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.
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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, Indonesian.
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

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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

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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