

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	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

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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
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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

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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

cubeabpm is the complete solution to manage Holter pressure tests (ABPM o MAPA).

cubeabpm combines all the typical procedures for the ABPM test in a single application: from recorder management to downloading the test to a PC and automatically archiving it, from

automatic analysis and review to printing out the final document and exporting it in electronic format.

cubeabpm can operate as a single workstation, or the database can be shared with other networked cube workstations.

Description

User Interface

cubeabpm makes the most of the graphic potential of Windows, guiding even inexperienced users through the correct execution of all phases of the ABPM test. Using menus, dedicated keys and guided procedures, working with **cubeabpm** is extremely practical and fast.

cubeabpm consists of several windows which can be used to monitor all program features at the same time: from simply displaying the trace in various formats to validating the automatic analysis and printing out the final document.

cubeabpm has five main windows, each designed to direct the attention of the operator to a particular aspect of the test:

- the **measurement page** displays the test chronogram and related table for the heart rate and the systolic, diastolic and mean pressure values. The graphic appearance of the page can be modified from the control panel, changing the colours and the number of variables displayed on the screen.
- the **means page** presents the mean values of the programme variables, presented in the form of chronograms and pie charts to indicate both the progression over time and the hour distribution of the values measured.
- the **statistics page** offers all the statistical tools needed to analyse the test. Specifically, it presents three different sections, with variables histograms, test measurement classification according to the theoretical reference values (e.g. hypertension guidelines from the European hypertension society) and, finally, measurement dispersion graphs.
- the **comparison page** allows two or more tests belonging to the same patient to be compared, synchronised using various criteria.

- the **mycube page** is fully customisable by the user, and is therefore composed of graphs or tables selected freely from a list.
- the **report page** allows the user to write conclusions, configure the final document for printing, or select one of the configurations saved in the system and proceed to **print out** the document. The conclusions, like the indications and treatments, are equipped with a preformatted dictionary that can be used to speed up preparation of the final documents. It is also possible to **export the document** to be printed out in electronic format, or to attach it automatically to an e-mail.

The principal feature of the **measurements page** is direct interaction with the pressure values: the *change or cancel measurement* functions are always available, and may be applied to individual measurements or to groups of measurements, as can the *print preview* and *copy graph or table to notes* functions. Changes may be made to the analysis using the mouse or dedicated keyboard keys.

To speed up writing of the *final report*, each window is also provided with a *free text* area which can automatically be included in the final conclusions of the printed document.

Use profile

The operator can choose to use all the displays available in **cubeabpm** or can select, to use only those that best meet his or her requirements and approach.

Automatic Analysis

The efficiency and performance of the analysis algorithms, together with the calculation power of the latest generation of PCs, guarantee the

accuracy of the analysis and allow the program to perform analysis very quickly.

Automatic analysis is based on statistical calculations performed using the measurements made by the recorder, and presents this data in different graphic formats, according to the clinical aspect focussed on.

From the first time the test is opened, **cubeabpm** presents a complete and detailed report of the measurements made.

All the analysis, printout and display parameters can be customised and saved as system configurations, or a particular configuration can be defined for a single user

Saving tests

cubeabpm includes a dedicated database in which acquired tests can be saved and organised.

cubeabpm places the patient at the centre of the system, creating a virtual clinical record in which all the tests performed by **cube** workstations are automatically saved.

Managing tests

cubeabpm offers a system of predefined views of the database, accessed by dedicated icons on the toolbar: so the operator can quickly access the list of tests to report on, and read and sign each test. The program also includes a *long term*

archiving function for the database, which allows tests that have already been analysed to be transferred to an external support (CD, DVD, etc.), maintaining the patient data and overall data on the archived test available online in the database.

cubeabpm also allows advanced searches to be made using the patient data, test or acquisition device as search parameters.

Management of test preparation and downloading procedures

cubeabpm offers innovative management of the procedures to prepare tests and download them to the PC. The operator can use guided procedures to successfully and efficiently prepare both the recorder and the downloading of the test to the PC, managing the *patient data* correctly, entering the *indications and treatment*, programming the *duration of the test and the type of recording profile to be used*.

Sharing the database with other cube stations

cubeabpm was designed with the capability to share its database with other **cube** workstations. This feature can be used to optimise work in a clinic or ward according to the specific clinical requirements of the individual physician. For example, workstations can be dedicated to downloading tests, and others to their analysis, or to the execution of different diagnostic techniques such as stress tests, Holter ECG and rest ECGs

- Technical Specifications

Analysis modes	Interactive, with the possibility of analysing and reviewing the test by using lists of chronograms, tables, histograms, pie carts (and) the tools available to define thresholds and customised analysis periods.
Colour coding	There is a specific colour for each programme variable: systolic pressure, diastolic pressure, mean pressure, heart rate.
Print document	Print document fully customisable. Possibility of saving a large number of models. Printing documents in black and white and in colour
Automatic archive function	Automatic in the database, optional DVD backup in the SW package
Export of final document	Export and transmission by e-mail of final document in PDF or XML.
Network connection	Can be networked and the database shared with other cube workstations
Display	La resolución de pantalla máxima permitida es Full HD

