CARDIOLINE

Cubestress System

General Information

Product name	Cubestress
Product code	KSS*XYYZWJ-@*
Manufacturer	Cardioline SpA Via Linz, 151 38121 Trento Italy
Description of Device	Cubestress System is a family of systems for carrying out cardiovascular stress tests. The system can be composed of the following devices, which are both medical and non-medical, with various configurations with: ▪ Software for viewing, analyzing and printing ECG traces and for managing tests (Cubestress); ▪ ECG acquisition unit (HD + series) with optional ECG suction cable (Handy VAQ); ▪ Computer on which the software is installed (with display, keyboard and mouse); ▪ Optional ergometer, controlled by the software, for performing physical exercise; ▪ Printer (laser or thermal Cardioline 200P); ▪ Isolation transformer; ▪ Trolley. The patient can be connected to the HD + ECG acquisition unit (HD + 12, HD + 15) via standard patient cable with electrodes or via Handy VAQ suction ECG cable. The acquisition unit is connected to the computer via Bluetooth or USB (depending on the HD + model), transmitting the ECG signals to it, then the Cubestress software displays and analyzes for reporting by the operator. The ergometer is controlled by the Cubestress software, automatically or with manual input from the operator.
Intended use	▪ Ability to enter / edit patient information directly. ▪ Acquisition and analysis of exercise ECG data ▪ Execution of an exercise test with the use and programming of ergometers according to a selected protocol or pharmacologically induced ▪ Printing of results via thermal and / or laser printer ▪ Review and repetition of the exercise ▪ Production of a report in PDF format ▪ Import a worklist and export the final report

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	Bluetooth 2.1+ EDR with "secure pairing" for HD+ Bluetooth Low Energy for HD+ 12 / HD+ 15 USB for HD+ 12 / HD+ 15

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
Noise-removal filters	25/40/150 Hz digital low pass filters, for display and F printing only SCF Filter (Source consistency filter)

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

Resting ECG with Glasgow interpretation (12/15 leads)

Continuous Print Format

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
- 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
  - Exam data
    - Exam Start Time
    - Ergometer type
    - Protocol type
  - Basal clinical parameters
  - Peak clinical parameters
  - End exam clinical parameters
  - Max clinical parameter
  - Risk scoring:
    - Duke score (treadmills)
    - % FAI (Functional Aerobic Impairment)
    - Framingham score
  - 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)

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 ▪ ERGOSELECT 1000 BP ▪ ERGOSELECT 1000 BED ERGOMETER ▪ ERGOSELECT 200P WITH BLOOD PRESSURE ▪ ERGOSELECT 4 P
Compatible treadmills	▪ 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

Compatible NIBP/SPO2 Monitors	▪ Trackmaster XMX 425 ▪ Trackmaster XMX 428 ▪ Trackmaster XMX 428CP ▪ CARDIOLINE XR100BP ▪ CARDIOLINE XR100BP+ ▪ ERGOSELECT 1200 NIBP SUPINE ERGOMETER ▪ ERGOSELECT 1000 NIBP ▪ ERGOSELECT 200P WITH NIBP/SPO2 ▪ TANGO ▪ METRONIK

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

Available configurations

Cubestress System config. Package HD+12/ HD+ 15

Code

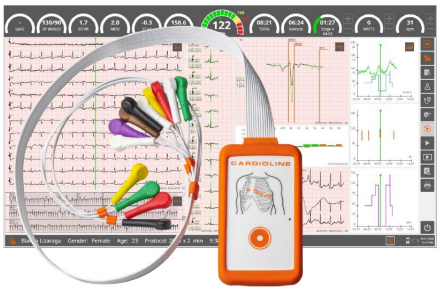
KSSM00000 with HD+ 12
KSSE00000 with HD+ 15

System components

- Cubestress Software
- HD+ (HD+ 12, HD+ 15)
- Patient cable 10 wire (HD+ 12, HD+ 15) or 13 wire (HD+ 15)

Available options

- Connectivity/Full Disclosure/2printers
- Full Disclosure
- Tango (Kit Tango M2 + Cable TTL-USB + Trolley support Cubestress)
- SpO2 Tango
- BL-6
- TTL
- Cardiopulmonary
- USB HD+
- Trolley LITE



Cubestress System config. Laser Printer B/N

Code

KSSMPCUL0 with HD+ 12
KSSEPCUL0 with HD+ 15

System components

- Cubestress Software
- HD+ (HD+ 12, HD+ 15)
- Patient cable 10 wire (HD+ 12, HD+ 15) or 13 wire (HD+ 15)
- All in one touch screen computer
- Trolley
- Integrated Laser printer B/N

Available options

- Connectivity/Full Disclosure/2printers
- Full Disclosure
- Tango (Kit Tango M2 + Cable TTL-USB + Trolley support Cubestress)
- SpO2 Tango
- BL-6
- TTL
- Cardiopulmonary
- USB HD+

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Cubestress System config. Laser Printer B/N ISO

Code

KSSMPCTL0 with HD+ 12
KSSEPCTL0 with HD+ 15

System components

- Cubestress Software
- HD+ (HD+ 12, HD+ 15)
- Patient cable 10 wire (HD+ 12, HD+ 15) or 13 wire (HD+ 15)
- All in one touch screen computer
- Isolation transformer
- Trolley
- Integrated Laser printer B/N

Available options

- Connectivity/Full Disclosure/2printers
- Full Disclosure
- Tango (Kit Tango M2 + Cable TTL-USB + Trolley support Cubestress)
- SpO2 Tango
- BL-6
- TTL
- Cardiopulmonary
- USB HD+

Cubestress System config. Thermal Printer 200P

Code

KSSMPCUT0 with HD+ 12
KSSMPCUT0 with HD+ 15

System components

- Cubestress Software
- HD+ (HD+ 12, HD+ 15)
- Patient cable 10 wire (HD+ 12, HD+ 15) or 13 wire (HD+ 15)
- All in one touch screen computer
- Thermal Printer Cardioline 200P
- Trolley

Available options

- Connectivity/Full Disclosure/2printers
- Full Disclosure
- Tango (Kit Tango M2 + Cable TTL-USB + Trolley support Cubestress)
- SpO2 Tango
- BL-6
- TTL
- Cardiopulmonary
- USB HD+

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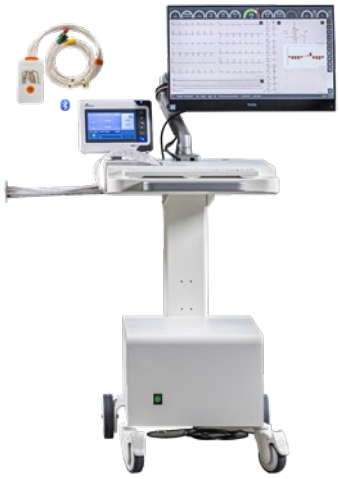
Cubestress System config. Thermal Printer 200P

Code	KSSMPCTT0 with HD+ 12 KSSEPCTT0 with HD+ 15
System components	▪ Cubestress Software ▪ HD+ (HD+ 12, HD+ 15) ▪ Patient cable 10 wire (HD+ 12, HD+ 15) or 13 wire (HD+ 15) ▪ All in one touch screen computer ▪ Thermal Printer Cardioline 200P ▪ Isolation transformer ▪ Trolley
Available options	▪ Connectivity/Full Disclosure/2printers ▪ Full Disclosure ▪ Tango (Kit Tango M2 + Cable TTL-USB + Trolley support Cubestress) ▪ SpO2 Tango ▪ BL-6 ▪ TTL ▪ Cardiopulmonary ▪ USB HD+



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 60601-1 – Electrical safety

Protection against electrical shock	HD+ Internally powered REOMED 1000 Class I
Applied parts	Type CF – defibrillation-proof
Protection against accidental ingress of water or substances	HD+: IP40 / IP42 (with protective shell)
Sterilisation methods	NA (not intended to be sterilised)
Suitability for use in oxygen-rich environments	No
Operation mode	Non-continuous operation

Classification according to IEC 60601-1-2 – Electromagnetic compatibility

Group	1
Class	B

Classification according to IEC 62304 – Software

Class of risk	B

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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 60601-1	Medical electrical equipment - Part 1: General requirements relating to 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 60601-1-6	Medical electrical equipment - Part 1: General safety rules - Collateral standard: Usability
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