CARDIOLINE

Cubestress

General Information

Product name	Cubestress
Product code	85050100
Manufacturer	Cardioline Spa Sede Legale e Produttiva: Via Linz, 151 38121 Trento Italy Sede Commerciale: Via F.lli Bronzetti, 8 20129 Milan Italy
Description of Device	Cubestress is a windows software, for the execution and review of a stress test. The ECG data are acquired by means of the acquisition unit HD+. HD+ is connected to the computer via the Cardioline Bluetooth Dongle. The patient cable is a 10 wires cable and the visualized leads are 12. Cubestress controls an ergometer (treadmill or bike) through pre-defined or user defined protocols. NIBP and/or SPO2 external monitoring devices can also be controlled (optionally) It prints on the Cardioline thermal ECG printer and/or a laser printer. Cubestress generates a report in PDF format. Cubestress is not back compatible with 3.xx release and lower.
Intended use	Cube stress is intended to analyze ECG signals during the execution of cardiovascular stress tests for the assessment and diagnosis of cardiac functions. Cube stress also allows to review and post analyze a stress test examination previously executed and recorded. The device is indicated for use in clinical settings, by a licensed physician trained in the use of ECG stress test systems or by trained personnel who are acting on the orders of a licensed physician. It is not intended as a sole mean of diagnosis. The device is not intended to be used as a vital signs physiological monitor. The device is intended for assessment and diagnosis of cardiac functions. In any case the results of analysis performed by Cubestress must be validated by a Clinician. ▪ The device is indicated for use to display, store and analyse ECG signals during the execution of cardiovascular stress tests ▪ The device is indicated for use to provide analysis of data for consideration by a physician. ▪ The device is not intended as a sole mean of diagnosis. ▪ The analysis of Cubestress data 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.
Cubestress System functions	▪ Directly entering / editing patient information. ▪ Acquire and analyze ECG data under stress ▪ Execute a stress test using and programming ergometers according with a selected protocol or pharmacologically induced ▪ Print results on thermal and/or laser printer ▪ Review and replay the exercise ▪ Produce a report in PDF format ▪ Import work-list and export final report

Stress test execution	▪ User selects an order for the patient or insert the patient demographics. ▪ User selects target HR as percentage of Max HR or insert it manually ▪ User connects the HD+ acquisition module ▪ User places the electrodes and check them ▪ User reviews the quality of the real-time waveform and adjusts settings if necessary. ▪ User selects a stress protocol or confirm the proposed protocol (the last used protocol) ▪ User executes pre-exercise test , collects up to three 10 s. resting ECG (respectively supine, standing and hyperventilation and acquires the basal parameters ECG medians and fiducial points, BP and SPO2, if present., ▪ User places the patient on the chosen ergometer or in case of pharmacologic test gives the stress inducing drug ▪ User starts stress test ▪ User analyses the Ecg and diagnostic parameters during the exam and insert comments ▪ User may start a continuous printout, using the default printout configuration (lead number, speed, gain) ▪ User may take one or more NIBP measures manually or via dedicated equipment, in addition to the one proposed by the stress protocol. ▪ User may start an automatic printout according with auto printout configuration ▪ User may insert a note, mark an event or insert a RPE score ▪ User goes to recovery voluntarily or execute all the protocol steps. ▪ User ends the stress test ▪ User reports the exam ▪ User produces and exports a PDF
Stress test review	▪ User selects a patient. ▪ User reviews the test ▪ User analyses the Ecg and diagnostic parameters and insert comments ▪ User edits the exam report ▪ User produces and exports a PDF final report
Analysis results	▪ Beat detection (with auto channel selection) ▪ Beat classification ▪ Arrhythmic events classification ▪ ST level and slope, ST/HR

Technical Specifications

ECG acquisition (HD+ unit)

ECG leads	12-leads (I, II, III, aVR-L-F, V1-6)
Patient cable	10 replaceable wire patient lead
CMRR	115dB
DC input impedance	100MΩ
A/D converter	24 bit, 32000 samples/second/channel
Sampling rate of the input stage	32000 samples/second/channel
Sampling rate for signal analysis	500/1000 samples/second/channel
A/D conversion	20 bit
Resolution	<1 µV/LSB
Dynamic range	+/- 400 mV

Bandwidth	Performances equivalent to 0,05-300 Hz
Pacemaker detection	Hardware detection coupled with digital convolution filter, in compliance with the requirements 60601-2-25 (HD+ acquisition unit)
Defibrillation protection	AAMI/IEC standard
Front-end performance	ANSI/AAMI IEC 60601-2-25:2011
Data transfer	Bluetooth 2.1+ EDR with "secure pairing"

Processing

Operating system	Windows
Lead-fail detection	Independent for all leads
Cardiac frequency range	30 - 300 bpm
Filters	Linear phase digital diagnostic high-pass filter (according to 60601-2-25 2nd ed.), Automatic baseline drift control filter 50/60 Hz AC interference adaptive digital filter Digital low pass filters at 25/40/150 Hz, for display and printing only

Main features

Data displayed

Data always present and displayed:

- Patient Info (first and last name, id, age, sex)
- HR, Max HR, Target HR and % of target HR

Data displayed only during the test:

- St level
- Double Product
- Blood pressure
- SpO2 level
- Mets
- ST/HR index
- Pre-test electrodes check and resting ECG acquisition
  - Real Time traces 6x2/12 channels
  - Electrodes check digital
- Pre-exercise phase
  - Real Time ECG 3/6/12 6x2 channels
  - Compacted Ecg (Full disclosure 1 channel)
  - Averaging 12 leads Real Time
  - Zoomed average heartbeat for a user-defined lead or lead showing maximum ST segment change. ST level and slope are also displayed
  - Arrhythmias or user events strip
  - ST profile view
  - Protocol name
  - Protocol phase/stage
  - Ergometric parameters
- Exercise/ recovery phase:
  - Real Time ECG 3/6/12 6x2 channels
  - Averaging 12 leads Real time with Baseline averaging superimposition
  - Compacted Ecg (Full disclosure 1 channel) (optional)
  - Zoomed average heartbeat for a user-defined lead or lead undergoing maximum ST segment with superimposed basal median beat. ST level and slope related to baseline median beat and to the selected lead also displayed
  - Arrhythmias or user events strip
  - Trend of the results of the ST analysis updated in real time for all 12

	channels (optional) o Trends: - HR/ METs, - NIBP - Double Product (HR*BP) - ST index - Ergometric parameters - ST level - ST slope o ECG snapshot selected from full disclosure data o Protocol name o Protocol phase/stage o Ergometric parameter
Print Type	Auto and Continuous
Auto Print Format	▪ 12x1 ▪ 12x1 +AVG ▪ 6x2 ▪ 6x2+AVG ▪ 3x4 ▪ 3x4 + 1 ▪ 3x4 + 3
Continuous Print Format	▪ I-avF, ▪ V1-V6, ▪ I-III ▪ aVr-aVf ▪ V1-V3 ▪ V4-V6 ▪ I-V6
Protocol management	▪ Protocol loading ▪ Automatic protocol management ▪ Manual stage control ▪ Manual control of ergometers ▪ Manual or Auto NIBP insertion ▪ Visive and audible alerts
Alerts	▪ Rhythm Events ▪ ST delta ▪ HR over target ▪ HR drop more than user defined percentage ▪ Systolic or Diastolic BP above or below thresholds ▪ SBP falling more than a threshold
Data saving on HD	▪ ECG full disclosure without loss of information ▪ Analysis results ▪ Ergometer parameters ▪ NIBP values ▪ SPO2 values ▪ Electrodes status
Review	▪ Playback of exercise ▪ Editing of conclusion ▪ Reason for end ▪ Auto printout as in RT plus trend page ▪ Test Summary o Exam data - Exam Start Time - Ergometer type

	- Protocol type o Basal clinical parameters o Peak clinical parameters o End exam clinical parameters o Max clinical parameter o Duke treadmill score o Fai % o Framingham score o HR Recovery index
PDF Report	▪ Editing conclusion ▪ Cover (examination data and conclusions) and Table (list of the steps performed). ▪ Resting ECG ▪ Table of measurement on ST level and slope (by stage or by minutes) ▪ Table of HR, SP02; METS,BP, DP, Ergometer parameters (by Stage or by minutes) ▪ Averaging: average heartbeat tracing (by stage or by minutes) ▪ Trend of measurements of ST ▪ Compacted: printing of the complete test, from 1 to 12 channels ▪ ECG - Manual sections selection: includes all the events ▪ ECG - Real time sections selection: includes all the ECG sections printed in real time during the test.
Settings	▪ Events to show ▪ Peripheral controls (link between peripheral and port) ▪ Manual and auto Print setting ▪ Display settings ▪ Formula settings ▪ Fiducial points for average ▪ Analysis ▪ Alert ▪ Report (header + blocks)
ECG trigger	TTL Output
Connectivity	
Import/Export	▪ Dicom modality Worklist ▪ Hl7 Worklist ▪ GDT (demo in, report out) ▪ Dicom encapsulated pdf cstore ▪ Hl7 pdf ▪ ECGWebapp Worklist ▪ ECGWebapp report storage (pdf) ▪ Dicom MPPS (TBD)
Compatible devices	
Compatible Cycloergometers	▪ CARDIOLINE XR50 ▪ CARDIOLINE XR50+ ▪ CARDIOLINE XR100 ▪ CARDIOLINE XR100+ ▪ CARDIOLINE XR100BP ▪ CARDIOLINE XR100BP+ ▪ ERGOSELECT 1200 BP SUPINE ERGOMETER ▪ ERGOSELECT 1200 ERGOMETER with bed ▪ ERGOSELECT 400K HAND CRANK ERGOMETER ▪ ERGOSELECT 600 P ▪ ERGOSELECT 1000 BP ▪ ERGOSELECT 1000 BED ERGOMETER ▪ ERGOSELECT 200P WITH BLOOD PRESSURE

Compatible treadmills	▪ ERGOSELECT 4 P ▪ XR450M-PC MEDICAL TREADMILL CONSOLE MAN. TOUCH ▪ XR450P-PC MEDICAL TREADMILL CONSOLE PROG. TOUCH ▪ XR600M-PC MEDICAL TREADMILL CONSOLE MAN.TOUCH CARDIOLINE_XR600 ▪ XR600P-PC MEDICAL TREADMILL CONSOLE PROG. TOUCH H_P_COSMOS ▪ XR600R MEDICAL TREADMILL ▪ Trackmaster XMX 425 ▪ Trackmaster XMX 428 ▪ Trackmaster XMX 428CP
Compatible NIBP/SPO2 Monitors	▪ CARDIOLINE XR100BP ▪ CARDIOLINE XR100BP+ ▪ ERGOSELECT 1200 NIBP SUPINE ERGOMETER ▪ ERGOSELECT 1000 NIBP ▪ ERGOSELECT 200P WITH NIBP/SPO2 ▪ TANGO ▪ METRONIK

PC minimum requirements

Operating System	Windows 10 64 bit or higher
Processor	Intel Core i5 or higher
RAM	8GB or Higher
Free space on Hard Disk	At least 2GB for the program plus the archive space Recommended 7200 rpm o higher
Screen	Color Touchscreen 16:9 15” minimum , Minimum resolution 1920x1080 Optimal configuration 16:9 24”, full HD
USB	Dongle Thermal Printer Laser Printer Cycle-ergometer Treadmill NiBp/SpO2 Keyboard/Mouse
Printer	Laser B/N or Thermal

Tests archive

Archive	Local database
Capacity	1000 exams
Data stored	▪ ECG full disclosure without loss of information ▪ Analysis results ▪ Ergometer parameters ▪ NIBP values ▪ SPO2 values ▪ Electrodes status
Patient data	▪ First name ▪ Middle name ▪ Last name ▪ ID ▪ Date of birth ▪ Age (calculated from 5.)

- Sex
- Race
- Height
- Weight
- Address
- Phone
- Email
- Reason for study
- Therapy
- Angina (yes/No)
- History of Myocardial infarction (Yes/No)
- Family History (Yes/No)
- Diabetic (Yes/No)
- Smoking (Yes/No)
- Cardiac catheterization (Yes/No)
- Prior coronary artery bypass (Yes/No)
- Pacemaker (yes/no)
- Target HR as percentage of MAX HR or manually inserted

Review

- Playback of exercise
- Editing of conclusion
- Reason for end
- Auto printout as in RT plus trend page
- Test Summary
- Exam data
- Exam Start Time
- Ergometer type
- Protocol type
- Basal clinical parameters
- Peak clinical parameters
- End exam clinical parameters
- Max clinical parameter
- Duke treadmill score
- Fai %
- Framingham score
- HR Recovery index

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 60601-2-25
Other classifications	
GMDN	36145 Stress Exercise System, Cardiac
CND	Z12050182 - STRUMENTAZIONE PER L'ANALISI SFORZO - COMPONENTI ACCESSORI SOFTWARE
RDM (Medical Device Catalogue)	1873875/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 60601-2-25	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
EN 60950-1	Information technology equipment - Safety - Part 1: General requirements
EN 55032	Electromagnetic compatibility of multimedia equipment - Emission Requirements
EN 55035	Electromagnetic compatibility of multimedia equipment. Immunity requirements
EN 60601-1-2	Medical electrical equipment. General requirements for basic safety and essential performance. Collateral Standard. Electromagnetic disturbances. Requirements and tests
ETSI 301 489 V.1.9.2	Electromagnetic Compatibility (EMC)standard for radio equipment and services; Part 1
ETSI 301 489-17 V.3.1.1	Electromagnetic Compatibility (EMC)standard for radio equipment and services; Part 17
EN 62479	Assessment of the compliance of low-power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)
EN 62311	Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz to 300 GHz)
ETSI 300 328 V2.1.1 (2016-11)	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques