CARDIOLINE

touchECG

General Information

Product name	TouchECG
Generic name	TouchECG - Android
Product code	81019582
Manufacturer	Cardioline Spa Head Office and Production: Via Linz, 151 38121 Trento Italy Sales Office: Via F.lli Bronzetti, 8 20129 Milan Italy

Digitally signed by Grabazei Alexandru
Date: 2021.10.21 16:20:30 EEST
Reason: MoldSign Signature
Location: Moldova

Description of Device

TouchECG is a software implementing a 12 channels diagnostic electrocardiograph which displays, acquires, prints and stores ECG traces for adults and children. It also calculates the principal global ECG parameters.
The device can be supplied with the optional 12-lead Glasgow resting ECG interpretation algorithm, with specific criteria for patients of different age, sex and race. If this option is enabled, the algorithm can provide the physician of reference with an automatic interpretation, generating diagnostic messages in the ECG report.
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 accessory equipment).
The device can be configured with the DICOM® function.
The device can be installed on any tablet and smartphone that complies with the minimum requisites listed.
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

TouchECG is designed to monitor and diagnose cardiac function. However, a Cardiologist must validate the results of the analysis run by the ECG.
TouchECG is intended for use in hospitals, clinics and outpatient departments of any size. It is suited for use at home and in emergencies (ambulances).

- 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

Minimum requirements for the computer

Operating System	Android 4.4 KitKat (API 19) or higher
Processor	Quad core 1.6 GHz or higher
RAM	1 GB or more
Free space on Hard Disk	8GB or more
Monitor	Tablet: 7” or more Smartphone: Samsung 4.7” or more
Bluetooth	Bluetooth 2.1 +EDR
Printer	Laser (colour/BW)
Additional applications	Acrobat “PDF” file format viewer

ECG acquisition (HD+ unit)

ECG leads	12-leads (I, II, III, aVR-L-F, V1-6)
Patient cable	10 replaceable wire patient lead
CMRR	115dB
DC input impedance	100MΩ
A/D converter	24 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	20 bit
Resolution	<1 µV/LSB
Dynamic range	+/- 400 mV
Bandwidth	Performances equivalent to 0,05-150 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
Data transfer	Bluetooth 2.1+ EDR with “secure pairing”

Processing

Operating system	Android
Pacemaker detection	Hardware recognition in compliance with the requirements 60601-2-25 (HD+ acquisition unit)
Lead-fail detection	Independent for all leads
Cardiac frequency range	30 - 300 bpm
Sampling rate	500 Hz
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 acquisition mode	Automatic (12 channels)
Lead configuration	Standard, Cabrera

CARDIOLINE

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.
ECG interpretation	Glasgow algorithm for adults, paediatric, STEMI (optional)
ECG interpretation parameters	Sex, age
Memory	Internal archive stores up to 1000 ECG's

Processing options

Interpretation	Glasgow algorithm for adults, paediatric, STEMI
Connectivity	DICOM

Exported formats

SCP-PDF-XML-GDT	Standard format (webgateway)
DICOM	Included in DICOM connectivity option
HL7	Optional

Connectivity

WiFi - 4G	Dependent on support device (computer)

Printing

Resolution	Variable in relation to printer
Paper type	Variable in relation to printer
Sensitivity/gain	5, 10, 20 mm/mV
Automatic print speed	25, 50 mm/s
Automatic print	3, 3+1, 6, 12 channels; Standard or Cabrera;
Automatic print formats	12x1, 6x2, 3x4, 3x4+1, 3x4+3
Calibration signal	Yes
Lead marker	Yes

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	K160746
Product Code:	DPS

Classification:	Class II
Regulation Number:	21 CFR 870.2340

Classification according to IEC 62304 – Software

Class of risk	B

Performances (ECG display)

Standard	EN 60601-2-25:2011

Other classifications

GMDN	16231 - Electrocardiographs, Interpretive
CND	Z12050302 - ELECTROCARDIOGRAPHS FOR ADVANCED DIAGNOSIS
RDM (Medical Device Catalogue)	1369845

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 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs. Partly applied – Applied in conjunction with HD+
IEC 60601-1-11	Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment. *Partly applied – Applied in conjunction with HD+*
EN 62304	Medical device software - Software life cycle processes
EN 62366	Medical devices - Application of usability engineering to medical devices

Product codes

Accessories

81018027	HD+