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

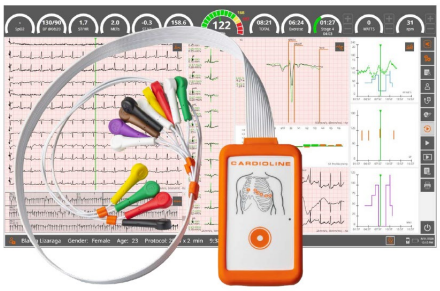
KSSM00000 with HD+ 12
KSSE00000 with HD+ 15

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+

CARDIOLINE

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

CARDIOLINE

HD+ 12 / HD+ 15

General Information

Product name	**HD+ 12** **HD+ 15**
Generic name	HD+
Product code	HD+ 12: **81018231** HD+ 15: **81018228**
Manufacturer	**Cardioline Spa** Head Office and Production: Via Linz, 151 38121 Trento Italy
Description of Device	HD+ 12 / HD+ 15 is a portable digital acquisition device that can acquire the physiological 12-lead or 15-lead ECG signal. HD+ 12 acquires the 12-lead signal, HD+ 15 acquires the 12- or 15-lead signal depending on the patient cable used. The device sends the acquired data by wireless/USB and in real time to a computer/mobile device (e.g. Windows or Android PC or tablet), where one of the compatible Cardioline software is installed. The HD+ 12 / HD+ 15 uses Bluetooth Low Energy (BLE) transmission technology to transmit ECG data remotely, allowing electrical isolation and freedom of movement for the patient. Alternatively, it can be connected via USB cable using the dedicated option (HD+ USB Option). HD+ 12 / HD+ 15 guarantees the acquisition of an ECG signal, meeting the most stringent standards used in clinical and diagnostic applications (AAMI, ANSI, AHA, ACC). It is light and compact, comfortable to wear, minimizing motion artifact caused by traditional electrodes and patient cables. An LED indicator allows for easy monitoring of the device link status (off when unit is powered down, blinking when unit is attempting to connect with the receiver, steady when unit is connected with the receiver) and a key press sends macro commands to the receiving system (i.e. acquires an ECG). Low-power technology enables low power consumption and continuous use of the device for over 10 hours or 500 ECGs when powered by AAA alkaline batteries.
Intended use	The function of the device is the acquisition and transmission of the ECG signal for viewing, processing and presenting the ECG signal in order to support diagnosis of the patient's conditions. HD+ is a wireless or USB (with appropriate option) ECG acquisition device, to be used primarily as common front-end for standard PC/tablet platforms (Windows/Android/others), for resting ECG as well as stress ECG applications. The device implements wireless communication via the Bluetooth wireless technology or wired with USB communication. With both connection modes, HD+ sends the data to the receiver device without performing any analysis or filtering. HD+ is not intended for monitoring or analysis of the cardiac function or to diagnose the patient's health condition. The analysis program on the receiver device is a separate product. The result of the analysis must always be validated by qualified and trained medical personnel. HD+ is not able to permanently store the acquired data, therefore it does not work unless a connection has been established with a receiver application. Furthermore, HD+ does not collect any of the patient's sensitive data (patient's name, age, previous health conditions etc.). HD+ is able to detect the heart rate only for the purpose of generating a synchronisation signal towards NIBP devices or ECHO systems.

HD+ is indicated for the acquisition of ECG signals for, but not limited to, resting ECG systems and ECG stress test systems.
HD+ is suitable for working at high altitudes, with restrictions (as indicated in para. 2).
HD+ is intended for use on adult and paediatric patients, with no limits of age or gender.
HD+ is intended for use in medical facilities (hospitals, clinics), at home or emergency settings (ambulances).
HD+ is intended for use by a doctor, nurse or skilled personnel who act following orders by a doctor or authorised nurse.
HD+ is not intended for monitoring vital physiological parameters.

Technical specifications

ECG acquisition

ECG leads	12-leads (I, II, III, aVR-L-F, V1-6) 15- leads (I, II, III, aVR-L-F, V1-6, E1-3)
Patient cable	10/13 wire, non-replaceable lead wires
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	1,000 samples/second/channel 500 samples/second/channel Selectable via software
A/D conversion	20 bit
Maximum Resolution	<1 µV/LSB
Maximum Dynamic range	+/- 500 mV
Bandwidth	Performances equivalent to 0,05-300 Hz (@1,000 m/s) Performances equivalent to 0,05-150Hz (@500 m/s)
Pacemaker detection	128,000 samples/second/channel software recognition, Pulse duration range: 0.2 ms - 2 ms, Pulse width range: 2mV – 250mV. Exceeds the IEC 60601-2-25:2011 performance
De fibrillation protection	AAMI/IEC standard
Lead-fail detection	Independent for all leads

Functions

Bluetooth data transfer	Bluetooth LE 5.0 The host Bluetooth radio must support BLE 5 (or higher) with 2M PHY to enable a sampling rate of 1,000 s/s. Bluetooth host radio must be at least BLE 4.2 with DLE (Data Length Extensions) to operate at 500 s/s
USB data transfer	Via HD+ USB option
LED	Yellow/blue LED to indicate: ▪ Switching off ▪ Switching on ▪ Connection ▪ Error condition ▪ Flat battery
Buzzer	Buzzer to indicate: ▪ Switching on

	▪ Connection ▪ Low battery / error condition ▪ Switching off
R-Wave Synch output	TTL output (0 - +5V)
Compatible devices	Cardioline touchECG, Cardioline Cubestress.

Electrical Characteristics

Power source	2 AAA standard batteries
Battery Duration	More than 500 ECGs

Physical Characteristics

Dimensions	115 x 65 x 15 mm
Weight	< 90 g with batteries
Protection against harmful ingress of water or particular matter	IP40 /IP42 with protective shell
Mechanical strength and temperature resistance	Compliant with EN 1789 (Ambulances) and EN 60601-1-11 (homecare)
Shipping container	27x21x8 mm - 1Kg

Operating Environmental Specifications

Temperature	0°C - +40°C (from -5°C for ambulance use, if transported at 20°C)
Humidity	15% - 90% without condensation
Pressure	USB: 700hPa - 1060hPa (0-3000 mt) BT: 540 hPa -1060hPa (0-5000 mt)

Storage Environmental Specifications

Temperature	-40 °C - +5 °C without relative humidity control +5 °C - +40 °C, up to 90 % relative humidity, without condensation +40 °C - 70 °C with water vapour pressure up to 50 hPa;
Humidity	15% - 90% without condensation
Pressure	540 hPa -1060hPa (0-5000 mt)

HD+ DONGLE

Technical specifications

Power supply	Via USB
Doors	1 USB type-C: for PC connection 1 USB type-A: for connection with HD+ 2 analogue outputs 3.5 mm audio jack: for signal TTL (0 - +5V)
TTL signals	One per ECG signal (I, II, V1...V6) and one per R-Wave synch
LED	To indicate: ▪ Connection to HD+ ▪ Switching on ▪ Error condition
Placement	Magnetic plate for placement on flat surfaces (trolley, laptop cover, etc.)
Protection against accidental ingress of water or substances	IP40 / IP42

Environmental operating specifications

Temperature	0°C - +40°C
Humidity	15% - 90% without condensation
Pressure	540 hPa -1,060hPa (0-5,000 mt)

Environmental storage specifications

Temperature	-40 °C - +5 °C without relative humidity control +5 °C - +40 °C, up to 90 % relative humidity, without condensation +40 °C - 70 °C with water vapour pressure up to 50 hPa;
Humidity	15 % - 90 % without condensation
Pressure	540 hPa -1,060hPa (0-5,000 mt)

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

510K number	Certification in progress
Classification	Class II
Product Code	DRG
Review Panel	Cardiovascular
Regulation Number	21 CFR 870.2910

Classification according to IEC 60601-1 - Electrical Safety

Protection against electric shock	BT: IP (Internal power supply) USB: compliant with IEC 60601-1
Applied parts	type CF – defibrillation-proof
Protection against harmful ingress of water or particular matter	IP40 / IP42 (with protective shell)
Method(s) of sterilization	NA (not intended to be sterilized)
Suitability for use in an oxygen rich environment	No
Mode of operation	Continuous operation

Classification according to IEC 60601-1-2 - Electro Magnetic Compatibility

Group	1
Class	B

Performances (ECG acquisition)

Standard	EN 60601-2-25:2011

Other classifications

GMDN	11407 - Electrocardiograph, general-purpose
CND	Z12050301 - ELECTROCARDIOGRAPHS GENERAL PURPOSE

RDM (Medical Device Catalogue)	2117422/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 1789	Medical Vehicles and their Equipment - Road Ambulances
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 safety requirements
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 requirements - Collateral standard: Usability IEC 60601-1-6:2010 (*)
IEC 60601-1-11	Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
EN 60601-2-25	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs. Partly applied – Applied in conjunction with HD+
EN 62304	Medical device software - Software life cycle processes
EN 62366	Medical devices - Application of usability engineering to medical devices

Product codes

Accessories

67040211	HD+ Stress Belt (strap with bag for HD+)
67040212	HD+ Safety Shell (protective silicone shell for HD+)
869060001	Set of 4 colored peripheral ECG electrode clamps, Ag/Agcl
63030106	Set of 4 peripheral ECG electric clamp Ag/Agl
63030107	4 peripheral ECG electric clamp pediatric
828030001	6 chest ECG electric suction type Ag/agcl
66030040C	Disposable electrodes ECG, tab, 100 pcs; pack of 10
N-10-A	ECG Disposable electrodes, neonatal, 25 units
SU-00-A	ECG Disposable electrodes, banana model, 60 units
M-00-S	ECG Disposable electrodes, snap, 50 units
T-00-S	Stress Test disposable electrode, snap, 25 pcs
9983248	ECG Disposable electrodes, snap, 50 units
SGFO3642	Stress Test disposable electrode, snap, 100 pcs
63090236	Set of 10 snap adapters for 4mm plug
66020008	Univ. adapter plug 4mm 10pcs.
63050104	IEC 10-wire patient cable snap HD+

63050105	IEC 10-wire patient cable plug HD+
63050106	AHA 10-wire patient cable snap HD+
63050107	AHA 10-wire patient cable plug HD+
63050118	IEC 13-wire patient cable snap HD+
63050127	AHA 13-wire patient cable snap HD+
63050131	IEC 13-wire patient cable banana HD+
63050133	AHA 13-wire patient cable banana HD+
63050128	IEC 13-wire patient cable snap HD+ - Blue
63050129	AHA 13-wire patient cable snap HD+ - Blue
63050132	IEC 13-wire patient cable banana HD+ - Blue
63050134	AHA 13-wire patient cable banana HD+ - Blue
81018229	HD+ DONGLE
81018230	HD+ USB option

CARDIOLINE

XR100+

XR100+ is a robust and reliable cycle ergometer, which is characterized by its high performance during the stress test and the ease of use. The handlebar and saddle have ample adjustment possibilities and a wide range of accessories is available.
The ergometer is equipped with a dual display, one for the operator to keep the situation under control and one for the patient to maintain the correct pedaling frequency. Thanks to the function keys and the graphic display, the operator console also allows the use of pre-set internal protocols or manually manage the load, as well as remote control via Cardioline Cubestress.
The **XR100BP+** version integrates a high quality oscillometric blood pressure monitor, automatically managed by Cubestress.

