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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 (>= 125% 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; ▪ Date of birth; ▪ Gender; ▪ Pacemaker; ▪ Phone; ▪ E-mail; ▪ Therapy; ▪ Anamnesis ▪ Date 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 Analysis ▪ Template analysis ▪ Arrhythmia analysis ▪ ST Analysis ▪ QT Analysis ▪ Strip Analysis ▪ 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:
    - Test length, Beats, HR med, HR min, HR max, Atrial fibrillation, Bradycardia, Supraventricular tachycardia, Ventricular tachycardia, Pauses, Ventricular arrhythmias, Supraventricular arrhythmiasPrint reservations;
- Data:
    - Trend: RR/FC, Arrhythmias, ST, QT, HRV;
    - Tables: RR/FC, Complete or simplified Arrhythmias, ST, QT, HRV;
    - 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);
- 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.

RR Window

Display parameters

- Interval displayed;
- Display type: trend or 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;
- 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

Display parameters

- Interval displayed;
- Template type: normal, ventricular, supraventricular or induced
- Averaged leads 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 leads 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

Strips 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 WebUploader software)
Transfer of recordings for remote reviewing	Optional (via Cardioline WebUploader and WebReceiver software)
Transmission of PDF reports to Cardioline ECGWebApp	Optional (via Cardioline WebUploader 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

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