

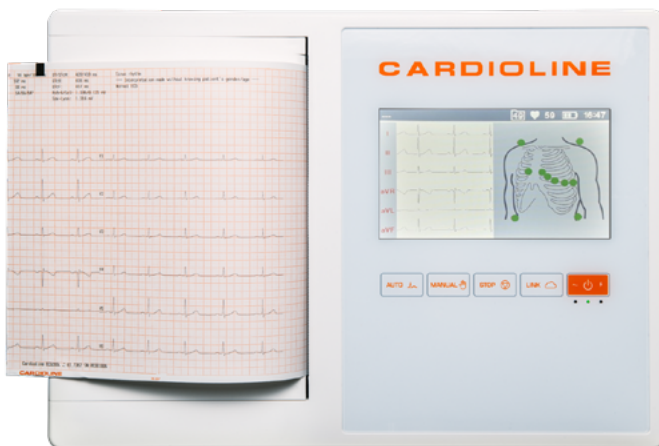
Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
						cardioline				
DM000499864	SOFT PENTRU ANALIZARE ŞI PRELUCRARE ECG		CUBESTRESS	85050100	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499862	SOFT PENTRU ANALIZARE ŞI PRELUCRARE ECG		CUBEHOLTER WEB	85039520	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499865	SOFT PENTRU ANALIZARE ŞI PRELUCRARE ECG		CUBESTRESS SYSTEM	KSSXYZWJ-@	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499899	SOFT PENTRU ELECTROCARDIOGR	CARDIOLINE	ECGWEBAPP	81019594	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499866	SOFT PENTRU ANALIZARE ŞI PRELUCRARE ECG		CUBE SUITE	81019557	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499861	ELECTROCARDIOGR AMBULATORY HOLTER		CLICKHOLTER	81018031, 8101012X	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499875	ELECTROCARDIOGR		HD+ 15	81018228 – 81018328	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499900	SOFT PENTRU ELECTROCARDIOGR	CARDIOLINE	ECGWEBAPP HOLTER	81019595	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499872	ELECTROCARDIOGR		ECG200S	80608069, 80608069S, 8060957X, 8060927X, 80608169, 8060957X	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499871	ELECTROCARDIOGR		ECG200L	80608070, 8060979X	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	

DM000499863	ANALIZARE ȘI PRELUCRARE ECG		COBEHOLTER WS	85039510	Italia	S.P.A.	DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499873	SOFT PENTRU ANALIZARE ȘI PRELUCRARE ECG		ECGWEBAPP	81019560	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499877	ELECTROCARDIOGR AMBULATYOR HOLTER		WALK400H	81018030 / 8101012X	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499867	ELECTROCARDIOGR		ECG100+	80508095, 8050959X, 8050929X, 80508195, 8050939X	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499860	ELECTROCARDIOGR		CLICKECG-HD 15	81018428	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499868	ELECTROCARDIOGR		ECG100L	80508097, 8050979X	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499874	ELECTROCARDIOGR		HD+ 12	81018231 – 81018331	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499870	ELECTROCARDIOGR		ECG200+	80608068, 80608068S, 8060957X, 8060927X, 80608168, 8060957X	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499869	ELECTROCARDIOGR		ECG100S	80508096, 8050959X, 8050929X, 80508196, 8050939X	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	
DM000499876	ELECTROCARDIOGR AMBULATOR HOLTER DE TENSIUNE ARTERIALA		WALK200B	87018307 – 87018308 – 87019308 - 87019305 – 87019305-C	Italia	CARDIOLINE S.P.A.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000101	10-05-2023	

Enter the Cardioline world

ECG200L

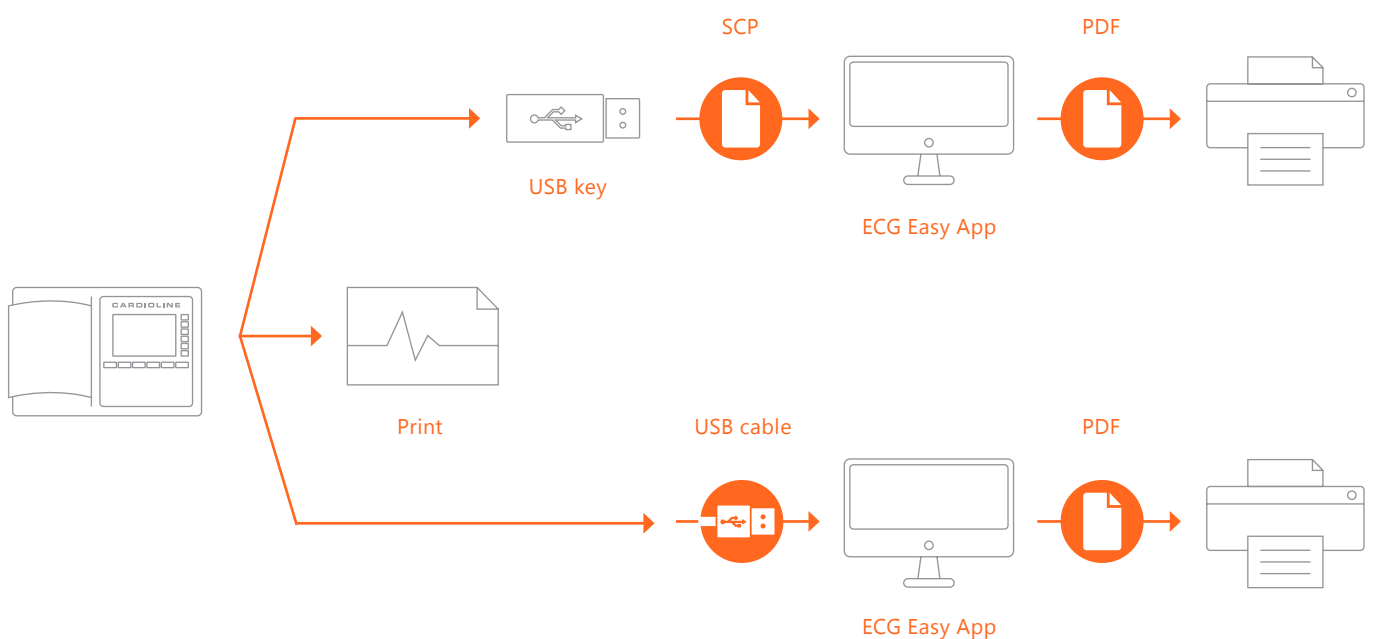
The full format 12 lead ECG for your medical practice



- The ECG 200L has been designed to provide simple and fast 12 lead resting ECG acquisition for the private practice.
- Particular attention has been dedicated to device usability using a brilliant 7 inches color touch screen display, as well as dedicated keys for fast operation.
- User is guided through ECG acquisition step by step, from electrode placement, to quality checking, acquisition, printing and storage.
- Automatic, manual, Stat or rhythm ECGs can alternatively be acquired at the simple touch of a key.
- The new Rhythm ECG function allows for rhythm analysis of 3 minutes of ECG, including HR trending and Variability.
- ECG files can be stored on the device or exported, through USB connection to a PC or a memory stick.
- Glasgow algorithm for interpretation is available for pediatric and adult ECGs.
- A specific ECG Management application for PC's, "ECG EasyApp," is designed to allow for easy but complete handling of patient ECGs.

Technical Specifications

ECG channels	12-lead (I, II, III, aVR-L-F, V1-6)
Patient cable	Standard 15D, 10-wires
CMRR	>100dB
Input impedance	100MΩ
Sampling rate of the input stage	32000 samples/second/channel
ECG resolution	5μV/LSB; 500 s/s
Dynamic range	+/- 325 mV
Bandwidth	Performance equivalent to 0,05-150 Hz
Pacemaker detection	Hardware detection coupled with convolution digital filtering
Filters	Linear phase digital diagnostic high-pass filter (acc. 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
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), Rhythm (1/3-leads)
Configuration	Standard or Cabrera
Lead fail detection	Independent on all leads
ECG measurements	All leads, average, QT corrected, Sokolow-Lyon Index
ECG interpretation	Glasgow Analysis Program for Adult, Pediatric, STEMI
Export format	SCP-PDF
PC-ECG "Easy App"	Dedicated ECG Management application for PC



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PRODUCT SHEET: ECG200L



Description of product:

The device is a 12-lead, fully diagnostic 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.

