CARDIOLINE

ECG200S

General Information

Product name	ECG200S
Generic name	ECG200S
Product code	80608067
Manufacturer	Cardioline Spa Head Office and Production: Via Linz, 19-20-21 Zona Ind. Spini di Gardolo 38121 Trento Italy Sales Office: Via F.lli Bronzetti, 8 20129 Milan Italy
Description of Device	The device is a 12-lead diagnostic electrocardiograph which views, acquires, prints and stores ECG tracings for adults and children. It also calculates the principal global ECG parameters. The device is equipped with USB (Standard), LAN (optional) and WiFi (optional) connectivityto send exams to the Cardioline ECG WebApp, a system for the centralised management and reporting of ECG exams. A number of export formats and protocols are available: SCP-PDF (standard), XML-GDT (included in the LAN/WiFi connection option). 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 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 channel in automatic mode, and 3, 6 or 12 printout channels of the rhythm strip.
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.

Technical specifications

ECG acquisition

ECG leads	12-leads (I, II, III, aVR-L-F, V1-6)
Patient cable	Standard 15D, 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 frequency for signal analysis	1000 samples/second/channel
A/D conversion	20 bit
Resolution	1 µV/LSB
Dynamic range	+/- 400 mV
Bandwidth	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 (12 leads), Manual (3/6/12 leads), Stat (12 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
Cardiac frequency range	30 - 300 bpm
Base line stabilisation	Fully digital diagnostic high pass filter
AC filter	Adaptive 50/60 Hz digital filter
Filters	Digital low pass filter, 25/40/150 Hz (for printout and display)
ECG measurements	All leads, medians, 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.

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ECG interpretation	Glasgow algorithm for adults, paediatric, STEMI (optional)
ECG interpretation parameters	Race, sex, age, drugs
Memory	Internal 100 ecg memory
Available languages	Czech, Croatian, 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
XML-GDT	Included in LAN/WiFi connectivity option
Connectivity	
USB	Standard
LAN	Optional
WiFi	Optional
Display	
Display type	Back-lit colour 7" LCD
Display resolution	800x480
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	Polycarbonate mechanical keyboard
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	2.5, 5, 10, 20 mV/mm
Automatic print speed	5, 10, 25, 50 mm/s
Automatic print	3, 3+1, 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
Calibration signal	Yes, 1 mV
Lead identifier	Yes, before each trace

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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	30 W, 18 V, 1.67 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	25% - 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)
Classification according to FDA	
510K Number	K160840

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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)	1348484

Applicable standards

EN 980	Symbol 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
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

Product and accessory codes

Accessories

63030105	4 Peripheral ECG electrodes clamp AG/ agcl
63030106	Set of 4 peripheral ECG electric clamp Ag/Agl
63030107	4 peripheral ECG electric clamp pediatric
63030163	6 chest ECG electric suction type Ag/agcl
63050025	Patient Cable Banana IEC 10-Wire
63050068	Patient Cable Banana AHA 10-Wire
63050108	Patient Cable Snap IEC 10-Wire
63050109	Patient Cable Snap AHA 10-Wire
69701886	Battery pack
63050032	PATIENT CABLE CLIP IEC 10-WIRE 4 mt
65090057	Carrying case “Cardioline ECG 100+”
66030031C	Disposable electrodes ECG, snap, 50 pics
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
66010052S	Z-FOLD PAPER 210x295mm (ECG200+)
63090688	ECG200+/S trolley

CERTIFICATE

The Certification Body TÜV Rheinland Italia S.r.l.

certifies, in accordance with the TÜV Rheinland Group procedures, that the Company

Cardioline S.p.a.

Via Linz, 151

IT - 38121 Trento (TN)

has established and applies a quality management system
for the following scope:

Design, manufacturing, trading, installation and servicing of electrical medical devices and medical software for cardiology

Through an Audit, Report No. 28111372 001, proof has been furnished that the
quality management system fulfils the requirements of the standard

UNI CEI EN ISO 13485:2016

Please refer to the Quality Manual for the details about
the exclusions with respect to the requirements of the standard.

