

CARDIOLINE

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 PORTABLE 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, 10 wires patient cable
CMRR	> 100dB
Input impedance	100M Ω
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 μ V/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)
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 and QTc (Hodges formula) intervals QTc Bazett interval QTc Fridericia interval max R[V5];[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	Czech, Croatian, French, English, Italian, Polish, Portuguese, Romanian, Russian, Serbian, Spanish, German, Turkish, Hungarian, Brazilian, Dutch
Autotest	The device perform an auto-test of its internal electronic functions at every start up.

Processing Options

Interpretation	Glasgow Analysis Program for Adults, Pediatric, STEMI
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Supported export formats

SCP	Standard
PDF	Through a dedicated application for files management on Personal Computer

Connectivity

USB	Standard
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Display

Display Type	7" TFT Backlit Color LCD with Capacitive Touch Panel
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Display resolution	800x480
Display data	3/6/12 leads realtime
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
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, 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)
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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

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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
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Other classifications

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

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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	4 Peripheral ECG electrodes clamp Ag/AgCl
63030106	Set of 4 peripheral ECG electric clamp Ag/AgCl
63030107	4 peripheral ECG electric clamp pediatric Ag/AgCl
63030163	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
66030031C	Disposable electrodes ECG, snap, 50 pics
66030040C	Disposable electrodes ECG, tab, 100 pics
66030036C	Disposable electrodes ECG neonatal, 25 pics
66030037C	Disposable electrodes ECG banana, 60 pics
66020008	Set of 10 4mm plug/snap adaptors
66010056	Thermal paper roll 210x3000 mm