GENERAL INFORMATION

Product Name	ECG200L
General Name	ECG200L
Product Code	80608070
Manufacturer	Cardioline S.p.A.
	Headquarters Via Linz, 151 38121 Trento Italia
Intended use	ECG200L is a 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 USB, print the 12 lead ECG in automatic or manual mode by means of its built-in thermal printer. ECG200L is intended for assessment and diagnosis of cardiac functions. In any case the results of analysis performed by the electrocardiograph must be validated by a Physician.

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	<p>ECG200L is intended for use in hospitals, in medical clinics and doctor's offices of any size.</p> <ul style="list-style-type: none"> ▪ The device is indicated for use to acquire, analyse, display and print electrocardiograms. ▪ The device is intended to provide the physician with an automatic interpretation of the ECG to be reviewed 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. ▪ 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. <p>The device is not intended to be used as a vital signs physiological monitor.</p>
Year marketed	2018

TECHNICAL SPECIFICATIONS

ECG Acquisition

ECG channels	12-lead (I, II, III, aVR-L-F, V1-6)
Patient Cable	Standard 15D connector, 10 wires patient cable
CMRR	> 100dB
Input impedance	100MΩ
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
A/D conversion	16 bit
Output Data Resolution	5 μV/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), Rhythm (1 Lead for 3 minutes or 3 Leads for 1 minute)
Lead Configuration	Standard, Cabrera
Processing	
Pace detection	Hardware detection in compliance with the requirements 60601-2-25

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Lead fail detection	Independent on all leads. "Torso" function that allows you to view the disconnected electrodes in red and those correctly connected in green.
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 interval and QTc interval, with Hodges, Bazget and Fridericia's formula max R[V5]or[V6] and S[V1] Sokolow-Lyon Index P, R, T axis.
ECG Interpretation	Glasgow Analysis Program for Adults, Pediatric, STEMI
ECG Interpr. Data input	Sex, age
Storage	50 ECG
Available languages	Brazilian, Czech, Croatian, Dutch, French, English, Italian, Polish, Portuguese, Romanian, Russian (with Russian keyboard), Serbian, Spanish, German, Turkish, Hungarian
Autotest	The device performs an auto-test of its internal electronic functions at every start up.
Processing Options	
Interpretation	Glasgow Analysis Program for Adults, Pediatric, STEMI (optional)
Supported export formats	
SCP	Standard
PDF	Through a dedicated application for files management on Personal Computer
Connectivity	
USB	Standard
Display	
Display Type	7" TFT Backlit Color LCD with Capacitive Touch Panel
Display resolution	800x480
Display data	3/6/12 leads real-time
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 – z-fold A4 295x210mm – letter 280x216mm

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Sensitivity/Gain	5, 10, 20 mm/mV
Auto print speed	5, 10, 25, 50 mm/s
Auto print	3, 3+1, 6, 12 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	12x1, 6x2, 6+6, 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)
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
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

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

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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

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
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
63050109 63050141	ECG patient cable AHA, 10 lead, snap
63050032	ECG patient cable IEC-10 CLIP 4 mt
M-00-S	Disposable electrodes ECG, snap, 50 pcs
66030040C	Disposable electrodes ECG, tab, 100 pcs; pack of 10
N-10-A	Disposable electrodes ECF neonatal, 25 pcs
SU-00-A	Disposable electrodes ECG banana, 60 pcs
63090236	Set of 10 snap adapters for 4 mm plug
66020008	Adapters for tab and button electrodes for 4 mm plug, 10 pcs
66010052S	Z-Fold paper A4 210x295mm, 180 sheets, 10 pcs
66010053S	Z-Fold paper Letter 216x280mm, 180 sheets, 10 pcs
63090713	ECG200+/S/L trolley II Edition hospital grade

CARDIOLINE

Walk200b

General Information

Product Name	Walk200b
Generic Name	Walk200b
Product Code	87018307
Manufacturer	Cardioline Spa

Registered Office and Production:
Via Linz, 151
38121 Trento
Italy

Sales Office:
Via F.lli Bronzetti, 8
20129 Milan
Italy

Description of Device

Walk200b is a recorder for monitoring blood pressure over a 24-hour period. Walk200b is compatible with CARDIOLINE® Cubeabpm reading and analysis software, please refer to the related documentation. Walk200b is an easy-to-use, lightweight and compact recorder to maximise patient comfort. In particular, Walk200b features:

- LCD display for displaying measured values and service messages (this function can be disabled via software);
- advanced PC connectivity based on standard Bluetooth technology or through USB (optional, requires data-transfer cable);
- self-adapting algorithm for controlling cuff inflation
- event marker and start/end of waking and sleeping periods functions;
- small size and noiseless pump.