Certificate Registration No. **39 05 0631503.**

This Certificate is valid from 2018-04-25 to 2021-04-24.

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

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

The certification responsible
TÜV Rheinland Italia S.r.l., Via E. Mattei, 3 - I - 20010 Pogliano Milanese (MI)

This certificate does not represent proof that the statutory requirements of the Directives 93/42/EEC. 90/385/EEC or 98/79/EC have been fulfilled.

ACCREDIA

SGQ N° 083A SGA N° 052D

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC

Signatory of EA, IAF and ILAC Mutual Recognition Agreement

TÜVRheinland CERTIFIED

Management System EN ISO 13485:2016

www.tuv.com ID 9105082907

www.tuvitalia.com

TÜVRheinland®

Certificato di conformità CE

EC Certificate of Conformity

TÜVRheinland®

Sistema completo di garanzia di qualità secondo direttiva 93/42/CEE allegato II escluso punto 4

EC Directive 93/42/EEC Annex II, excluded clause 4 Full Quality Assurance System Medical Devices

Certificato n°: **HD 60146561**

Registration No:

Fabbricante: **Cardioline S.p.a.**

Manufacturer:

Sede legale: **Via Linz, 151**

Registered Headquarter: **38121 Trento (TN) - Italia**

Sede operativa: **Via Linz, 151**

Operational Headquarter: **38121 Trento (TN) - Italia**

Scopo: **Dispositivi di monitoraggio di parametri fisiologici vitali /**

Scope: *Monitoring devices of vital physiological parameters*

Software / *Software*

(Vedere allegato tecnico al presente Certificato per tipologie, modelli e codici)

(*See the attachment for typologies, models and codes designation)*

L'organismo notificato dichiara che il Sistema di qualità stabilito ed applicato dalla società sopra specificata soddisfa i requisiti dell'allegato II, articolo 3 della suddetta direttiva. Questa approvazione è soggetta a sorveglianza periodica, così come definita nell'allegato II, articolo 5 della suddetta direttiva e può essere utilizzata congiuntamente alla dichiarazione di conformità redatta dal fabbricante. / The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5, of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

L'organismo notificato/ ***Notified Body***

Data di emissione/*Issue date*: **15/04/2020**

Data di ultima modifica/*Last revision date:* **15/04/2020**

Data di scadenza/*Expiry date:* **26/05/2024**

Paolo Caglio

TÜV Rheinland Italia S.r.l. Certification Body

TÜV Rheinland Italia S.r.l. - Via Mattei, 3 - 20010 - Pogliano Milanese (MI)

Autorizzata dal Ministero della Salute e dal Ministero dello Sviluppo Economico

Accredited by Ministry of Health and by Ministry of Economic Development

Organismo notificato con il numero 1936 presso la Commissione Europea

Notified under No. 1936 to the EC Commission

CE La marcatura CE può essere apposta esclusivamente se vengono soddisfatti i requisiti di tutte le direttive CE applicabili CE

The CE marking may be used if all relevant and effective EC Directives are complied with

Allegato tecnico al Certificato n° HD 60146561

Attachment to the certificate:

TÜVRheinland®

Fabbricante/*Manufacturer:* **Cardioline S.p.a.**

Scopo/*Scope:* **Dispositivi di monitoraggio di parametri fisiologici vitali /** *Monitoring devices of vital physiological parameters*

Tipologia/ *Typology:* **Holter abpm /** *Abpm Holter*

Modello/ *Model:*

Walk200b, bp one +

Tipologia/ *Typology:* **Holter ECG /** *ECG Holter*

Modello/ *Model:*

Clickholter; Walk400h, click holter+

Tipologia/ *Typology:* **Unità di acquisizione ECG /** *ECG Acquisition Units*

Modello/ *Model:*

HD+ ; CLICKECG-HD

Tipologia/ *Typology:* **Elettrocardiografi /** *Electrocardiograph*

Modello/ *Model:*

ECGxxx (z) (+)

