AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
3. Certificatul CE	Certificat CE
2. Declarația de conformitate CE	Declaratii de conformitate CE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
						cardioline				
DM000499863	SOFT PENTRU ANALIZARE ȘI PRELUCRARE ECG		CUBEHOLTER WS	85039510	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499873	SOFT PENTRU ANALIZARE ȘI PRELUCRARE ECG		ECGWEBAPP	81019560	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499877	ELECTROCARDIOGRA AMBULATYOR HOLTER		WALK400H	81018030 / 8101012X	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499867	ELECTROCARDIOGRA		ECG100+	80508095, 8050959X, 8050929X, 80508195, 8050939X	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499860	ELECTROCARDIOGRA		CLICKECG-HD 15	81018428	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499868	ELECTROCARDIOGRA		ECG100L	80508097, 8050979X	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499874	ELECTROCARDIOGRA		HD+ 12	81018231 – 81018331	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499870	ELECTROCARDIOGRA		ECG200+	80608068, 80608068S, 8060957X, 8060927X, 80608168, 8060957X	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499869	ELECTROCARDIOGRA		ECG100S	80508096, 8050959X, 8050929X, 80508196, 8050939X	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499876	ELECTROCARDIOGRA AMBULATOR HOLTER DE TENSIUNE ARTERIALA		WALK200B	87018307 – 87018308 – 87019308 - 87019305 – 87019305-C	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	

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AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

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I.3. Certificatul CE	Certificat CE
I.2. Declarația de conformitate CE	Declaratii de conformitate CE

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Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
						cardioline				
DM000499864	SOFT PENTRU ANALIZARE ȘI PRELUCRARE ECG		CUBESTRESS	85050100	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499862	SOFT PENTRU ANALIZARE ȘI PRELUCRARE ECG		CUBEHOLTER WEB	85039520	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499865	SOFT PENTRU ANALIZARE ȘI PRELUCRARE ECG		CUBESTRESS SYSTEM	KSSXYYZWJ-@	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499899	SOFT PENTRU ELECTROCARDIOGRA	CARDIOLINE	ECGWEBAPP	81019594	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499866	SOFT PENTRU ANALIZARE ȘI PRELUCRARE ECG		CUBE SUITE	81019557	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499861	ELECTROCARDIOGRA AMBULATYOR HOLTER		CLICKHOLTER	81018031, 8101012X	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499875	ELECTROCARDIOGRA		HD+ 15	81018228 – 81018328	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499900	SOFT PENTRU ELECTROCARDIOGRA	CARDIOLINE	ECGWEBAPP HOLTER	81019595	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499872	ELECTROCARDIOGRA		ECG200S	80608069, 80608069S, 8060957X, 8060927X, 80608169, 8060957X	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499871	ELECTROCARDIOGRA		ECG200L	80608070, 8060979X	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	

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CARDIOLINE

Cubestress

General Information

Product name	Cubestress
Product code	85050100
Manufacturer	Cardioline SpA Head Office and Production facility: Via Linz, 151 38121 Trento Italy
Description of Device	Cubestress is a Windows software for performing and reviewing stress tests. ECG data are acquired via the acquisition unit HD+, HD+ 12 or HD+ 15, connected to the computer via Bluetooth (using the Cardioline HD+ Dongle) or USB. Depending on the HD+ model and the patient cable used, 12 or 15 ECG leads can be acquired: HD+ and HD+ 12 can acquire 12 leads, HD+ 15 can acquire 12 or 15 leads. Cubestress can control an ergometer (treadmill or bike) via predefined or user-defined protocols and via customisable generic protocols. External NIBP and/or SPO2 monitoring devices can also be controlled (optionally). If external NIBP or SPO2 devices are present, NIBP or SPO2 measurements can be carried out automatically by the software, which controls the devices and acquires the measurement, or manually by the user, who can enter them by typing them in Cubestress Cubestress acquires ECG data and processes them to calculate and infer the typical measurements and parameters of a stress test: ▪ Heartbeat detection (with automatic channel selection) ▪ Classification of heartbeats ▪ Detection and classification of arrhythmic events ▪ ST level and slope, ST/HR, dual product ▪ QT and QTc At the end of the test, Cubestress generates a PDF report containing ECG traces, trends and other data forming the results of the analysis. During the test, Cubestress can generate print-outs either in 'Auto' mode (10s ECG print-out) or in continuous mode (continuous ECG printing). Compatible printers are the Cardioline thermal printer (200P) and/or laser printers that meet the minimum requirements defined. Cubestress is not backwards-compatible with versions 3.xx or lower. Cubestress can be equipped with a Cardiopulmonary option. When this option is present and enabled, Cubestress can connect to a cardiopulmonary system that implements the "XSCRIBE CP Cardiopulmonary interface rev.1" communication protocol. When Cubestress is in Cardiopulmonary mode, it carries out a stress test fully guided by the cardiopulmonary system which it is connected to: it receives the values set or acquired from any other devices connected to the cardiopulmonary system and displays them within its user interface and, in turn, sends the Heart Rate and ST measurements to the Cardiopulmonary system. At the end of the test, Cubestress creates a PDF report, displaying the acquired data (trends, tables, strips, etc.), and sends it to the cardiopulmonary system for reviewing. The conclusions of the medical report are drawn up in the cardiopulmonary system, with the physician's signature.

Intended use

Cubestress is intended for performing and reviewing cardiovascular exercise stress testing. It is designed to analyse and display ECG signals, acquired with the HD+ series devices, and other biometric parameters (NIBP, SpO2), acquired with external devices, during cardiovascular exercise stress tests for the assessment and diagnosis of cardiac functions.
Cube stress also allows to review and post analyze a stress test examination previously executed and recorded.
When used in 'Cardiopulmonary' mode, Cubestress is designed to carry out cardiovascular exercise stress tests guided by an external Cardiopulmonary system. Its purpose is to analyse and display ECG signals, acquired with the HD+ series unit, as well as display other biometric data (NIBP, SpO2), acquired with external devices driven by the cardiopulmonary system, during the performance of cardiovascular stress tests for the assessment and diagnosis of cardiac functions. In this mode, Cubestress does not allow the conclusions to be written in the final medical report nor the physician to sign, as these functions are carried out within the cardiopulmonary system.
The device is indicated for use in clinical settings, by a licensed physician trained in the use of ECG stress test systems or by trained personnel who are acting on the orders of a licensed physician. It is not intended as a sole mean of diagnosis.
The device is not intended to be used as a vital signs physiological monitor.
The device is intended for assessment and diagnosis of cardiac functions. In any case the results of analysis performed by Cubestress must be validated by a Clinician.

- The device is indicated for use to display, store and analyse ECG signals during the execution of cardiovascular stress tests
- The device is indicated for use to provide analysis of data for consideration by a physician.
- The device is not intended as a sole mean of diagnosis.
- The analysis of Cubestress data offered by the device are only significant when used in conjunction with a physician over-read as well as consideration of all other relevant patient data.

