen rich environment:	No
Mode of operation:	continuous operation

Classification according to IEC 60601-1-2 - Electro Magnetic Compatibility

Group	1
Class	B

Performances

Standard	EN 60601-2-25:2011

Other classifications

GMDN	110407 - Electrocardiographs, Multichannel, Interpretive
CND	Z12050302 - ELETTROCARDIOGRAFI PER DIAGNOSI AVANZATA
RDM (Registration number in Italy)	1760532

Applicable Standards

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 1041	Information supplied by the manufacturer of medical devices
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
EN ISO 14971	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
EN 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2	Medical electrical equipment - Part 1-2: 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 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 62366	Medical devices - Application of usability engineering to medical devices
EN 60601-2-25	Medical electrical equipment - Part 2-25: Particular requirements for the safety of electrocardiographs

Product codes and accessories

Accessories

63030105	Set of 4 Peripheral ECG electrodes clamp Ag/AgCl
63030106	Set of 4 peripheral ECG electric clamp Ag/AgCl
63030107	Set of 4 peripheral ECG electric clamp pediatric Ag/AgCl
63030163	Set of 6 chest ECG electric suction type Ag/AgCl
63050025	ECG patient cable IEC, 10 lead, plug 4 mm
63050068	ECG patient cable AHA, 10 lead, plug 4 mm
63050108	ECG patient cable IEC, 10 lead, snap
63050109	ECG patient cable AHA, 10 lead, snap
63050032	ECG patient cable IEC-10 CLIP 4 mt
66030031C	Disposable electrodes ECG, snap, 50 pcs
66030040C	Disposable electrodes ECG, tab, 100 pcs; pack of 10
66030036C	Disposable electrodes ECF neonatal, 25 pcs
66030037C	Disposable electrodes ECG banana, 60 pcs
63090236	Set of 10 snap adapters for 4 mm plug
66020008	Adapters for tab and button electrodes for 4 mm plug, 10 pcs
66010052S	Z-Fold paper A4 210x295mm (ECG200L)
66010053S	Z-Fold paper Letter 210x295mm (ECG200L)
63090713	ECG200+/S/L trolley II Edition hospital grade

CARDIOLINE

pneumos500

pneumos500 is a portable spirometer that can measure the most important respiratory parameters such as FVC, VC, and MVV.

pneumos500 is compact and lightweight (it weighs only 300 g) and is provided with a large 3.3" color display with a touch-screen user interface showing the patient's data and examinations.
To allow you using the device in a more intuitive manner, a video tutorial on the display describes in detail the procedures to be followed.

The ultrasonic measurement system with patented IDEGEN technology has no mechanical moving parts which makes the instrument particularly reliable. The IDEGEN patent uses three ultrasonic sensors that are able to measure the direction and the flow of air with extreme accuracy, this without any latency time, typical of the turbine systems.

Among the accessories available for the **pneumos**500, there is a disposable mouthpiece. This is the only part in direct contact with the patient. It is made with white paper free of chlorine and toxic materials and is finished externally with a special film to prevent the sticking of the lining of the mouth. Due to its high quality characteristics, The mouthpiece is certified in class IIa according to the Medical Device Directive.

The internal memory of the **pneumos**500 handles up to 20,000 tests/patients. The **pneumos** software supplied allows the direct control of the device, displaying the "real time" examination data, the download of the exams stored from **pneumos**500 to a database. You can also review, display and print reports of the examinations through customizable reports. Thanks to the **pneumos** software, you can print reports in Dicom format and transfer data via GDT and HL7.

The main features of the product are as follows:

- Database of the patients and tests
- Management and printing software
- Automatic comparison of the values measures with the theoretical ones
- Graphical, touch screen 1/4 VGA (320 X 240 pixels), 256 k colors interface
- Ultrasound technology with no moving part inside
- Automatic calibration
- Internal rechargeable battery

Note:
Manufacturer USCOM Kft - Bogdanfy str. 10 – Budapest H-1117

Reference markets

- Pulmonology surgery
- Cardiology surgery
- Sports medicine
- Occupational medicine
- Home nursing service

CARDIOLINE

Technical features

pneumos500

Parameters measured:……..	FVC, VC, PEF, FEV1, FEV1/FVC, FEF2575, FEF2550, FEF25, FEF50, FEF75, FEV3, FEV6, EV, ZeroTime, FET, PEFT, FIVC, PIF, FIV1, FIV1/FIVC, FIT, EVC, IVC, IC, IRV, ERV, TV.
Memory capacity:……	The device can store up to 20,000 patients and /or measurements.
Display:……	1/4 VGA (320X240 pixels), 262k colors touch-screen
Communication ports:……	Connection to the PC via a USB
Measurement system:……..	IDEGEN™ technology
Measurement principle:……...	IDEGEN™ ultrasonic multiple-path
Maximum value:……	± 20 l
Flow range:……	± 18 l/s
Volume accuracy:……	± 3% or 50 ml
Flow accuracy:……	± 3% or 50 ml/s
Sampling frequency:……	100 Hz
Dynamic resistance at 14 l/s:……	< 110 Pa/l/s
Internal battery:……	3,7 V Li-Ion (rechargeable via 5V 500mA miniUSB)
Electrical protection:……	Internal power supply
Electric protection level:……	BF
Device dimensions:……..	92x80x35 mm
Flowmeter dimensions:……	⌀30 mm X 150 mm
Weight:……..	300 g
Use and storage conditions:	
Temperature:……	10-40°C
Relative humidity:……	5 - 95%, non-condensing

CARDIOLINE

pneumos500

Standard accessories supplied

Description	
Pneumos PC software	1
Disposable bacterial filter	1
Battery charger	1
USB cable	1
Device case	1
Plastic noseclip	1
Warranty months	24

Accessories

Code	*Description*
67040208	Disposable Kit 50pcs – Bacterial Filter + Mouthpiece spiro
67040015	Plastic mouthpiece, pack of 100 pieces
67040016	Reusable bacterial filter
67040017	Disposable bacterial filter insert, pack of 100 pieces
60401007	Disinfectant
67040018	Pneumos PC software
65090056	Bag, "Cardioline 60" model
89100154	Plastic noseclip 10 pcs
62000034	PC desktop & monitor TFT 22”
62000031	W/B printer

CARDIOLINE

Walk400h

General Information

Product name	Walk400h
Generic name	Walk400h
Product code	81018030
Manufacturer	Cardioline Spa Head Office and Production facility: Via Linz, 151 38121 Trento Italy Sales Office: Via F.lli Bronzetti, 8 20129 Milan Italy
Description of Device	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. 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 and the option of using rechargeable batteries allows you to contain the costs of the material.

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
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 *at the moment this function isn't managed by Cardioline Cubeholter software

Electrical features

Power supply	1 standard AA battery: ▪ Alkaline ▪ Lithium
Battery life	Alkaline battery (2500 mAh): ▪ More than 48h of recording (10 wire cable, 1000 Hz) Lithium Battery (3000mAh): ▪ 7 days of recording (10 wire cable) Possibility of replacing the battery without interrupting the 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	90 gr
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

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)

CARDIOLINE

Enter the Cardioline world

walk400h

Next generation 3-12 lead ECG Holter recorder - up to 7 days and to 1000 Hz

- High resolution recordings with user selectable sampling rates of 250/500/1000 samples/second.
- 5/7/10 wires patient cable for 3 to 12 lead recordings.
- Signal bandwidth equivalent or superior to resting ECG.
- Recordings up to 7 days.
- Simple and intuitive user interface. Recorder is equipped with a color LCD display with 4-way joystick that allows for easy navigation of menus.
- Voice recorder for patient identification.
- Light and small: only 100g for maximum patient comfort.

CARDIOLINE

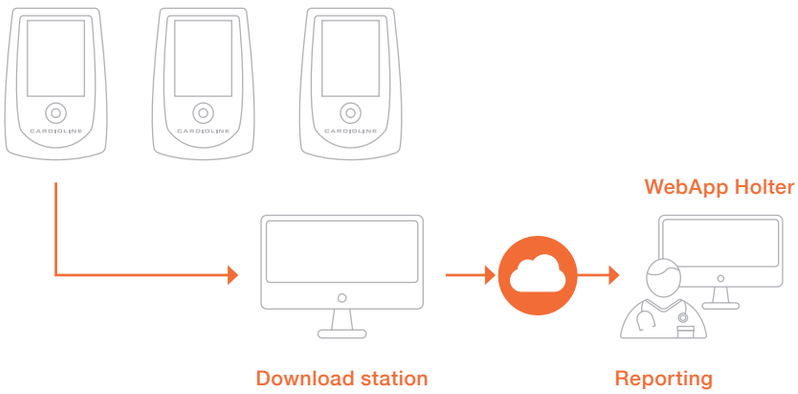
walk400h

Technical Specifications

ECG leads	Up to 12-Leads
Patient cable	5 wire cable – 3 unipolar channels 7 wire cable – 3 bipolar channels 10 wire cable – 8 channels/12 Leads (standard ECG assembly)
CMRR	> 85dB
Input DC impedance	> 60MOhm
A/D converter	24 bit 96000 samples/second/channel
ECG resolution	<1 µV/LSB
Dynamic range	+/- 400 mV
ECG bandwidth	Performance equivalent to 0,05 - 300 Hz (at 1000 c/s)
Filters	Linear phase digital diagnostic high-pass filter (compl. with IEC 60601-2-25 2nd ed.)
Pacemaker detector	Hardware detection combined with digital convolution filtering Complies with 60601-2-47 201.12.4.4.109.
Patient cable recognition	Automatic identification of patient cable used
Maximum recording duration	500/1000 samples/second/channel: 48 hours 250 samples/second/channel: 7 Days Regardless of the number of channels
Internal memory	16 GB SD data card Capacity above 100 3-channel recordings, 24 hours at 250 c/s
Data transfer	USB 2.0

Holter recordings can be downloaded via USB from the recorder to Cardioline CubeHolter SW for analysis and report generation.

Holter recordings from different recorders can be uploaded to the Cardioline Web Holter remote for analysis and report generation. Ideal for TeleHealthcare applications.



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 electrical medical devices and medical software for cardiology

Through an Audit, Report No. 28111372 001, 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 2018-04-25 to 2021-04-24.

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

Milan, 2018-04-24. First Certification: 2012-06-13

The certification responsible
TÜV Rheinland Italia S.r.l., Via E. Mattei, 3 - I - 20010 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° 083A SGA N° 052D

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC

Signatory of EA, IAF and ILAC Mutual Recognition Agreement

TÜVRheinland CERTIFIED

Management System EN ISO 13485:2016

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