Legenda/ *Key.*

- **xxx : dimensione stampante** / *printer size*
- **(z): interfaccia** / *interface*
- **(+) : connettività internet** / *internet connection*

L'organismo notificato
Notified Body

TÜV Rheinland Italia S.r.l. TÜVRheinland Certification Body

Data di ultima modifica: **15/04/2020**
Last revision date:

Tipologia/ *Typology:* **Sistemi elettrocardiografi /** *Electrocardiographic systems*

Modello/ *Model*

touchECG System

Codice/Code

KTCH$XXYZ-@

Legenda/ *Key:*

- **$= sistema operativo** / *Operating system (Windows or Android)*
- **XX=tipo di computer** / *kind of computer,*
- **Y= tipologia di carrello** / *kind of cart,*
- **Z= altri accessori** / *other accessories,*
- **@=Elettrodi, cavi paziente, caratterizzazioni estetiche** / *Electrodes, patient cable and esthetical customizations*

Tipologia/ *Typology:* **Sistema per l'analisi di sforzo cardiavascolari/** *Cardiovascular stress test system*

Modello/ *Model*

Cubestress System

Codice/Code

KSSXYYZWJ-@

Legenda/ *Key*

- **X=tipologia di sistema** / *system type,*
- **YY=tipo di computer** / *kind of computer,*
- **Z= tipologia di carrello** / *kind of cart,*
- **W= tipologia di stampante** / *kind of printer,*
- **J= accessori** / *other accessories,*
- **@=Caratterizzazioni estetiche** / *esthetical customizations*

L'organismo notificato
Notified Body

TÜV Rheinland Italia S.r.l. TÜVRheinland® Certification Body

Data di ultima modifica: **15/04/2020**
Last revision date:

Scopo/*Scope:* **Software /** *Software*

Tipologia/ *Typology:* **Software elettrocardiografico /** *Electrocardiographic software*

Modello/ *Model*

touchECG rel. 3.xy Ed: z

Codice/Code

81019579 – for Windows
81019582 – for Android

Tipologia/ *Typology:* **Sistemi software di importazione, analisi, refertazione e archiviazione esami Holter ECG /** *Software systems for importing, analyzing, reporting and archiving Holter ECG exams*

Modello/ *Model*

Cubeholter WS Rel. 3.xy Ed: z

Codice/Code

85039510

Modello/ *Model*

Cubeholter Web Rel. 3.xy Ed: z

Codice/Code

85039520

Legenda/ *Key*

x= versioni minori / minor changes
y= correzioni / bug fix release

Se xy=00, è idenfiticato con 0 / If xy = 00, it's identified as 0

z: contenuto della configurazione / content of the distribution media

L'organismo notificato
Notified Body

TÜV Rheinland Italia S.r.l. TÜVRheinland Certification Body

Data di ultima modifica: **15/04/2020**
Last revision date:

Tipologia/ *Typology:* **Software di archiviazione, misurazione e refertazione esami /**
Software for exams archiving, measurement and review

Modello/ *Model:*

ECGWebApp Rel. 2.xy Ed: z

Codice/Code:

81019560

Tipologia/ *Typology:* **Sistemi software di monitoraggio /** *Monitoring systems software*

Modello/ *Model:*

CUBE SUITE; Cubeabpm; Cubestress Lite; Cubestress Rel. 1.4 .x.y Ed: z

Modello/ *Model:*

Cubestress Rel. 4.xy Ed: z

Codice/Code:

85050100

Legenda/ *Key:*

x= versioni minori / minor changes
y= correzioni / bug fix release

Se xy=00, è idenfiticato con 0 / If xy = 00, it's identified as 0

z: contenuto della configurazione / content of the distribution media

L'organismo notificato
Notified Body

Data di ultima modifica: **15/04/2020**
Last revision date: