CARDIOLINE

PRODUCT SHEET: Walk400h

Description of product:
Walk400h is a new generation holter ECG recorder that allows you to record, with any patient cable configuration, up to 48 hours, with a sampling rate of up to 1000 samples/second and up to 7 days, with a sampling rate of 250 samples per second, for both adult and pediatric patients.
It is possible to choose the number of channels to be recorded using a 5, 7 or 10-wire cable. The device automatically recognises the inserted cable and consequently selects the type of recording. Through the software it is also possible to select the sampling rate to be used by the device while recording.
Walk400h offers the operator the option to record a 20s voice message during the preparation of the exam.
The user interface is simple and intuitive. A TFT 2.2" colour display shows up to 6 traces simultaneously, allowing the physician to check good signal quality before starting recording. A 4-way joystick plus pressure allows you to easily navigate the menu and configure the device. Two LEDs, a green one and a blue one, provide indications on battery and device status, while a buzzer signals any errors.
The recorder comes with a compact design in terms of weight and dimensions to ensure that the appliance is comfortable to wear.
The recorded data may be downloaded and analysed via the Cardioline Cubeholter software or downloaded and sent to a remote computer via the Cardioline DeviceWebManage or Webuploader software. Data are transferred via a USB cable.
With DeviceWebManager or Webuploader it is also possible to prepare the recorder, by transferring patient data onto it and the type of recording to be performed.
The power supply with standard AA battery ensures that the recorder is easy to prepare.

General Information	
Product name	Walk400h
Generic name	Walk400h
Product code	81018030
Manufacturer	Cardioline Spa
	Headquarters Via Linz, 151 38121 Trento Italia
Intended use	Walk400h/Clickholter is an ECG Holter recorder intended for continuous ECG signal recording. The signal recorded in the devices' internal storage is intended to be transferred to a PC for analysis via a designated ECG Holter analysis software.

	The ECG signal is recorded with a patient cable that may have 5, 7 or 10 wires (Walk400h only), according to the number of ECG channels to be recorded: 3 channels with 5 or 7-wire cables and 12 leads with 10-wire cable (Walk400h only). The recorded data are transferred to the PC through a USB connection. A colour graphic display shows up to 6 channels during preparation of the recorded. This feature allows the physician to check signal quality before starting recording. The device is indicated for use in a clinical setting: hospitals, clinics and outpatient facilities of any size. It is also suited for home use. ▪ The device is indicated for continuously recording the ECG signal. ▪ The device is not indicated for use as physiological monitoring of vital signs. ▪ The device is not intended as the only means for determining the diagnosis. ▪ The device is indicated for use on adult and paediatric patients. ▪ The device is indicated for use by a physician or trained personnel acting on behalf of an authorised physician.
Year marketed	2018

Technical specifications	
ECG recording	
ECG leads	Up to 12 leads
Patient Cable	5-wire cable – 3 single-pole channels 7-wire cable – 3 double-pole channels 10-wire cable – 8 channels/12 leads (standard ECG assembly)
CMRR	> 85 dB
DC input impedance	> 60MOhm
A/D Converter Features	24 bit, 96000 samples/second/channel
Sampling rate for signal analysis and storage	User selected: 250 – 500 – 1000 samples/second/channel
Resolution A/D Converter	<1 µV/LSB
Signal resolution for analysis and storage	2.5uV
Dynamic range	+/- 400 mV
ECG Bandwidth	Performances equivalent to 0.05 - 300 Hz (at 1000 sps)
Filters	Linear phase digital diagnostic high-pass filter (compliant with IEC 60601-2-25 2nd ed.)
Front-end performance	ANSI/AAMI/EN 60601-2-47 2nd ed.
Pacemaker detection	Hardware detection coupled with digital convolution filter Compliant with 60601-2-47 201.12.4.4.109

Defibrillation protection	Not present
Patient cable recognition	Automatic identification of patient cable used
Lead-fail detection	Independent for all leads
Maximum recording duration	500/1000 samples/second/channel: 48 hours 250 samples/second/channel: 7 days Regardless of number of channels
Internal memory	16 GB SD card Capacity above 100 3-channel recordings, 24 hours at 250 sps
Data transfer	USB 2.0
Compatible devices	Cardioline Cubeholter, Webuploader
Electrical features	
Power supply	1 standard AA battery: ▪ Alkaline ▪ Lithium
Battery life	Alkaline battery (~2500 mAh): ▪ More than 48h of recording Lithium Battery (3000mAh, 1.5V): ▪ 7 days of recording
User interface	
Display	TFT 2.2” colour display displaying 6 traces Resolution: 240 x 320 px
Buttons	1 multifunction button (4 direction buttons + 1 central button)
LED	Green battery status indication LED Blue device status indication LED
Buzzer	A buzzer to signal errors
Voice recorder	Voice recorder for any comments while preparing the patient
Configurable settings	Recording type: 250-500-1000 Hz Maximum recording duration: 24hrs, 48hrs, 7 dd Dates and time Language
Patient data	ID Name Surname Date of birth Gender
Specifications	
Dimensions	96 x 64 x 20 mm
Weight	100g with battery (80g without battery)
Protection against accidental entry of water or substances	IP 4X IP 42 with Walk400h waterproof case

Packaging	15x21x5 cm, 1 Kg
Environmental operating specifications	
Temperature	5º C ÷ 40º C
Humidity	50% ÷ 95% - without the pouch 15% ÷ 95% - with the pouch
Pressure	500 ÷1060 mbar
Environmental storage specifications	
Temperature	-25º C ÷ 70º C
Humidity	5% ÷ 95%
Pressure	500 ÷1060 mbar

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	
Number 510K	Unavailable
Classification	Unavailable
Product Code:	Unavailable
Review Panel:	Unavailable
Regulation Number:	Unavailable
Classification according to IEC 60601-1 – Electrical safety	
Protection against electrical shock	IP (Internal power supply)
Applied parts	CF type
Protection against accidental entry of water or substances	IP 4X IP 42 with Walk400h 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 60601-2-47

Other classifications	
GMDN	12388 Recorders, Long-Term, ECG, Portable
CND	Z12050403 ECG HOLTER RECORDERS
RDM (Medical Device Catalogue)	1706791/R
Applicable standards	
EN ISO 15223-1	Medical devices - Symbols to be used with labels, labels and information on medical devices 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 electromedical devices and electromedical systems used in a domestic 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 basic safety and essential performance of ambulatory electrocardiographic systems.

Product and accessory codes	
Accessories	
63050099	IEC 5-wire patient cable
63050100	IEC 7-wire patient cable
63050101	IEC 10-wire patient cable
63090306	Walk400h USB connection cable
VL-00-S	Disposable button electrodes 25 pcs
9983015	Disposable button electrodes 50 pcs
SGFO3642	Disposable button electrodes 100 pcs (only for Telemedicine)
65090069	Pouch for Walk400h
66030038C	Fixing system for patient cable

63090732	Walk400h waterproof case (waterproof pouch IPX2)
P-00-S	Pediatric disposable button electrode, 50 pcs.

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Cubeholter WS

General Information

Product name	Cubeholter WS
Generic name	Cubeholter WS
Product code	85039510
Manufacturer	Cardioline Spa Via Linz, 151 38121 Trento Italy

Description of Device

Cubeholter WS is a software system for importing, analysing and reporting Holter ECG traces, acquired by means of Walk400h and Clickholter recorders, with sampling rates from 250 to 1000 Hz and recording duration from 1 to 7 days.
Cubeholter WS creates a complete ECG Holter local work station where it is possible to prepare the Holter recorder, download the test, analyse it, review it and store it locally. It can be used with Cardioline connectivity software to manage a complex workflow, which allows you to receive and use work lists, receive tests remotely for reviewing, send PDF reports of the tests provided to Cardioline ECGWebApp.

The software consists of the following main functions:

1) **Preparing the recorder and entering patient data.** By connecting the Holter recorder, it is possible to enter the patient's data and set the recording parameters.
2) **Downloading and storing recorded tests.** By connecting the Holter recorder, any recorded tests and patient data are downloaded to the computer in a local archive. Patient data can also be imported from GDT files.
3) **Test analysis and creation of specific parameters.** The software performs a series of automatic analyses on the downloaded test: recognition and removal of artefacts, heartbeat recognition, heart rate and Atrial Fibrillation analysis, template generation, strip configuration, recognition and classification of supra-and sub-ventricular arrhythmias, ST analysis, QT/QTc analysis, HRV analysis and pacemaker analysis.
4) **Holter test display and reviewing.** By using a display, it is possible to view the entire ECG Holter test and the results of the analyses referred to in the previous point, change its parameters and review it, creating the relevant PDF report.
5) **Exporting the PDF and GDT Holter report.** The Holter report can be exported in PDF and GDT format.

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Technical Specifications

Minimum Requirements for Work Stations

Operating System	Windows 7 or higher, 32 or 64 bit
Processor	Intel core i5 or higher
RAM	More than or equal to 8GB
Free space on Hard Disk	At least 2GB for the program plus the space for the archive
Screen	16:10 form factor @ 1600x1050, 22” or more (100% resizing) 16:9 form factor @ 1920x1080, 15.4” or more (>= 100% resizing) Maximum recommended resolution: 4096×2160 (4K)
USB	At least 1 USB port
Printer	Laser B/N or Colour
Safety Standard	IEC 60950-1

Tests archive

Archive type	Local database
Archive capacity	1,000 tests (recommended limit)
Functions	▪ View, delete and modify patient data and test parameters of archived recordings ▪ Prepare a recorder ▪ Import recordings from a recorder ▪ Delete recordings from a recorder
Compatible devices	▪ Walk400h ▪ Clickholter
Patient data	▪ Name; ▪ Surname; ▪ Patient ID; ▪ Second ID; ▪ Date of birth; ▪ Gender; ▪ Pacemaker; ▪ Phone; ▪ E-mail; ▪ Reason for study; ▪ Therapy; ▪ Date and time of recording.
Test parameters	▪ Patient cable: 5, 7 or 10 wires; ▪ Recording duration: 24h, 48h or multiple days (multiday - up to a maximum of 7 days); ▪ Sampling rate: 250 Hz, 500 Hz or 1000 Hz.

Automatic analysis

Analysis windows	▪ RR with histogram , trend, table analysis ▪ Template analysis ▪ Arrhythmia analysis ▪ ST Analysis ▪ QT Analysis ▪ Events ▪ HRV Analysis
Preview	▪ Allows to stop the analysis process to directly open and review the recorded exam in preview mode, and manually mark part of the tracing as artifacts, if necessary,

	before restarting the automatic analysis;
Final report	Customisable final report: ▪ Header; ▪ Summary per page; ▪ Glossary: multiple editable glossary available for therapy, anamnesis, diary and signature fields; ▪ Templates: option to add textual parts also containing clinical parameters that can be entered through tags. The following tags available: o Test length, Beats, HR med, HR min, HR max, Atrial fibrillation, Bradycardia, Supraventricular tachycardia, Ventricular tachycardia, Pauses, Ventricular arrhythmias, Supraventricular arrhythmiasPrint reservations; ▪ Data: o Trend: RR/FC, Arrhythmias, ST, QT, HRV; o Tables: Resume, RR/FC, Complete or simplified Arrhythmias, ST, QT, HRV; o ECG: RRmax/RRmin, FCmax/FCmin (manually editable) Arrhythmia Strips, Templates, ST Analysis.
Tracings display format	▪ Interval displayed; ▪ Leads displayed; ▪ Tracing format: 1 (compacted display - only in the RR window), 3, 12; ▪ Amplitude: 1, 5, 10, 20, 40 mm/mV; ▪ Speed: 5, 10, 25, 50, 100 mm/s. ▪ Signal filtering (display): ON (25 Hz), OFF
Parameters for analysis	Criteria: ▪ SVS: Number of consecutive beats to classify an Arrhythmia as Supraventricular. ▪ SVT: Number of consecutive beats to classify an Arrhythmia as Supraventricular Tachycardia. ▪ BRA: Number of consecutive beats to classify an Arrhythmia as Bradycardia. ▪ PAU: Minimum RR value to classify an Arrhythmia as a Pause. ▪ BRA: Maximum frequency value to classify an Arrhythmia as Bradycardia. ▪ SVT: Minimum frequency value to classify an Arrhythmia as Supraventricular Tachycardia. ▪ AIVR: Minimum frequency value to classify an Arrhythmia as Accelerated Idioventricular Rhythm. ▪ VT: Minimum frequency value to classify an Arrhythmia as Ventricular Tachycardia. ▪ Pacemaker Analysis: on/off. ▪ Type of pacemaker: atrial, ventricular, atria-ventricular, unknown. ▪ Pacemaker operating frequency: between 40 and 110 bpm. Thresholds: ▪ Normal premature: Negative variation of RR as a percentage of the average value to classify a normal beat as premature. ▪ Atypical premature: Negative variation of RR as a percentage of the average value to classify an atypical beat as premature. ▪ Rhythmic (%): RR variation in percentage with respect to the average value to classify a normal beat as normal even in terms of rhythm. ▪ Delayed: Positive variation of RR as a percentage of the average value to classify a beat as delayed.
Classified heartbeats	▪ Normal heartbeat; ▪ Ventricular heartbeat; ▪ Supraventricular heartbeat; ▪ Artefacts; ▪ Induced heartbeat (if pacemaker analysis is active).
Arrhythmia detection	▪ Atrial fibrillation; ▪ Bradycardia

