

CARDIOLINE

Cubestress System

General Information

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| Product name | Cubestress |
| Product code | KSSXYZWJ-@ |
| 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)

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| 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 | >100M Ω |
| A/D converter | Up to 24 bit |
| Sampling rate of the input stage | 128,000 samples/second/channel |

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|-----------------------------------|---|
| Sampling rate for signal analysis | 1000 samples/second/channel 500 samples/second/channel Selected via software |
| A/D conversion | 20 bit |
| Resolution | <1 μ V/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

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| 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

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| Data displayed | Data always present and displayed: <ul style="list-style-type: none">▪ Patient Info (first and last name, id, age, sex)▪ HR, Max HR, Target HR and % of target HR Data displayed only during the test: <ul style="list-style-type: none">▪ St level▪ Double Product▪ Blood pressure▪ SpO2 level▪ Mets▪ ST/HR index▪ Pre-test electrodes check and resting ECG acquisition<ul style="list-style-type: none">○ 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<ul style="list-style-type: none">○ 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 |
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- 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

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- 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
- Visible 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, SPO2; 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

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- 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

- DICOM modality Worklist
- HL7 Worklist
- GDT (input: reading demographics data for new test run by effort or test review already performed; output: report and pdf)

Import/Export

- 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

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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

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|--------------|--|
| Archive | Local database |
| Capacity | 1000 exams |
| Data stored | <ul style="list-style-type: none">▪ ECG full disclosure without loss of information▪ Analysis results▪ Ergometer parameters▪ NIBP values▪ SPO2 values▪ Electrodes status |
| Patient data | <ul style="list-style-type: none">▪ 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 | <ul style="list-style-type: none">▪ 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 |

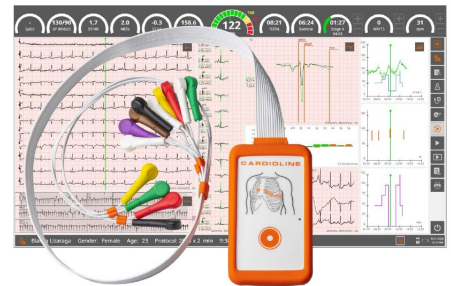
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- Peak clinical parameters
- End exam clinical parameters
- Max clinical parameter
- Duke treadmill score
- Fai %
- Framingham score
- HR Recovery index

Available configurations

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

- | | |
|-------------------|---|
| Code | KSSM00000 with HD+ 12 KSSE00000 with HD+ 15 |
| System components | <ul style="list-style-type: none">▪ Cubestress Software▪ HD+ (HD+ 12, HD+ 15)▪ Patient cable 10 wire (HD+ 12, HD+ 15) or 13 wire (HD+ 15) |
| Available options | <ul style="list-style-type: none">▪ 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

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|-------------------|--|
| Code | KSSMPCULO with HD+ 12 KSSEPCULO with HD+ 15 |
| System components | <ul style="list-style-type: none">▪ 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 | <ul style="list-style-type: none">▪ 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

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|-------------------|---|
| Code | KSSMPCTLO with HD+ 12 KSSEPCTLO with HD+ 15 |
| System components | <ul style="list-style-type: none">▪ 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 | <ul style="list-style-type: none">▪ 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

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| Code | KSSMPCUTO with HD+ 12 KSSMPCUTO with HD+ 15 |
| System components | <ul style="list-style-type: none">▪ 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 | <ul style="list-style-type: none">▪ 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

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|-------------------|--|
| Code | KSSMPCTTO with HD+ 12 KSSEPCTTO with HD+ 15 |
| System components | <ul style="list-style-type: none">▪ 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 | <ul style="list-style-type: none">▪ 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

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|---------------|---|
| 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

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| 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

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| 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