Cubestress System functions

- Directly entering / editing patient information.
- Acquire and analyze ECG data under stress
- Execute a stress test using and programming ergometers according with a selected protocol or pharmacologically induced
- Print results on thermal and/or laser printer
- Review and replay the exercise
- Produce a report in PDF format
- Import work-list and export final report

Stress test execution

- User selects an order for the patient or insert the patient demographics.
- User selects target HR as percentage of Max HR or insert it manually
- User connects the HD+ acquisition module
- The operator places the electrodes and checks them with the help of the impedance measurement
- User reviews the quality of the real-time waveform and adjusts settings if necessary.
- User selects a stress protocol or confirm the proposed protocol (the last used protocol)
- User executes pre-exercise test , collects up to three 10 s. resting ECG (respectively supine, standing and hyperventilation and acquires the basal parameters ECG medians and fiducial points, BP and SPO2, if present.,
- User places the patient on the chosen ergometer or in case of pharmacologic test gives the stress inducing drug
- User starts stress test
- User analyses the Ecg and diagnostic parameters during the exam and insert comments

	▪ User may start a continuous printout, using the default printout configuration (lead number, speed, gain) ▪ User may take one or more NIBP measures manually or via dedicated equipment, in addition to the one proposed by the stress protocol. ▪ User may start an automatic printout according with auto printout configuration ▪ The operator can mark an event or enter a score on the RPE scale ▪ The operator switches to voluntary recovery or carries out all steps of the protocol. ▪ The operator can start reviewing during recovery ▪ User ends the stress test ▪ User reports the exam ▪ User produces and exports a PDF
Stress test review	▪ User selects a patient. ▪ User reviews the test ▪ User analyses the Ecg and diagnostic parameters and insert comments ▪ User edits the exam report ▪ User produces and exports a PDF final report
Analysis results	▪ Beat detection (with auto channel selection) ▪ Beat classification ▪ Arrhythmic events classification ▪ ST level and slope, ST/HR

Technical Specifications

ECG acquisition (HD+ unit)

ECG leads	12-leads (I, II, III, aVR-L-F, V1-6) with HD+ and HD+ 12 15-leads (I, II, III, aVR-L-F, V1-6, E1-3) with HD+ 15
Patient cable	10 wire (HD+, HD+ 12, HD+ 15) or 13 wire (HD+ 15) replaceable patient cable
CMRR	>100dB
DC input impedance	>100MΩ
A/D converter	Up to 24 bit
Sampling rate of the input stage	128,000 samples/second/channel
Sampling rate for signal analysis	1000 samples/second/channel 500 samples/second/channel Selected via software
A/D conversion	20 bit
Resolution	<1 µV/LSB
Dynamic range	+/- 500 mV
Bandwidth	300 Hz (@1000 c/s) 150Hz (@500 c/s)
Pacemaker detection	Hardware detection coupled with digital convolution filter, in compliance with the requirements 60601-2-25 (HD+ acquisition unit)
Defibrillation protection	AAMI/IEC standard
Front-end performance	ANSI/AAMI IEC 60601-2-25:2011
Data transfer	Connectivity HD+12/15: • Bluetooth with Cardioline Dongle 2.0 • HD+ USB option Connectivity HD+: • Bluetooth with Cardioline Dongle 1.0

Processing

Operating system	Windows 10 or higher
Lead-fail detection	Independent for all leads
Cardiac frequency range	30 - 300 bpm
Filters	Linear phase digital diagnostic high-pass filter (according to 60601-2-25 2nd ed.), Automatic baseline drift control filter 50/60 Hz AC interference adaptive digital filter
Noise-removal filters	25/40/150 Hz digital low pass filters, for display and F printing only SENSA Filter (Stress ECG Noise Suppression Algorithm)

Main features

Data displayed

Data always present and displayed:

- Patient Info (first and last name, id, age, sex)
- HR, Max HR, Target HR and % of target HR

Data displayed only during the test:

- St level
- Double Product
- Blood pressure
- SpO2 level
- Mets
- ST/HR index
- Pre-test electrodes check and resting ECG acquisition
  - Real-time traces 6x2/12 channels (10-wire cable) or 6X2+3/15 channels (13-wire cable)
  - Electrode impedance control
  - Electrodes check digital
- Pre-exercise phase
  - Real-time ECG channels (10-wire cable) or 6X2+3/15 channels (13-wire cable)
  - Compacted ECG (Full disclosure 1 channel)
  - Averaging 12/13 leads Real Time
  - Zoomed average heartbeat for a user-defined lead or lead showing maximum ST segment change. ST level and slope are also displayed
  - Arrhythmias or user events strip
  - ST profile view
  - Protocol name
  - Protocol phase/stage
  - Ergometric parameters
- Exercise phase:
  - Real-time ECG channels (10-wire cable) or 6X2+3/15 channels (13-wire cable)
  - Averaging 12/15 leads Real time with Baseline averaging superimposition
  - Compacted ECG (Full disclosure 1 channel) (optional)
  - Zoomed average heartbeat for a user-defined lead or lead undergoing maximum ST segment with superimposed basal median beat. ST level and slope related to baseline median beat and to the selected lead also displayed
  - Arrhythmias or user events strip
  - Trend of the results of the ST analysis updated in real time for all 12/15 channels (optional)
  - Trends:
    - HR/ METs,

- NIBP
- Double Product (HR*BP)
- ST index
- Ergometric parameters
- ST level
- ST slope
- QT/QTc

  - ECG snapshot selected from full disclosure data
  - Protocol name
  - Protocol phase/stage
  - Ergometric parameter
- Recovery phase
  - Same parameters as in Exercise Phase
  - Possibility of writing conclusions

Print Type	Auto and Continuous
Auto Print Format	12 leads: ▪ 12x1 ▪ 12x1+AVG ▪ 6x2 ▪ 6x2+AVG ▪ 3x4 ▪ 3x4 +1 ▪ 3x4 +3 15 leads: ▪ 15x1 ▪ 3X5 ▪ 3X5+1 ▪ 3x5+3
Continuous Print Format	Resting ECG with Glasgow interpretation (12/15 leads) 12 leads: ▪ 3 channels I-III ▪ 3 channels aVr-aVf ▪ 3 channels V1-V3 ▪ 3 channels V4 V6 ▪ 6 channels: I-aVF ▪ 6 channels: V1-V6 ▪ 12 channels: I-V6 15 leads: ▪ 3 extra lead channels ▪ 15 I-V6 channels + extra leads
Protocol management	▪ Protocol loading ▪ Automatic protocol management ▪ Manual stage control ▪ Manual control of ergometers ▪ Manual or Auto NIBP insertion ▪ Visive and audible alerts
Alerts	▪ Rhythm Events ▪ ST delta ▪ HR over target ▪ HR drop more than user defined percentage ▪ Systolic or Diastolic BP above or below thresholds

Data saving on HD	▪ SBP falling more than a threshold ▪ ECG full disclosure without loss of information ▪ Analysis results ▪ Ergometer parameters ▪ NIBP values ▪ SPO2 values ▪ Electrodes status

Review	▪ Playback of exercise
	▪ Editing of conclusion
	▪ Reason for end
	▪ Auto printout as in RT plus trend page
	▪ Test Summary
	  o Exam data
	  - Exam Start Time
	  - Ergometer type
	  - Protocol type
	  o Basal clinical parameters
	  o Peak clinical parameters
	  o End exam clinical parameters
	  o Max clinical parameter
	  o Risk scoring:
	  - Duke score (treadmills)
	  - % FAI (Functional Aerobic Impairment)
	  - Framingham score
	  o HR Recovery index

PDF Report	▪ Editing conclusion ▪ Cover (examination data and conclusions) and Table (list of the steps performed). ▪ Resting ECG ▪ Table of measurement on ST level and slope (by stage or by minutes) ▪ Table of QT and QTc measurements ▪ Table of HR, SP02; METS, BP, DP, Ergometer parameters (by Stage or by minutes) ▪ Averaging: average heartbeat tracing (by stage or by minutes) ▪ Trend of measurements: ST, HR , DP,SPO2, METS, QT/QTc, ergometer parameters ▪ ECG - protocol, user, arrhythmia and RPE events
Settings	▪ Arrhythmias to show and print ▪ Connectivity (work list and PDF exporting), GDT ▪ Acquisition settings ▪ Display configuration ▪ Peripheral controls (link between peripheral and port) ▪ Manual and auto Print setting ▪ Display settings ▪ Formula settings ▪ Fiducial points for average ▪ Analysis ▪ Alert ▪ PDF and print reports (header + blocks) ▪ TTL outputs
Protocol editing and creation	Types of protocol supported: ▪ Treadmill ▪ Cycle ▪ Generic ▪ Pharmacological Supported functions:

