CARDIOLINE

Cubestress

General Information

Product name	Cubestress
Product code	85050100
Manufacturer	Cardioline SpA Head Office and Production facility: Via Linz, 151 38121 Trento Italy
Description of Device	Cubestress is a Windows software for performing and reviewing stress tests. ECG data are acquired via the acquisition unit HD+, HD+ 12 or HD+ 15, connected to the computer via Bluetooth (using the Cardioline HD+ Dongle) or USB. Depending on the HD+ model and the patient cable used, 12 or 15 ECG leads can be acquired: HD+ and HD+ 12 can acquire 12 leads, HD+ 15 can acquire 12 or 15 leads. Cubestress can control an ergometer (treadmill or bike) via predefined or user-defined protocols and via customisable generic protocols. External NIBP and/or SPO2 monitoring devices can also be controlled (optionally). If external NIBP or SPO2 devices are present, NIBP or SPO2 measurements can be carried out automatically by the software, which controls the devices and acquires the measurement, or manually by the user, who can enter them by typing them in Cubestress Cubestress acquires ECG data and processes them to calculate and infer the typical measurements and parameters of a stress test: ▪ Heartbeat detection (with automatic channel selection) ▪ Classification of heartbeats ▪ Detection and classification of arrhythmic events ▪ ST level and slope, ST/HR, dual product ▪ QT and QTc At the end of the test, Cubestress generates a PDF report containing ECG traces, trends and other data forming the results of the analysis. During the test, Cubestress can generate print-outs either in 'Auto' mode (10s ECG print-out) or in continuous mode (continuous ECG printing). Compatible printers are the Cardioline thermal printer (200P) and/or laser printers that meet the minimum requirements defined. Cubestress is not backwards-compatible with versions 3.xx or lower. Cubestress can be equipped with a Cardiopulmonary option. When this option is present and enabled, Cubestress can connect to a cardiopulmonary system that implements the "XSCRIBE CP Cardiopulmonary interface rev.1" communication protocol. When Cubestress is in Cardiopulmonary mode, it carries out a stress test fully guided by the cardiopulmonary system which it is connected to: it receives the values set or acquired from any other devices connected to the cardiopulmonary system and displays them within its user interface and, in turn, sends the Heart Rate and ST measurements to the Cardiopulmonary system. At the end of the test, Cubestress creates a PDF report, displaying the acquired data (trends, tables, strips, etc.), and sends it to the cardiopulmonary system for reviewing. The conclusions of the medical report are drawn up in the cardiopulmonary system, with the physician's signature.

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Intended use

Cubestress is intended for performing and reviewing cardiovascular exercise stress testing. It is designed to analyse and display ECG signals, acquired with the HD+ series devices, and other biometric parameters (NIBP, SpO2), acquired with external devices, during cardiovascular exercise 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.
When used in 'Cardiopulmonary' mode, Cubestress is designed to carry out cardiovascular exercise stress tests guided by an external Cardiopulmonary system. Its purpose is to analyse and display ECG signals, acquired with the HD+ series unit, as well as display other biometric data (NIBP, SpO2), acquired with external devices driven by the cardiopulmonary system, during the performance of cardiovascular stress tests for the assessment and diagnosis of cardiac functions. In this mode, Cubestress does not allow the conclusions to be written in the final medical report nor the physician to sign, as these functions are carried out within the cardiopulmonary system.
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
- The operator places the electrodes and checks them with the help of the impedance measurement
- 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 ▪ The operator can mark an event or enter a score on the RPE scale ▪ The operator switches to voluntary recovery or carries out all steps of the protocol. ▪ The operator can start reviewing during recovery ▪ 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) with HD+ and HD+ 12 15-leads (I, II, III, aVR-L-F, V1-6, E1-3) with HD+ 15
Patient cable	10 wire (HD+, HD+ 12, HD+ 15) or 13 wire (HD+ 15) replaceable patient cable
CMRR	>100dB
DC input impedance	>100MΩ
A/D converter	Up to 24 bit
Sampling rate of the input stage	128,000 samples/second/channel
Sampling rate for signal analysis	1000 samples/second/channel 500 samples/second/channel Selected via software
A/D conversion	20 bit
Resolution	<1 µV/LSB
Dynamic range	+/- 500 mV
Bandwidth	300 Hz (@1000 c/s) 150Hz (@500 c/s)
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	Connectivity HD+12/15: • Bluetooth with Cardioline Dongle 2.0 • HD+ USB option Connectivity HD+: • Bluetooth with Cardioline Dongle 1.0

Processing

Operating system	Windows 10 or higher
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
Noise-removal filters	25/40/150 Hz digital low pass filters, for display and F printing only SENSA Filter (Stress ECG Noise Suppression Algorithm)

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 (10-wire cable) or 6X2+3/15 channels (13-wire cable)
  - Electrode impedance control
  - Electrodes check digital
- Pre-exercise phase
  - Real-time ECG channels (10-wire cable) or 6X2+3/15 channels (13-wire cable)
  - Compacted ECG (Full disclosure 1 channel)
  - Averaging 12/13 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 phase:
  - Real-time ECG channels (10-wire cable) or 6X2+3/15 channels (13-wire cable)
  - Averaging 12/15 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 12/15 channels (optional)
  - Trends:
    - HR/ METs,

- NIBP
- Double Product (HR*BP)
- ST index
- Ergometric parameters
- ST level
- ST slope
- QT/QTc

  - ECG snapshot selected from full disclosure data
  - Protocol name
  - Protocol phase/stage
  - Ergometric parameter
- Recovery phase
  - Same parameters as in Exercise Phase
  - Possibility of writing conclusions

Print Type	Auto and Continuous
Auto Print Format	12 leads: ▪ 12x1 ▪ 12x1+AVG ▪ 6x2 ▪ 6x2+AVG ▪ 3x4 ▪ 3x4 +1 ▪ 3x4 +3 15 leads: ▪ 15x1 ▪ 3X5 ▪ 3X5+1 ▪ 3x5+3
Continuous Print Format	Resting ECG with Glasgow interpretation (12/15 leads) 12 leads: ▪ 3 channels I-III ▪ 3 channels aVr-aVf ▪ 3 channels V1-V3 ▪ 3 channels V4 V6 ▪ 6 channels: I-aVF ▪ 6 channels: V1-V6 ▪ 12 channels: I-V6 15 leads: ▪ 3 extra lead channels ▪ 15 I-V6 channels + extra leads
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

Data saving on HD	▪ SBP falling more than a threshold ▪ 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 Risk scoring:
	  - Duke score (treadmills)
	  - % FAI (Functional Aerobic Impairment)
	  - 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 QT and QTc measurements ▪ 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: ST, HR , DP,SPO2, METS, QT/QTc, ergometer parameters ▪ ECG - protocol, user, arrhythmia and RPE events
Settings	▪ Arrhythmias to show and print ▪ Connectivity (work list and PDF exporting), GDT ▪ Acquisition settings ▪ Display configuration ▪ Peripheral controls (link between peripheral and port) ▪ Manual and auto Print setting ▪ Display settings ▪ Formula settings ▪ Fiducial points for average ▪ Analysis ▪ Alert ▪ PDF and print reports (header + blocks) ▪ TTL outputs
Protocol editing and creation	Types of protocol supported: ▪ Treadmill ▪ Cycle ▪ Generic ▪ Pharmacological Supported functions:

	▪ Create new protocol ▪ Edit existing protocol ▪ Copy protocol
ECG trigger	TTL output and ECG analogue output (via HD+ Dongle)
Options	
Connectivity	To connect Cubestress to ECGWebApp and other external management systems (CIS / PACS) via the Internet.
Dicom	To connect Cubestress to external management systems (CIS / PACS) via DICOM protocol.
GDT	To connect Cubestress to external management systems (CIS / PACS) using the GDT protocol.
2 printers	To connect and manage 2 printers.
Full Disclosure	To review and enter events during the execution of the test, even in a previously acquired ECG section. During the review it allows you to select an instant of the exam and review the ECG, the medians, the relative trends. It also enables the Play function of the exam.
15 leads	To acquire 15-lead ECG (in combination with HD + 15).
TTL	Enable and configure HD + Dongle TTL outputs.
Cardiopulmonary	For interfacing with a cardiopulmonary system.
Glasgow	To use the Glasgow interpretation algorithm on resting ECGs acquired before or during the exam.
Cardiopulmonary option	
Compatible protocol	XSCRIBE CP Cardiopulmonary interface rev.1
Minimum requirements for the Cardiopulmonary system:	▪ Windows 10 operating system support; ▪ PC with features compatible with those defined for Cubestress or better
Supported CP mode	▪ Test execution ▪ Test review
Connectivity	
Import/Export	▪ DICOM modality Worklist ▪ HL7 Worklist ▪ GDT (input: reading demographs data for new test run by effort or test review already performed; output: report and pdf) ▪ 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

Compatible treadmills	▪ ERGOSELECT 1000 BP ▪ ERGOSELECT 1000 BED ERGOMETER ▪ ERGOSELECT 200P WITH BLOOD PRESSURE ▪ ERGOSELECT 4 P ▪ XR450M-PC MEDICAL TREADMILL CONSOLE MAN. TOUCH ▪ XR450P-PC MEDICAL TREADMILL CONSOLE PROG. TOUCH ▪ XR450R MEDICAL TREADMILL ▪ 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 Font scaling to 100% Optimal configuration 16:9 24”, full HD
USB	Dongle Thermal Printer Laser Printer Cycle-ergometer Treadmill NiBp/SpO2 Keyboard/Mouse
Printer	Laser B/N Brother model HL- L2310D or thermal Cardioline model 200P
Other Software	.NET Framework 4.7.2 Runtime PDF Reader (ex. Acrobat TM Reader, Foxit Reader)

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 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