- Tachycardia
- Supraventricular couplets
- Supraventricular save
- Idioventricular rhythm (accelerated)
- Supraventricular tachycardia
- Ventricular couplets
- Ventricular triplet
- Ventricular tachycardia
- Bigeminy
- Trigeminy
- Pause
- Junctional rhythms
- Capture fault (if pacemaker analysis is active);
- Sensitivity fault: oversensing (if the pacemaker analysis is active);
- Sensitivity fault: undersensing (if the pacemaker analysis is active).
- Possibility to manually add Bundle Branch block, Ventricular R on T, Interpolated, Fusion events.

Actions on the tracings

- Measurements by means of callipers (duration and amplitude). The calliper can also be moved over the ECG;
- Entering, removing, and editing beats and arrhythmias:
  - Enter/edit an arrhythmia;
  - Enter, edit or remove a heartbeat;
  - Report the presence of atrial fibrillation in an ECG section;
  - Remove an atrial fibrillation;
  - Edit heartbeat classification;
  - Cancel the last operation performed.

Summary Window

Displayed parameters

- Interval displayed;
- Display type: trend, table, histogram for RR and artifacts, resume table;
- Duration of the interval to be analysed: complete, 12h, 6h;
- Events displayed Arrhythmias shown: Atrial fibrillation (AFIB), Artefacts, Induced heartbeat intervals (pacemaker), Sleep and Wake time zones, or all;
- View RR-HR diagram and ECG waveform, or only ECG in full windows
- 12, 6, 3 channels view, or 1 channel compacted view

Actions on data and on the tracings

- Adding or excluding an arrhythmia;
- Adding, modifying or removing a beat;
- Navigation on the tracings with mouse and keyboard;
- Zoom and drag of the tracings;
- Automatic scrolling of the tracings;
- Measuring duration, HR and amplitude;

Parameters for analysis

RR:

- Threshold correlation: Template creation threshold. Increasing the threshold increases the accuracy (beats of the same template more similar to each other) in the creation of templates by increasing the number of templates;
- Template compression;
- Bundle branch block;
- Min QRS amplitude;
- Mains filter: 50 or 60 Hz

Noise recognition:

- Noise algorithm: To activate/deactivate the noise recognition algorithm and the dynamic lead selection for beat recognition.
- Channel 1 and Channel 2: Channels used for beat recognition (if Noise algorithm is deactivated).

Template Window

Displayed parameters

- Interval displayed;
- Template type: normal, ventricular, supraventricular or induced;
- Ventricular and supraventricular beat have a different color;
- Averaged lead view: configurable channel 1 and/or channel 2 and/or channel 3, compact or expanded view;
- 3, 6 or 12 channel ECG waveform.

Actions on data

- Joining two templates;
- Modification of template type;
- Removal of a template or beat in the selected template

Arrhythmia Window

Display parameters

- Interval displayed;
- Display type: trend, table or strips;
- Averaged lead view (in strips view): configurable channel 1 and/or channel 2 and/or channel 3, compact or expanded view;
- Duration of the interval to be analysed: complete, 12h, 6h;
- Arrhythmias shown: SVEB, DEL, SVCPT, SVS, SVT, NOR, APB, AAB, BRA, AR, AT, ASVT, AFLU, AFIB, VEB, ESC, CPT, VTRIP, VRUN, IVR, AIVR, VTRI, VRUN, VT, BYG, TRI1, TRI2, VFLU, VFIB, QUAD, JPB, JR, AJR, PAU, other arrhythmias manuals BBB, RonT, Interpolated and Fusion;
- Sorting options: Beats, Duration, MaxHR, MinHR, Time.

ST Window

Display parameters

- Interval displayed;
- Display type: trend, table or strips;
- Leads to be displayed: channel 1 and/or channel 2 and/or channel 3;
- Duration of the interval to be analysed: complete, 12h, 6h;
- ST length: 60, 80 ms;
- ST episodes (in strip display): ST+, ST-.

Actions on data

- Editing markers: QRSOnSet, j and ToffSET
- Add ST+/ST- episodes;
- Removing an episode.

Parameters for analysis

Criteria:

- Max: Maximum duration to classify a variation of the ST as an ST episode.
- Min: Minimum duration to classify a variation of the ST as an ST episode.

Thresholds:

- J point elevation: J point elevation to classify a variation of the ST as an ST episode.
- J point depression: J point depression to classify a variation of the ST as an ST episode.

QT Window

Display parameters

- Interval displayed;
- Display type: trend or table;
- First trend to be displayed (only in trend display): RR, QT, QTc Bazett, QTc Fredericia, QTc Hodges;
- Second trend to be displayed (only in trend display): RR, QT, QTc Bazett, QTc Fredericia, QTc Hodges;
- Duration of the interval to be analysed: complete, 12h, 6h.

Actions on data

- Marker of fiducial points: QRSOnSet, j and ToffSET
- Add ST+/ST- episodes;
- Removing an episode.

HRV window

Display parameters	▪ Displayed interval; ▪ Display type: trend or table ▪ First trend to be displayed (only in trend display): RR, FC, RMSSD, SDNN; ▪ Second trend to be displayed (only in trend display): RR, FC, RMSSD, SDNN; ▪ Duration of the interval to be analysed: complete, 12h, 6h.
Actions on data	▪ Selection of an interval on trends and calculation of the relative HRV parameters

Events window

Display parameters	▪ Strip Types (automatic or selected by the user)
Types of automatic strips	▪ Maximum heart rate and/or ▪ Templates ▪ Arrhythmia ▪ ST Analysis
Automatic strips configuration	▪ Gain: 1, 5,10 20, 40 mm / mv ▪ 3-lead printing format: 1 or 3. ▪ 12-lead printing format: 1,3, 6 or 12.
Strips selectable by the user	▪ ECG - selected from the Rhythm Section ▪ ECG long - selected from the RR Window ▪ Template - selected from the Template Window ▪ Arrhythmia - selected from the Arrhythmia Window ▪ ST - selected from the ST Window ▪ HRV - selected from the HRV Window
Strip Management	▪ Strip enabling/disabling for insertion in the report ▪ Strip deletion ▪ Edit label and printing format ▪ Strip printing

Connectivity

Reception of worklists	Optional (via Cardioline Device Web Manager software)
Transfer of recordings for remote reviewing	Optional (via Cardioline Device Web Manager and WebReceiver software)
Transmission of PDF reports to Cardioline ECGWebApp	Optional (via Cardioline Device Web Manager software)

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

Classification	in the works
Product Code:	in the works
Review Panel:	in the works
Regulation Number:	in the works

Classification according to IEC 62304 – Software

Class of risk	B

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Performance	
Standard	EN 60601-2-47:2012

Other classifications	
GMDN	36827 Electrocardiograph, Holter analyser
CND	Z12050482 - INSTRUMENTATION FOR HOLTER SYSTEMS FOR CARDIAC PARAMETERS - SOFTWARE ACCESSORY COMPONENTS
RDM (Medical Device Catalogue)	1719714

Applicable Standards	
EN 1041	Information supplied by the manufacturer of medical devices
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 ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971	Medical devices - Application of risk management to medical devices
EN 60601-2-47	Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
EN 62304	Medical device software - Software life-cycle processes
EN 62366	Medical devices - Application of usability engineering to medical devices

Compatible Devices	
81018030	Walk400h – v. 1.0 and onward
81018026	Walk400h (old model) – v. 1.0 and onward
81018031	Clickholter – v. 1.0 and onward
81018009	Clickholter (old model) – v. 1.0 and onward
810195xx	ECGWebApp v. 2.20 and onward

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)

	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

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

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

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cubeabpm

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 inexpert users through the correct execution of all phases of the ABPM test. Using menus, dedicated keys and guided procedures, working with **cube**abpm is extremely practical and fast.

cubeabpm consists of a 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 analysise 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 the 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 **cube**abpm 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, **cube**abpm 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