Technical Specifications

Acquisition

Method	Oscillometric
Pressure value range	Systolic from 60 to 290 mmHg Diastolic from 30 to 195 mmHg
Pressure accuracy	± 3 mmHg in the indicated interval
Static pressure range	from 0 to 300 mmHg
Frequency accuracy	Higher than or equal to ± 3 bpm (or 2%)
Frequency range	30 to 240 beats per minute
Measurement range	5, 10, 15, 20, 25, 30, 40, 50, 60, 90 and 120 minutes
Measurement protocol	2 editable interval groups
Memory capacity	300 measurements or 48 hours
Data transfer	Bluetooth (Class 1 / 100 m) USB (optional)
Compatible devices	Cardioline Cubabpm (version 1.4.5 or higher required for USB option) Cardioline Webuploader (version 1.9 or higher required for USB option)

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Cardioline Device Web Manager

Electrical specifications

Power supply	2 rechargeable batteries: <ul style="list-style-type: none">Ni-MH 1.2 V each and min. 1500 mAh (AA)2 alkaline batteries 1.5 V (AA)
Battery life	> 300 measurements

User interface

Display	To see the menu
Buttons	4 buttons (Start, Day/Night, Event, On/Off)
Buzzer	A buzzer to signal the main operations (on or off, start and completion of a measurement) and errors
Configurable settings	Measurement protocol (time interval and number of measurements) Maximum recording duration: 24hrs Dates and time Language

Physical specifications

Dimensions	128 x 75 x 30 mm
Weight	240 g with batteries
Protection against accidental ingress of water or substances	IP X0 IP X2 with Walk200b waterproof case
Packaging	30x21x61 cm, 1 Kg

Environmental operating specifications

Temperature	10° C - 40° C
Humidity	15% - 90%
Altitude	up to 3000 meters above sea level

Environmental storage specifications

Temperature	-20° C - 50° C
Humidity	15% - 95%

Regulations and Safety

Classification according to MDD 93/42/EEC

Class	Class IIa
Rationale	Rule 10 annex IX Directive 93/42/EEC and its amendments
Notified Body	TUV (1936)

Classification according to FDA

Number 510K	Unavailable
Classification	Unavailable
Product Code:	Unavailable
Review Panel:	Unavailable
Regulation Number:	Unavailable

CARDIOLINE

Classification according to IEC 60601-1 – Electrical safety

Protection against electrical shock	IP (Internal power supply)
Applied parts	Type BF – defibrillation-proof
Protection against accidental ingress of water or substances	IP X0 IP X2 with Walk200b waterproof case
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	B

Performance

Standard	EN 80601-2-30
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Other classifications

GMDN	36888 Patient data recorder, long-term, sphygmomanometer
CND	Z12050404 - HOLTER BLOOD PRESSURE RECORDERS
RDM (Medical Device Catalogue)	597697/R

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 60601-1-11	Electromedical devices - 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.
EN 62366	Medical devices - Application of usability engineering to medical devices
EN 60601-2-47	Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems.
EN 80601-2-30	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

Product and accessory codes

Product Configurations

CARDIOLINE

87019307	Walk200b – BT connectivity
87019305	Walk200b - BT and USB
87019305-C	Walk200b - BT and USB (includes n. 1 Walk200b-PC USB data transfer cable)
KW200TEL	Walk200b config. BT ABPM TEL
87019305-T	Walk200b config. BT/USB ABPM TEL
87019305-CT	Walk200b config. BT/USB ABPM with cable USB TEL

Accessories

01020009	Large cuff for walk200b
01020008	Medium cuff for walk200b
01020007	Small cuff for walk200b
01020006	Extra Small cuff for walk200b
01020010	Extra Large Cuff for Walk200b
65090070	Pouch for Walk200b
69400074	Undercuff band 50-ply roll
63090733	Walk200b waterproof case
67040301	USB data transfer cable