	▪ Create new protocol ▪ Edit existing protocol ▪ Copy protocol
ECG trigger	TTL output and ECG analogue output (via HD+ Dongle)
Options	
Connectivity	To connect Cubestress to ECGWebApp and other external management systems (CIS / PACS) via the Internet.
Dicom	To connect Cubestress to external management systems (CIS / PACS) via DICOM protocol.
GDT	To connect Cubestress to external management systems (CIS / PACS) using the GDT protocol.
2 printers	To connect and manage 2 printers.
Full Disclosure	To review and enter events during the execution of the test, even in a previously acquired ECG section. During the review it allows you to select an instant of the exam and review the ECG, the medians, the relative trends. It also enables the Play function of the exam.
15 leads	To acquire 15-lead ECG (in combination with HD + 15).
TTL	Enable and configure HD + Dongle TTL outputs.
Cardiopulmonary	For interfacing with a cardiopulmonary system.
Glasgow	To use the Glasgow interpretation algorithm on resting ECGs acquired before or during the exam.
Cardiopulmonary option	
Compatible protocol	XSCRIBE CP Cardiopulmonary interface rev.1
Minimum requirements for the Cardiopulmonary system:	▪ Windows 10 operating system support; ▪ PC with features compatible with those defined for Cubestress or better
Supported CP mode	▪ Test execution ▪ Test review
Connectivity	
Import/Export	▪ DICOM modality Worklist ▪ HL7 Worklist ▪ GDT (input: reading demographs data for new test run by effort or test review already performed; output: report and pdf) ▪ Dicom encapsulated pdf cstore ▪ Hl7 pdf ▪ ECGWebApp Worklist ▪ ECGWebApp report storage (pdf) ▪ DICOM MPPS (TBD)
Compatible devices	
Compatible Cycloergometers	▪ CARDIOLINE XR50 ▪ CARDIOLINE XR50+ ▪ CARDIOLINE XR100 ▪ CARDIOLINE XR100+ ▪ CARDIOLINE XR100BP ▪ CARDIOLINE XR100BP+ ▪ ERGOSELECT 1200 BP SUPINE ERGOMETER ▪ ERGOSELECT 1200 ERGOMETER with bed ▪ ERGOSELECT 400K HAND CRANK ERGOMETER ▪ ERGOSELECT 600 P

Compatible treadmills	▪ ERGOSELECT 1000 BP ▪ ERGOSELECT 1000 BED ERGOMETER ▪ ERGOSELECT 200P WITH BLOOD PRESSURE ▪ ERGOSELECT 4 P ▪ XR450M-PC MEDICAL TREADMILL CONSOLE MAN. TOUCH ▪ XR450P-PC MEDICAL TREADMILL CONSOLE PROG. TOUCH ▪ XR450R MEDICAL TREADMILL ▪ XR600M-PC MEDICAL TREADMILL CONSOLE MAN.TOUCH CARDIOLINE_XR600 ▪ XR600P-PC MEDICAL TREADMILL CONSOLE PROG. TOUCH H_P_COSMOS ▪ XR600R MEDICAL TREADMILL ▪ Trackmaster XMX 425 ▪ Trackmaster XMX 428 ▪ Trackmaster XMX 428CP
Compatible NIBP/SPO2 Monitors	▪ CARDIOLINE XR100BP ▪ CARDIOLINE XR100BP+ ▪ ERGOSELECT 1200 NIBP SUPINE ERGOMETER ▪ ERGOSELECT 1000 NIBP ▪ ERGOSELECT 200P WITH NIBP/SPO2 ▪ TANGO ▪ METRONIK

PC minimum requirements

Operating System	Windows 10 64 bit or higher
Processor	Intel Core i5 or higher
RAM	8GB or Higher
Free space on Hard Disk	At least 2GB for the program plus the archive space Recommended 7200 rpm o higher
Screen	Color Touchscreen 16:9 15” minimum , Minimum resolution 1920x1080 Font scaling to 100% Optimal configuration 16:9 24”, full HD
USB	Dongle Thermal Printer Laser Printer Cycle-ergometer Treadmill NiBp/SpO2 Keyboard/Mouse
Printer	Laser B/N Brother model HL- L2310D or thermal Cardioline model 200P
Other Software	.NET Framework 4.7.2 Runtime PDF Reader (ex. Acrobat TM Reader, Foxit Reader)

Tests archive

Archive	Local database
Capacity	1000 exams
Data stored	▪ ECG full disclosure without loss of information ▪ Analysis results ▪ Ergometer parameters ▪ NIBP values ▪ SPO2 values ▪ Electrodes status

Patient data	▪ First name ▪ Middle name ▪ Last name ▪ ID ▪ Date of birth ▪ Age (calculated from 5.) ▪ Sex ▪ Race ▪ Height ▪ Weight ▪ Address ▪ Phone ▪ Email ▪ Reason for study ▪ Therapy ▪ Angina (yes/No) ▪ History of Myocardial infarction (Yes/No) ▪ Family History (Yes/No) ▪ Diabetic (Yes/No) ▪ Smoking (Yes/No) ▪ Cardiac catheterization (Yes/No) ▪ Prior coronary artery bypass (Yes/No) ▪ Pacemaker (yes/no) ▪ Target HR as percentage of MAX HR or manually inserted
Review	▪ Playback of exercise ▪ Editing of conclusion ▪ Reason for end ▪ Auto printout as in RT plus trend page ▪ Test Summary ▪ Exam data ▪ Exam Start Time ▪ Ergometer type ▪ Protocol type ▪ Basal clinical parameters ▪ Peak clinical parameters ▪ End exam clinical parameters ▪ Max clinical parameter ▪ Duke treadmill score ▪ Fai % ▪ Framingham score ▪ HR Recovery index

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 IEC 62304 – Software

Class of risk	B

Performance	
Standard	EN 60601-2-25
Other classifications	
GMDN	36145 Stress Exercise System, Cardiac
CND	Z12050182 - STRUMENTAZIONE PER L'ANALISI SFORZO - COMPONENTI ACCESSORI SOFTWARE
RDM (Medical Device Catalogue)	1873875/R
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
EN ISO 14971	Medical devices - Application of risk management to medical devices
EN 60601-2-25	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
EN 60950-1	Information technology equipment - Safety - Part 1: General requirements
EN 55032	Electromagnetic compatibility of multimedia equipment - Emission Requirements
EN 55035	Electromagnetic compatibility of multimedia equipment. Immunity requirements
EN 60601-1-2	Medical electrical equipment. General requirements for basic safety and essential performance. Collateral Standard. Electromagnetic disturbances. Requirements and tests
ETSI 301 489 V.1.9.2	Electromagnetic Compatibility (EMC)standard for radio equipment and services; Part 1
ETSI 301 489-17 V.3.1.1	Electromagnetic Compatibility (EMC)standard for radio equipment and services; Part 17
EN 62479	Assessment of the compliance of low-power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)
EN 62311	Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz to 300 GHz)
ETSI 300 328 V2.1.1 (2016-11)	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques

CARDIOLINE

ECG200S

General Information

Product name	ECG200S
Generic name	ECG200S
Product code	80609574
Manufacturer	Cardioline S.p.A. Head Office and Production: Via Linz, 151 38121 Trento Italy
Description of Device	The device is a diagnostic electrocardiograph with 12 simultaneous leads which displays, acquires, prints and stores ECG tracings for adults and children. 15 leads are available in print: 12 + Frank leads. Frank's X,Y,Z deviations are calculated using the inverse Dower transform (IDT) method (which are present when the Glasgow option is active). It also calculates the principal global ECG parameters. The device is equipped with USB (Standard), LAN (optional) and Wi-Fi (optional) connectivity to send exams to the Cardioline ECGWebApp, a system for the centralised management and reporting of ECG exams. The available export formats are SCP-PDF. The device can be supplied with the optional algorithm of the University of Glasgow, equipped with age and gender specific criteria. If this option is enabled, the algorithm provides complete ECG interpretation in short or extended format, including neonatal, paediatric interpretation, and acute myocardial infarction detection with ST elevation. For further information on the resting ECG interpretation algorithm, see the Instruction Manual for doctors for its use with adults and children (see list of accessories). The device can be powered by battery or the mains. It prints out in the following formats: standard or Cabrera 3, 3+1, 3+3, 6 or 12 channels in automatic mode, and 3, 6 or 12 printout channels of the rhythm strip. 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).
Intended use	ECG200S is a high performance, multi-channel, interpretive electrocardiograph. The ECG signal is acquired by means of a 10-wire patient cable and is displayed in real time on an LCD screen built into the device. The electrocardiograph is able to analyse and store the ECG tracings, send them to an external device via the Internet or via USB, print a 12-lead ECG in automatic or manual mode by means of thermal printer. ECG200S is designed to monitor and diagnose cardiac function. However, a Physician must validate the results of the analysis performed by the ECG. ECG200S is intended for use in hospitals, clinics and outpatient facilities of any size. ▪ The device acquires, analyses, displays and prints out electrocardiograms. ▪ The device interprets the data for review by a doctor. ▪ The device must be used by a doctor or by specialised staff on behalf of an authorised doctor in clinical facilities. It is not intended as the only means for determining the diagnosis. ▪ The device's interpretation of the ECG analysis is only significant if used together with an additional analysis by the physician of reference and by an assessment of all the patient's important data. ▪ The device can be used on adult and paediatric patients. ▪ The device must not be used as a physiological monitoring of vital signs. ▪

CARDIOLINE

Technical specifications

ECG acquisition

ECG leads	15 simultaneous (I, II, III, aVF, aVR, aVL, V1, V2, V3, V4, V5, V6, X, Y, Z)
Patient cable	Standard 15D connector, 10 wire patient cable
CMRR	> 100dB
DC input impedance	100MΩ
A/D converter	24 bit, 32000 samples/second/channel
Front-end sampling frequency	32000 samples/second/channel
Sampling rate for signal analysis	1000 samples/second/channel
A/D conversion	20 bit
Resolution	<1 µV/LSB
Dynamic range	+/- 400 mV
Bandwidth	Performances equivalent to 0,05-300 Hz
Pacemaker detection	Hardware detection coupled with digital convolution filter
De fibrillation protection	AAMI/IEC standard
Front-end performance	ANSI/AAMI IEC 60601-2-25:2011
Acquisition mode	Automatic (15 leads), Manual (3/6/12 leads), Stat (15 leads)
Lead configuration	Standard, Cabrera

Processing

Operating system	Linux
Pacemaker detection	Hardware recognition compliant with 60601-2-25 requirements
Lead-fail detection	Independent for all leads. “Torso” function that allows you to view the disconnected electrodes in red and those correctly connected in green.
Electrode reversal detection	Detection of reversed electrodes in the patient connecting step.
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 25/40/150 Hz, for display and printing only
ECG measurements	All leads, medians, corrected HR Average RR PR Interval QRS Duration QT interval and QTc interval, with Hodges, Bazzet and Fridericia’s formula J-Tp and Tp-Te intervals max R[V5] o r[V6] and S[V1] Sokolow-Lyon Index P, R, T axis.
ECG interpretation	Glasgow algorithm for adults, paediatric, STEMI (optional)
ECG interpretation parameters	Sex, age

Automatic printing program for arrhythmias	This program, if activated, automatically printouts (10 seconds) if the electrocardiogram presents ventricular arrhythmias, supraventricular ectopic beats, extreme brachycardia or tachycardia, or atrial fibrillation.
Memory	Internal 100 ECG memory
Available languages	Brazilian Czech, Croatian, Dutch, French, English, Italian, Polish, Portuguese, Romanian, Russian, Serbian, Spanish, German, Turkish, Hungarian
Self-test	The device performs a self-test of its electronic functions at each switch-on.

Processing options

Interpretation	Glasgow algorithm for adults, paediatric, STEMI
Memory	Storage extended to 1000 ECG

Exported formats

SCP-PDF	Standard format

Connectivity

USB	Standard
LAN	Optional
WiFi	Optional

Wireless Protocol	IEEE 802.11 b/g/n 2.4GHz
Channels	Up to 14* @2.4 GHz (* country dependent)
Safety	• WEP 64/128bit WPA/WPA2 • WPA -PSK • WPA2-PSK • WPA2-EAP-TLS • WPA2-PEAP
Encryption	• WEP • TKIP • CCMP (AES 256)
Radius Authentication and Authorization Protocol	Supported

Display

Display type	Back-lit colour 7" LCD
Display resolution	800x480, 24 bit
Data displayed	3/6/12 leads in real time
Formats displayed	12x1, 6x2, 6x1 1st, 6x1 2nd, 6x1 3rd, 3x1 1st, 3x1 2nd, 3x1 3rd, 3x1 4th, 3x1 5th

Keyboard

Keyboard type	Full alphanumerical
Keyboard technology	Silicon overlay mechanical keypad, easy to clean and disinfect
Special keys	ID, Start, Stop, Auto, Link – Function keys

Printer

Technology	216 mm thermal head
Resolution	8 dots/mm
Paper type	A4 z-fold thermosensitive paper
Sensitivity/gain	5, 10, 20 mm/mV
Automatic print speed	5, 10, 25, 50 mm/s
Automatic print	3, 3+1, 3+3, 6, 12 channels; Standard or Cabrera
Manual print speed	5, 10, 25, 50 mm/sec
Manual Printing	3/6/12 channels; Standard or Cabrera
Printing formats	12x1, 6x2, 3x4, 3x4+1, 3x4+3; 3x5, 3x5+1, 3x5+3; that includes Frank leads of Glasgow option (only if equipped)
Calibration signal	Yes, 1 mV
Lead identifier	Yes, before each trace
Printing time	15s with pre-acquisition 25s without pre-acquisition (time between analysis and printing)

External USB devices

Bar-code reader	Optional
Magnetic cards reader	Optional
External storage	Optional

Electrical features

Power supply	Medical AC power-supply unit and internal rechargeable battery
Power supply unit	Medical - Mod. AFM60US18 - XP Power Limited
Power supply unit input voltage	100-240 VAC
Power supply unit input current	1.5A
Power supply unit input frequency	50/60 Hz
Nominal power supply unit output	60 W, 18 V, 3.34 A
Power supply unit protection class	I
Power supply unit protection rating	IP20
Battery type	NiMH
Battery life	More than 500 ECG – more than 5 hours
Battery recharging time	4 hours until 85% of total capacity

Specifications

Dimensions	396 x 290 x 80 mm
Weight	2.6 Kg
Packaging	600x470x280 mm - 8.5Kg

Environmental operating specifications

Temperature	+10°C - +40°C
Humidity	50% - 95%

Pressure	700hPa - 1060hPa

Environmental storage specifications

Temperature	0°C - +40°C
Humidity	25% - 95%
Pressure	700hPa - 1060hPa

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)

GDPR Compliance (General Data Protection Regulation)

Access control	An advanced access control mode through a NFC badge is foreseen. With this function the device foresees two operating modes: ▪ Locked: the device works in anonymous mode, limiting the functions only to the acquisition and sending of ECGs on the net ▪ Unlocked: the complete operating mode is enabled through a NFC badge, so the user has access to the parts containing sensitive data too. After a period of inactivity or at the operator's command, the system returns to the locked state.
Data at rest protection	The data are kept in the internal memory of the cardiograph and are not accessible until the system has been unlocked by the operator through a badge.
Audit trail	Logging of the transactions associated with the users, with association of the operator code if the system is unlocked.
Patient data removal (right to be forgotten)	Foreseen cancellation of the archive.

Classification according to FDA

510K Number	K160840
Product Code:	DPS
Classification	II
Regulation Number:	21 CFR 870.2340

Classification according to IEC 60601-1 – Electrical safety

Protection against electrical shock	IP (Internal power supply) - class I on AC/DC external power supply unit
Applied parts	Type CF – defibrillation-proof
Protection against accidental ingress of water or substances	IP20
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	A
Performance	
Standard	EN 60601-2-25:2011
Other classifications	
GMDN	110407 - Electrocardiographs, Multichannel, Interpretive
CND	Z12050302 - ELECTROCARDIOGRAPHS FOR ADVANCED DIAGNOSIS
RDM (Medical Device Catalogue)	1400066
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
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 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
Conformity with Recommendations	
AHA, ACC, HRS	Recommendations for the Standardization and Interpretation of the Electrocardiogram - Kligfield P, Gettes LS, Bailey JJ, et al. – Circulation 2007
ANMCO, AIIC, SIT	Informed consent form ANMCO/AIIC/SIT: Definition, accuracy and appropriateness of the electrocardiographic signal of electrocardiographs, ergometry systems, Holter ECG systems, telemetry and bedside monitors - G Ital Cardiol 2016

Product codes and accessories

Standard Accessories

	Leaflet
	ECG patient cable standard IEC, 10 leads, 4mm plugs
	Univ. adapter plug 4mm 10pcs.
	ECG Disposable electrodes, plug model, 100 units

	ECG z-fold paper 210x295mm x 180 sheets
	LAN Connectivity
	ECG200S Device protection cover
	Medical power supply AC/DC
	10 A – Power supply cable
Versions	
80609575	ECG200S AHA
80609274	ECG200S reusable
80609275	ECG200S AHA reusable
Options	
9ECG1-GW	Glasgow ECG Interpretation
9ECG1-LS	LAN
9ECG1-ME	Memory extension to 1000
9ECG1-WF	Wi-Fi
9ECG1-LD	DICOM
81019594	ECG EasyApp
PRY-ECG	GDPR ECG Option
67040240	NFC device & contactless card (only one contactless card)
67040241C	contactless card (10 pcs)
Accessories	
869060001	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
828030001	Set of 6 chest ECG electric suction type Ag/AgCl
63030164	Set of 6 periph. pediatric ECG electr. suction chests Ag/AgCl
63050025 63050142	ECG patient cable IEC, 10 lead, plug 4 mm
63050068 63050143	ECG patient cable AHA, 10 lead, plug 4 mm
63050108 63050130	ECG patient cable IEC, 10 lead, snap
66030040	ECG Disposable electrodes, tab, 100pcs
M-00-S	Disposable electrodes ECG, snap, 50 pcs
66030040C	Disposable electrodes ECG, tab, 100 pcs; pack of 10
N-10-A	Disposable electrodes ECG neonatal, 25 pcs
SU-00-A	Disposable ECG plug electrodes, 60 pcs
66020002	Gel bottle for ECG electrodes, 260 ml
63090236	Set of 10 snap adapters for 4 mm plug

66020008	Adapters for tab and button electrodes for 4 mm plug, 10 pcs
63090729	Patient cable extension kit
67040225	ECG200 Device protection cover
66010052S	ECG paper z-fold 210x295 x 180sheets, 10 pcs
66010053S	ECG paper z-fold 216x280mm x180 sheets, 10 pcs
83080022	Medical power supply AC/DC
63090713	ECG200 L/S/+ Trolley Hospital grade

CARDIOLINE

PRODUCT SHEET: ECG200L

Description of product:

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.

GENERAL INFORMATION

Product Name	ECG200L
General Name	ECG200L
Product Code	80608070
Manufacturer	Cardioline S.p.A.
	Headquarters Via Linz, 151 38121 Trento Italia
Intended use	ECG200L is a multi-channel, interpretative resting electrocardiograph. The ECG signal is acquired with a 10-wires patient cable and is displayed in real time on a LCD screen integrated in the device. The electrocardiograph can analyse and store the ECG traces, send them to an external peripheral via USB, print the 12 lead ECG in automatic or manual mode by means of its built-in thermal printer. ECG200L is intended for assessment and diagnosis of cardiac functions. In any case the results of analysis performed by the electrocardiograph must be validated by a Physician.

	ECG200L is intended for use in hospitals, in medical clinics and doctor's offices of any size. ▪ The device is indicated for use to acquire, analyse, display and print electrocardiograms. ▪ The device is intended to provide the physician with an automatic interpretation of the ECG to be reviewed by a physician. ▪ The device is indicated for use in a clinical setting, by a physician or by trained personnel who are acting on the orders of a licensed physician. It is not intended as a sole means of diagnosis. ▪ The interpretations of ECG offered by the device are only significant when used in conjunction with a physician over-read as well as consideration of all other relevant patient data. ▪ The device is indicated for use on adult and pediatric populations. The device is not intended to be used as a vital signs physiological monitor.
Year marketed	2018

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
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

CARDIOLINE

Lead fail detection	Independent on all leads. “Torso” function that allows you to view the disconnected electrodes in red and those correctly connected in green.
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
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

CARDIOLINE

Sensitivity/Gain	5, 10, 20 mm/mV
Auto print speed	5, 10, 25, 50 mm/s
Auto print	3, 3+1, 6, 12 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

CARDIOLINE

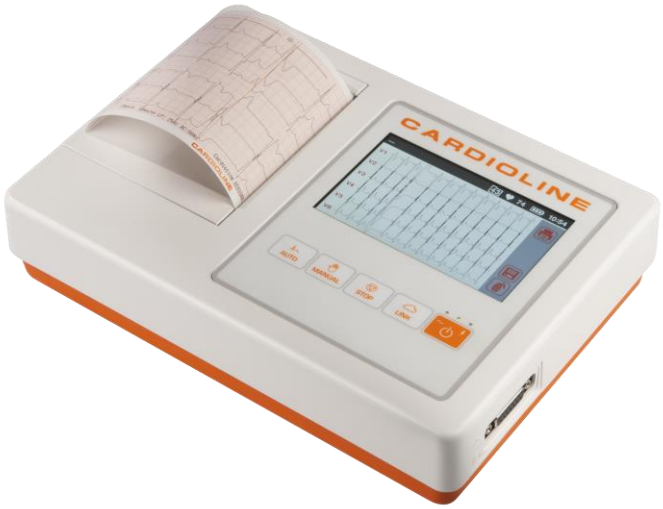
REGULATORY AND SAFETY	
Classification according MDD 93/42/CEE	
Class	Class IIa
Rationale	rule 10 annex IX 93/42/EEC Directive and its amendments
Notified body	TUV (1936)
Classification according to FDA regulation	
Classification:	In progress
Product Code:	In progress
Review Panel:	In progress
Regulation 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	
869060001	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
828030001	Set of 6 chest ECG electric suction type Ag/AgCl
63050025 63050142	ECG patient cable IEC, 10 lead, plug 4 mm
63050068 63050143	ECG patient cable AHA, 10 lead, plug 4 mm
63050108 63050130	ECG patient cable IEC, 10 lead, snap
63050109 63050141	ECG patient cable AHA, 10 lead, snap
63050032	ECG patient cable IEC-10 CLIP 4 mt
M-00-S	Disposable electrodes ECG, snap, 50 pcs
66030040C	Disposable electrodes ECG, tab, 100 pcs; pack of 10
N-10-A	Disposable electrodes ECF neonatal, 25 pcs
SU-00-A	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, 180 sheeets, 10 pcs
66010053S	Z-Fold paper Letter 216x280mm, 180 sheeets, 10 pcs
63090713	ECG200+/S/L trolley II Edition hospital grade

CARDIOLINE

PRODUCT SHEET: ECG100L



Description of product:

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.

GENERAL INFORMATION	
Product Name	ECG100L
General Name	ECG100L
Product Code	80508097
Manufacturer	Cardioline S.p.A.
	Headquarters Via Linz, 151 38121 Trento Italia
Intended use	ECG100L is a multi-channel, interpretative resting electrocardiograph. The ECG signal is acquired with a 10-wires patient cable and is displayed in real time on a LCD screen integrated in the device. The electrocardiograph can analyse and store the ECG traces, send them to an external peripheral via USB, print the 12 lead ECG in automatic or manual mode by means of its built-in thermal printer.

	ECG100L is intended for assessment and diagnosis of cardiac functions. In any case the results of analysis performed by the electrocardiograph must be validated by a Physician. ECG100L is intended for use in hospitals, in medical clinics and doctor's offices of any size. ▪ The device is indicated for use to acquire, analyse, display and print electrocardiograms. ▪ The device is intended to provide the physician with an automatic interpretation of the ECG to be reviewed by a physician. ▪ The device is indicated for use in a clinical setting, by a physician or by trained personnel who are acting on the orders of a licensed physician. It is not intended as a sole means of diagnosis. ▪ The interpretations of ECG offered by the device are only significant when used in conjunction with a physician over-read as well as consideration of all other relevant patient data. ▪ The device is indicated for use on adult and pediatric populations. ▪ The device is not intended to be used as a vital signs physiological monitor.
Year marketed	2017

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
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

CARDIOLINE

Processing	
Pace detection	Hardware detection in compliance with the requirements 60601-2-25
Lead fail detection	Independent on all leads. “Torso” function that allows you to view the disconnected electrodes in red and those correctly connected in green.
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

CARDIOLINE

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	
869060001	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
828030001	Set of 6 chest ECG electric suction type Ag/AgCl
63050025 63050142	ECG patient cable IEC, 10 lead, plug 4 mm
63050068 63050143	ECG patient cable AHA, 10 lead, plug 4 mm
63050108 63050130	ECG patient cable IEC, 10 lead, snap 180cm
63050109 63050141	ECG patient cable AHA, 10 lead, snap
M-00-S	Disposable electrodes ECG, snap, 50 pcs
66030040C	Disposable electrodes ECG, tab, 100 pcs; pack of 10
N-10-A	Disposable electrodes ECF neonatal, 25 pcs
SU-00-A	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
66010055S	Paper Roll 100mm x 20m (ECG100L); 70 pcs
67010223	Carrying case “Cardioline ECG 100”

63090712	ECG100+/S/L trolley II Edition

CARDIOLINE

Cubestress System

General Information

Product name	Cubestress
Product code	KSS*XYYZWJ-@*
Manufacturer	Cardioline SpA Via Linz, 151 38121 Trento Italy
Description of Device	Cubestress System is a family of systems for carrying out cardiovascular stress tests. The system can be composed of the following devices, which are both medical and non-medical, with various configurations with: ▪ Software for viewing, analyzing and printing ECG traces and for managing tests (Cubestress); ▪ ECG acquisition unit (HD + series) with optional ECG suction cable (Handy VAQ); ▪ Computer on which the software is installed (with display, keyboard and mouse); ▪ Optional ergometer, controlled by the software, for performing physical exercise; ▪ Printer (laser or thermal Cardioline 200P); ▪ Isolation transformer; ▪ Trolley. The patient can be connected to the HD + ECG acquisition unit (HD + 12, HD + 15) via standard patient cable with electrodes or via Handy VAQ suction ECG cable. The acquisition unit is connected to the computer via Bluetooth or USB (depending on the HD + model), transmitting the ECG signals to it, then the Cubestress software displays and analyzes for reporting by the operator. The ergometer is controlled by the Cubestress software, automatically or with manual input from the operator.
Intended use	▪ Ability to enter / edit patient information directly. ▪ Acquisition and analysis of exercise ECG data ▪ Execution of an exercise test with the use and programming of ergometers according to a selected protocol or pharmacologically induced ▪ Printing of results via thermal and / or laser printer ▪ Review and repetition of the exercise ▪ Production of a report in PDF format ▪ Import a worklist and export the final report

Technical Specifications

ECG acquisition (HD+ unit)

ECG leads	12-leads (I, II, III, aVR-L-F, V1-6) with HD+ and HD+ 12 15-leads (I, II, III, aVR-L-F, V1-6, E1-3) with HD+ 15
Patient cable	10 wire (HD+, HD+ 12, HD+ 15) or 13 wire (HD+ 15) replaceable patient cable
CMRR	>100dB
DC input impedance	>100MΩ
A/D converter	Up to 24 bit
Sampling rate of the input stage	128,000 samples/second/channel

Sampling rate for signal analysis	1000 samples/second/channel 500 samples/second/channel Selected via software
A/D conversion	20 bit
Resolution	<1 µV/LSB
Dynamic range	+/- 500 mV
Bandwidth	300 Hz (@1000 c/s) 150Hz (@500 c/s)
Pacemaker detection	Hardware detection coupled with digital convolution filter, in compliance with the requirements 60601-2-25 (HD+ acquisition unit)
Defibrillation protection	AAMI/IEC standard
Front-end performance	ANSI/AAMI IEC 60601-2-25:2011
Data transfer	Bluetooth 2.1+ EDR with "secure pairing" for HD+ Bluetooth Low Energy for HD+ 12 / HD+ 15 USB for HD+ 12 / HD+ 15

Processing

Operating system	Windows
Lead-fail detection	Independent for all leads
Cardiac frequency range	30 - 300 bpm
Filters	Linear phase digital diagnostic high-pass filter (according to 60601-2-25 2nd ed.), Automatic baseline drift control filter 50/60 Hz AC interference adaptive digital filter
Noise-removal filters	25/40/150 Hz digital low pass filters, for display and F printing only SCF Filter (Source consistency filter)

Main features

Data displayed

Data always present and displayed:

- Patient Info (first and last name, id, age, sex)
- HR, Max HR, Target HR and % of target HR

Data displayed only during the test:

- St level
- Double Product
- Blood pressure
- SpO2 level
- Mets
- ST/HR index
- Pre-test electrodes check and resting ECG acquisition
  - Real-time traces 6x2/12 channels (10-wire cable) or 6X2+3/15 channels (13-wire cable)
  - Electrode impedance control
  - Electrodes check digital
- Pre-exercise phase
  - Real-time ECG channels (10-wire cable) or 6X2+3/15 channels (13-wire cable)
  - Compacted ECG (Full disclosure 1 channel)
  - Averaging 12/13 leads Real Time
  - Zoomed average heartbeat for a user-defined lead or lead showing maximum ST segment change. ST level and slope are also displayed

- Arrhythmias or user events strip
- ST profile view
- Protocol name
- Protocol phase/stage
- Ergometric parameters

- Exercise phase:
  - Real-time ECG channels (10-wire cable) or 6X2+3/15 channels (13-wire cable)
  - Averaging 12/15 leads Real time with Baseline averaging superimposition
  - Compacted ECG (Full disclosure 1 channel) (optional)
  - Zoomed average heartbeat for a user-defined lead or lead undergoing maximum ST segment with superimposed basal median beat. ST level and slope related to baseline median beat and to the selected lead also displayed
  - Arrhythmias or user events strip
  - Trend of the results of the ST analysis updated in real time for all 12/15 channels (optional)
  - Trends:
    - HR/ METs,
    - NIBP
    - Double Product (HR*BP)
    - ST index
    - Ergometric parameters
    - ST level
    - ST slope
    - QT/QTc
  - ECG snapshot selected from full disclosure data
  - Protocol name
  - Protocol phase/stage
  - Ergometric parameter
- Recovery phase
  - Same parameters as in Exercise Phase
  - Possibility of writing conclusions

Print Type

Auto and Continuous

Auto Print Format

12 leads:

- 12x1
- 12x1+AVG
- 6x2
- 6x2+AVG
- 3x4
- 3x4 +1
- 3x4 +3

15 leads:

- 15x1
- 3X5
- 3X5+1
- 3x5+3

Resting ECG with Glasgow interpretation (12/15 leads)

Continuous Print Format

12 leads:

- 3 channels I-III
- 3 channels aVr-aVf
- 3 channels V1-V3
- 3 channels V4 V6

- 6 channels: I-aVF
- 6 channels: V1-V6
- 12 channels: I-V6

15 leads:
- 3 extra lead channels
- 15 I-V6 channels + extra leads

Protocol management
- Protocol loading
- Automatic protocol management
- Manual stage control
- Manual control of ergometers
- Manual or Auto NIBP insertion
- Visive and audible alerts

Alerts
- Rhythm Events
- ST delta
- HR over target
- HR drop more than user defined percentage
- Systolic or Diastolic BP above or below thresholds
- SBP falling more than a threshold

Data saving on HD
- ECG full disclosure without loss of information
- Analysis results
- Ergometer parameters
- NIBP values
- SPO2 values
- Electrodes status

Review
- Playback of exercise
- Editing of conclusion
- Reason for end
- Auto printout as in RT plus trend page
- Test Summary
  - Exam data
    - Exam Start Time
    - Ergometer type
    - Protocol type
  - Basal clinical parameters
  - Peak clinical parameters
  - End exam clinical parameters
  - Max clinical parameter
  - Risk scoring:
    - Duke score (treadmills)
    - % FAI (Functional Aerobic Impairment)
    - Framingham score
  - HR Recovery index

