

CARDIOLINE

ECG100+

General Information

Product Name	ECG100+
General Name	ECG100+
Product Code	80509590
Manufacturer	Cardioline Spa

Registered Office and Factory:

Via Linz, 19-20-21
Zona Ind. Spini di Gardolo
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. It also calculates the main overall ECG parameters.

The device is equipped with full connectivity: USB(standard), LAN and WiFi (optional), Different export formats and protocols are available: SCP-PDF (standard), XML-GDT (included into the standard connectivity option), DICOM (included into the DICOM connectivity option) and HL7 (optional) to interface with all standard management systems.

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 or 6 channels rhythm strip printing.

Intended Use

ECG100+ is a high-performance, 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 Internet or via USB, print the 12 lead ECG in automatic or manual mode by means of a thermal printer.

ECG100+ is intended for control and diagnosis of cardiac functions. In any case the results of analysis performed by the electrocardiograph must be validated by a Cardiologist.

ECG100+ 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 indicated for use to provide interpretation of the data for consideration 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.

CARDIOLINE

- 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.

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	24 bit, 32000 samples/second/channel
Sampling rate of the input stage	32000 samples/second/channel
Sampling rate for signal analysis	1000 samples/second/channel
A/D conversion	20 bit
Output Data Resolution	1 μ V/LSB
Dynamic Range	+/- 400 mV
Bandwidth	0,05-300 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)
Lead Configuration	Standard, Cabrera

Processing

Operating system	Linux
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
Baseline stabilization	Diagnostic fully digital high pass filter
AC Filter	50/60 Hz adaptive digital filter
Filters	Digital low pass filters at 25/40/150 Hz, for display and printing only
ECG Measurements	All leads, average, corrected...
ECG Interpretation	Glasgow Analysis Program for Adults, Pediatric, STEMI (Optional)
ECG Interpr. Data input	Race, sex, age, drugs
Storage	Internal storage up to 100 ECGs

Processing Options

Interpretation	Glasgow Analysis Program for Adults, Pediatric, STEMI
----------------	---

CARDIOLINE

Storage Extended memory to 1000 ECGs

Supported export formats

SCP-PDF	Standard format
XML-GDT	Included in standard connectivity option
DICOM	Included in DICOM connectivity option
HL7	Optional

Connectivity

USB	Standard
LAN	Optional
WiFi	Optional

Display

Display Type	4.3" Backlit Color LCD
Display resolution	640x480
Display data	3/6/12 leads realtime
Display formats	6x2, 6x1 1st, 6x1 2nd, 6x1 3rd, 3x1 1st, 3x1 2nd, 3x1 3rd, 3x1 4th, 3x1 5th

Keyboard

Keyboard Type	Full alphanumeric
Keyboard Technology	Silicon overlay mechanical keypad
Dedicated Keys	ID, Start, Stop, Auto, Link - Function keys

Printer

Technology	108 mm Thermal printhead
Resolution	8 dots/mm
Speed	5, 10, 25, 50 mm/s
Sensitivity/Gain	2.5, 5, 10, 20 mV/mm
Paper Type	Z-Fold thermal paper pack 100x150 mm
Auto Print	3, 3+1, 6 channels; Standard or Cabrera
Printing formats	6x2, 3x4, 3x4+1, 3x4+3
Manual Print	3/6 channels; 5,10,25,50 mm/sec

USB External Peripherals

Barcode reader	Optional
USB Printer	Optional
Magnetic Card Reader	Optional
External data storage	Optional

Electrical Characteristics

Power source	Medical grade - Mod. AFM60US18 - XP Power Limited
Power supply	Medical grade - Mod. AFM60US18 - XP Power Limited
Input Voltage power supply	100-240 Vac

CARDIOLINE

Input Current power supply	1.5A
Input frequency power supply	50/60 Hz
Rated Output power supply	30 W, 18 V, 1.67 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	285x204x65 mm
Weight	1,8 Kg
Shipping container	360x360x250 mm - 4Kg

Operating Environmental Specifications

Temperature	+10°C - +40°C
Humidity	25% - 95%
Pressure	700hPa - 1060hPa

Storage Environmental Specifications

Temperature	0°C - +40°C
Humidity	25% - 95%
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:	II without exemption
Product Code:	DPS
Review Panel:	Cardiovascular
Regulation Number:	870.2340

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)

CARDIOLINE

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) 1356358

Applicable Standards

EN 980 Symbols for use in the labelling of medical devices

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/AgI

63030107 4 peripheral ECG electric clamp pediatric

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

650900057 Carrying case "Cardioline ECG 100+"

66030031C Disposable electrodes ECG, snap, 50 pics

CARDIOLINE

66030034C	Disposable electrodes ECG, tab, 100 pics
66030036C	Disposable electrodes ECF neonatal, 25 pics
66030037C	Disposable electrodes ECG banana, 60 pics
63090236	Set of 10 snap adapters for 4 mm plug
66010051	Z-FOLD 100X150 PAPER