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: • 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	10º C - 40º C
Humidity	15% - 90%
Altitude	up to 3000 meters above sea level

Environmental storage specifications

Temperature	-20º C - 50º 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

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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

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

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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