PDF Report
- Editing conclusion
- Cover (examination data and conclusions) and Table (list of the steps performed).
- Resting ECG
- Table of measurement on ST level and slope (by stage or by minutes)
- Table of QT and QTc measurements
- Table of HR, SP02; METS, BP, DP, Ergometer parameters (by Stage or by minutes)
- Averaging: average heartbeat tracing (by stage or by minutes)
- Trend of measurements: ST, HR , DP,SPO2, METS, QT/QTc, ergometer parameters
- ECG - protocol, user, arrhythmia and RPE events

Settings
- Arrhythmias to show and print
- Connectivity (work list and PDF exporting), GDT

	▪ Acquisition settings ▪ Display configuration ▪ Peripheral controls (link between peripheral and port) ▪ Manual and auto Print setting ▪ Display settings ▪ Formula settings ▪ Fiducial points for average ▪ Analysis ▪ Alert ▪ PDF and print reports (header + blocks) ▪ TTL outputs
Protocol editing and creation	Types of protocol supported: ▪ Treadmill ▪ Cycle ▪ Generic ▪ Pharmacological Supported functions: ▪ Create new protocol ▪ Edit existing protocol ▪ Copy protocol
ECG trigger	TTL output and ECG analogue output (via HD+ Dongle)

Connectivity

Import/Export	▪ DICOM modality Worklist ▪ HL7 Worklist ▪ GDT (input: reading demographs data for new test run by effort or test review already performed; output: report and pdf) ▪ Dicom encapsulated pdf cstore ▪ Hl7 pdf ▪ ECGWebApp Worklist ▪ ECGWebApp report storage (pdf) ▪ DICOM MPPS (TBD)

Compatible devices

Compatible Cycloergometers	▪ CARDIOLINE XR50 ▪ CARDIOLINE XR50+ ▪ CARDIOLINE XR100 ▪ CARDIOLINE XR100+ ▪ CARDIOLINE XR100BP ▪ CARDIOLINE XR100BP+ ▪ ERGOSELECT 1200 BP SUPINE ERGOMETER ▪ ERGOSELECT 1200 ERGOMETER with bed ▪ ERGOSELECT 400K HAND CRANK ERGOMETER ▪ ERGOSELECT 600 P ▪ ERGOSELECT 1000 BP ▪ ERGOSELECT 1000 BED ERGOMETER ▪ ERGOSELECT 200P WITH BLOOD PRESSURE ▪ ERGOSELECT 4 P
Compatible treadmills	▪ XR450M-PC MEDICAL TREADMILL CONSOLE MAN. TOUCH ▪ XR450P-PC MEDICAL TREADMILL CONSOLE PROG. TOUCH ▪ XR450R MEDICAL TREADMILL ▪ XR600M-PC MEDICAL TREADMILL CONSOLE MAN.TOUCH CARDIOLINE_XR600 ▪ XR600P-PC MEDICAL TREADMILL CONSOLE PROG. TOUCH H_P_COSMOS ▪ XR600R MEDICAL TREADMILL

Compatible NIBP/SPO2 Monitors	▪ Trackmaster XMX 425 ▪ Trackmaster XMX 428 ▪ Trackmaster XMX 428CP ▪ CARDIOLINE XR100BP ▪ CARDIOLINE XR100BP+ ▪ ERGOSELECT 1200 NIBP SUPINE ERGOMETER ▪ ERGOSELECT 1000 NIBP ▪ ERGOSELECT 200P WITH NIBP/SPO2 ▪ TANGO ▪ METRONIK

Tests archive

Archive	Local database
Capacity	1000 exams
Data stored	▪ ECG full disclosure without loss of information ▪ Analysis results ▪ Ergometer parameters ▪ NIBP values ▪ SPO2 values ▪ Electrodes status
Patient data	▪ First name ▪ Middle name ▪ Last name ▪ ID ▪ Date of birth ▪ Age (calculated from 5.) ▪ Sex ▪ Race ▪ Height ▪ Weight ▪ Address ▪ Phone ▪ Email ▪ Reason for study ▪ Therapy ▪ Angina (yes/No) ▪ History of Myocardial infarction (Yes/No) ▪ Family History (Yes/No) ▪ Diabetic (Yes/No) ▪ Smoking (Yes/No) ▪ Cardiac catheterization (Yes/No) ▪ Prior coronary artery bypass (Yes/No) ▪ Pacemaker (yes/no) ▪ Target HR as percentage of MAX HR or manually inserted
Review	▪ Playback of exercise ▪ Editing of conclusion ▪ Reason for end ▪ Auto printout as in RT plus trend page ▪ Test Summary ▪ Exam data ▪ Exam Start Time ▪ Ergometer type ▪ Protocol type ▪ Basal clinical parameters

- Peak clinical parameters
- End exam clinical parameters
- Max clinical parameter
- Duke treadmill score
- Fai %
- Framingham score
- HR Recovery index

Available configurations

Cubestress System config. Package HD+12/ HD+ 15

Code

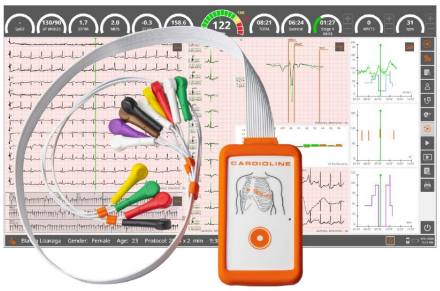
KSSM00000 with HD+ 12
KSSE00000 with HD+ 15

System components

- Cubestress Software
- HD+ (HD+ 12, HD+ 15)
- Patient cable 10 wire (HD+ 12, HD+ 15) or 13 wire (HD+ 15)

Available options

- Connectivity/Full Disclosure/2printers
- Full Disclosure
- Tango (Kit Tango M2 + Cable TTL-USB + Trolley support Cubestress)
- SpO2 Tango
- BL-6
- TTL
- Cardiopulmonary
- USB HD+
- Trolley LITE



Cubestress System config. Laser Printer B/N

Code

KSSMPCUL0 with HD+ 12
KSSEPCUL0 with HD+ 15

System components

- Cubestress Software
- HD+ (HD+ 12, HD+ 15)
- Patient cable 10 wire (HD+ 12, HD+ 15) or 13 wire (HD+ 15)
- All in one touch screen computer
- Trolley
- Integrated Laser printer B/N

Available options

- Connectivity/Full Disclosure/2printers
- Full Disclosure
- Tango (Kit Tango M2 + Cable TTL-USB + Trolley support Cubestress)
- SpO2 Tango
- BL-6
- TTL
- Cardiopulmonary
- USB HD+

CARDIOLINE

Cubestress System config. Laser Printer B/N ISO

Code

KSSMPCTL0 with HD+ 12
KSSEPCTL0 with HD+ 15

System components

- Cubestress Software
- HD+ (HD+ 12, HD+ 15)
- Patient cable 10 wire (HD+ 12, HD+ 15) or 13 wire (HD+ 15)
- All in one touch screen computer
- Isolation transformer
- Trolley
- Integrated Laser printer B/N

Available options

- Connectivity/Full Disclosure/2printers
- Full Disclosure
- Tango (Kit Tango M2 + Cable TTL-USB + Trolley support Cubestress)
- SpO2 Tango
- BL-6
- TTL
- Cardiopulmonary
- USB HD+

Cubestress System config. Thermal Printer 200P

Code

KSSMPCUT0 with HD+ 12
KSSMPCUT0 with HD+ 15

System components

- Cubestress Software
- HD+ (HD+ 12, HD+ 15)
- Patient cable 10 wire (HD+ 12, HD+ 15) or 13 wire (HD+ 15)
- All in one touch screen computer
- Thermal Printer Cardioline 200P
- Trolley

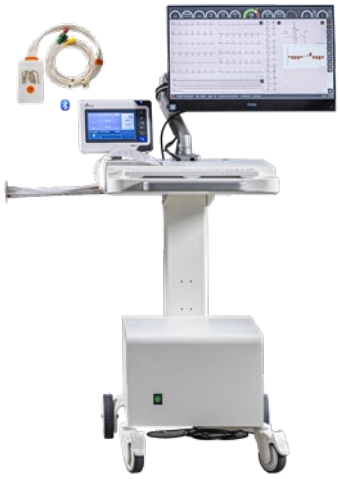
Available options

- Connectivity/Full Disclosure/2printers
- Full Disclosure
- Tango (Kit Tango M2 + Cable TTL-USB + Trolley support Cubestress)
- SpO2 Tango
- BL-6
- TTL
- Cardiopulmonary
- USB HD+

CARDIOLINE

Cubestress System config. Thermal Printer 200P

Code	KSSMPCTT0 with HD+ 12 KSSEPCTT0 with HD+ 15
System components	▪ Cubestress Software ▪ HD+ (HD+ 12, HD+ 15) ▪ Patient cable 10 wire (HD+ 12, HD+ 15) or 13 wire (HD+ 15) ▪ All in one touch screen computer ▪ Thermal Printer Cardioline 200P ▪ Isolation transformer ▪ Trolley
Available options	▪ Connectivity/Full Disclosure/2printers ▪ Full Disclosure ▪ Tango (Kit Tango M2 + Cable TTL-USB + Trolley support Cubestress) ▪ SpO2 Tango ▪ BL-6 ▪ TTL ▪ Cardiopulmonary ▪ USB HD+



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 IEC 60601-1 – Electrical safety

Protection against electrical shock	HD+ Internally powered REOMED 1000 Class I
Applied parts	Type CF – defibrillation-proof
Protection against accidental ingress of water or substances	HD+: IP40 / IP42 (with protective shell)
Sterilisation methods	NA (not intended to be sterilised)
Suitability for use in oxygen-rich environments	No
Operation mode	Non-continuous operation

Classification according to IEC 60601-1-2 – Electromagnetic compatibility

Group	1
Class	B

Classification according to IEC 62304 – Software

Class of risk	B

CARDIOLINE

Performance	
Standard	EN 60601-2-25
Other classifications	
GMDN	36145 Stress Exercise System, Cardiac
CND	Z12050182 - STRUMENTAZIONE PER L'ANALISI SFORZO - COMPONENTI ACCESSORI SOFTWARE
RDM (Medical Device Catalogue)	1873875/R
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
EN ISO 14971	Medical devices - Application of risk management to medical devices
EN 60601-1	Medical electrical equipment - Part 1: General requirements relating to basic safety and essential performance
EN 60601-1-2	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6	Medical electrical equipment - Part 1: General safety rules - Collateral standard: Usability
EN 60601-2-25	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
EN 60950-1	Information technology equipment - Safety - Part 1: General requirements
EN 55032	Electromagnetic compatibility of multimedia equipment - Emission Requirements
EN 55035	Electromagnetic compatibility of multimedia equipment. Immunity requirements
EN 60601-1-2	Medical electrical equipment. General requirements for basic safety and essential performance. Collateral Standard. Electromagnetic disturbances. Requirements and tests
ETSI 301 489 V.1.9.2	Electromagnetic Compatibility (EMC)standard for radio equipment and services; Part 1
ETSI 301 489-17 V.3.1.1	Electromagnetic Compatibility (EMC)standard for radio equipment and services; Part 17
EN 62479	Assessment of the compliance of low-power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)
EN 62311	Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz to 300 GHz)
ETSI 300 328 V2.1.1 (2016-11)	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques

CARDIOLINE

General Information

Product Name:	**xr**450**p** / **xr**450**m**
Manufacturer:	Runner Srl Via G. di Vittorio, 391 41032 Cavezzo (MO) Italy
Distributed by:	Cardioline S.p.A. Registered Office and Factory: Via Linz, 151 38121 Trento Italy

xr450m – xr450p

xr450

xr450 is a treadmill designed to guarantee high performances, comfort and security for the patient. It has gradual-compression foot plates, able to adapt to the patient's stride, so drastically reducing articular impact to ankles, knees and back.
xr450 is an ideal instrument for use in combination with CARDIOLINE exercise test systems: silent and reliable, also at high speed, it has a wide tread surface being an extremely compact and light unit.
The **xr**450 treadmill is available in three different versions, all equipped with a wide colour LCD touch-screen display and with different functionalities, as described in the technical specifications section. The **xr**450 treadmill can be upgraded with lateral hand rails.

Intended use

xr450 is treadmill for the execution of exercise tests and cardiovascular rehabilitation. It can be used both as an independent unit, configured with optional console (model **xr**450**m**, **xr**450**p)**, or in connection with a digital electrocardiograph equipped with an RS232 interface.
Correct use of the unit is in a medical environment. Use of this device is at the responsibility of qualified and suitably trained personnel, and must conform to the instructions contained in the User's Manual.
The unit must be handled with care and with every care to avoid bumps, vibration, heat sources, liquids and anything else that could cause it damage.
The **xr**450 treadmill can be used both on adult and pediatric patients in hospital or in the doctor's office.

CARDIOLINE

Technical specifications

Width	70 cm
Length	188 cm
Height	142 cm
Weight	145 kgs
Max. working speed	20.0 km/h constant;
Min. working speed	0.1 km/h constant;
Max inclination	22 %
Min. inclination	0 %
Walking surface	140 x 48 cm
Toroidal transformer of isolation	1900VA;
Engine power (peak)	2 HP (AC)
Inverter	Fuji
Electric power supply	220/240 V – 50/60 Hz – 10 amp
Auxiliary circuit power supply for inclination	low tension 18 V ac
Auxiliary circuit power supply for console/motor electric card	low tension 12 V dc
Absorbed power at max. speed	2000 VA
Nominal absorbed power	1500 VA
Noise	< 30 DB
User's max. weight	150 kgs

Damped board
Self-centring belt system
Self-oiling belt system
Acoustic warning to the pressure of the keys
Cardio recording with chest belt
EEC 93/42 certification (medical device)
Serial interface with Trackmaster protocol
Push button and pull rope stop emergency
Console with colour LCD touch-screen display for all the versins (R, M, P)
Electronic variation of inclination and speed

xr450m – xr450p

CARDIOLINE

Features

Console functions (M)	- speed and inclination control; - liquid crystal display shows heart beats, speed, time, distance and inclination.
Programmable console functions (P)	- speed and inclination control; - liquid crystal display shows heart beats, speed, time, distance and inclination;
PROFILES	- 6 basic profiles that can be modified with speed, inclination and time independent setting; - 50 free profiles with time, inclination and speed setting;
CARDIO	training at constant pulsations (until 80% of max. theoretical own heart rate) with machine self-adjustment of the speed to keep heart rate within max. set value;
FAT BURNING	training at constant pulsations (until 65% of max. theoretical own heart rate) with machine self-adjustment of the inclination to keep heart rate within max. set value;
FOUR TESTS	two auto tests, CHR (Constant Heart Rate) and CWL (Constant Work Level), let making a constant heart rate or load exercise. The third, RUNNER TEST, lets making an increasing load exercise with 1 km/h rising speed per minute. The fourth, COOPER TEST, lets making a 12 minutes exercise to achieve the maximum distance;
PERSONAL DATA	setting of user's personal data (age and weight);
COUNT DOWN	decreasing setting of exercise timing.

xr450m – xr450p

Models

model/operation	*remote controlled*	*stand alone manual*	*stand alone automatic*
xr450**m** ref 67019385	X	X	
xr450**p** ref 67019386	X	X	X

Standard Accessories

Description	*Quantity*
Power supply cable	1
RS232 connection cable to PC	1
User manual	1

Accessories and consumables

Code	*Description*
63090686	RS232 connection cable
67010036	Fall prevention support
67010021	Power supply cable
67010037	Polar belt receiver
67019310	Long lateral support bars
67010039	Underam kit
67010040	Can of lubricant
67019311	Access ramp
67019312	Lateral pediatric support bars