XR100+

Technical features

Ergometer

Model	Modular ergometer system **XR100+**
Operating mode	Continuous operation
Power supply	from 100 to 240 V / 50 to 60 Hz
Absorbed power	max. 60 VA
Principle of brake	computer-controlled electrodynamic brake with torque measurement; independent of the speed in accordance with DIN VDE 0750-0238
Load variation range	from 6 to 999 Watt, independent of the number of revolutions
RPM range	from 30 to 130 rpm
Deviation of the absorbed power	according to DIN VDE 0750-0238
Load stages	configurable as desired
Max patient weight	160 kg
Saddle height adjustment	continuous, for height ranging from 120 to 210 cm; manual adjustment of saddle height
Handlebar adjustment	for stature between 120 to 210 cm, 350° continuously adjustable handlebar, fixed handlebar column
Crank length	170 mm (possibility to order optional cranks with adjustable length)
Display	Display LCD Display: 93 x 70 mm / 128 x 64 pixels, 7-segment LED display as additional speed indicator
Internal protocol	5 fixed protocols and 10 protocols programmable by the operator; manual load controls
Interfaces	USB digital connection; RS232 digital connection + remote control
Dimensions and weight	Length: 1030 mm Width: 490 mm (Handlebar width: approx 530 mm) Height: from 1140 mm to 1400 mm Weight: approx 66 kg
Safety rules	DIN EN 60601-1, DIN EN 60601-1-2, DIN VDE 0750-238
Protection class	II / B (according to DIN EN 60601-1)
MDD classification	Classe IIa according to 93/42 CEE
Other Classifications	CND Z129003 RDM (Medical Device Catalogue) 1767070
Radio interference suppression	Limit class B according to DIN EN 55011 / 5.0 DIN EN 60601-1-2
Environmental conditions	*Operation:*

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Temperature: from +10 to +40 °C
Relative humidity: from 30 to 75%, without condensation
Pressione atmosferica: da 800 a 1060 hPa
Transport and storage:
Temperature: from -20 to +70 °C
Relative humidity: from 10 to 95%, without condensation
Atmospheric pressure: da 500 a 1060 hPa:

Blood pressure module

Measurement principle	Korotkoff method, oscillometric, comparison of plausibility of both measurements for resting measurement
Range	Systolic: from 40 to 280 mmHg Diastolic: from 40 to 280 mmHg Pulse: from 35 to 230 P/min
Errors	Measurement errors: +/- 3 mmHg Measurement resolution: +/- 1 mmHg
Pumping pressure	max. 300 mmHg, automatic adaptation of inflation pressure during the pumping phase
Pumping speed	between about 6 sec (at 140 mmHg) and about 18 sec (300 mmHg)
Max cuff pressure	300 mmHg
Pressure discharge method	Discharge rate depending on pulse of around 3 mmHg / pulse or about 3 mmHg / sec
Calibration	Calibration with external pressure measuring device
Artifact suppression	Automatic

XR100+

Standard Accessories

Ergometer
USB Cable, 5mt
User Manual

Accessories

Code	Description
69400074	Band sub-frame roll 50 rips
63090260	Horizontally adjustable saddle support
63090261	Pediatric saddle
67019434	USB connection cable, 7 mt
63090279	RS232 connection cable
63090262	Agonistic saddle
63090263	Horizontally adjustable pediatric saddle support
63090264	Adjustable pedals
67019340	Gas saddle adjustable in height
67019341	Motorized saddle adjustable in height
67019342	Adjustable motorized saddle and handlebars
67019343	Adjustable stretcher for pedals
67019346	Handlebar for Triathlon

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Cubestress

12/15 Lead wireless or USB connectiviry Stress Test System

Designed in collaboration with Physicians and Cardiac physiologists, Cubestress enhances the productivity of the Stress Clinic by providing exceptional ECG signal quality and sophisticated analysis, fast and secure test performance and seamless bidirectional connectivity to improve data workflow. When combined with the Cardioline ECGWebApp, Cubestress can store and retrieve the full test allowing web based remote stress performance and physician review. Cubestress configuration is scalable to meet your laboratory needs.

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Acquisition units, ECG signal quality and analysis

The ECG data is acquired through our HD+ acquisition unit, connected to the PC via Low Energy Bluetooth (BLE) or USB cable. HD+ is lightweight and robust, comfortable for the patient who is performing exercise on the treadmill or ergometer. Two configurations available:

- **HD+ 12** (12 leads, 10-wire cable)
- **HD+ 15** (12/15 leads, 13-wire cable)

The new HD+ can accurately check and measure electrode contact impedance allowing the operator to ensure a high quality Patient contact Pre Test.

Industry leading algorithms

High quality signal and automatic measurements help clinicians quickly analyse the stress ECG with total confidence. New algorithms for beat detection, arrhythmia classification, ST analysis, as well as QTc measurements and risk factor calculations, have been designed to provide diagnostic information you can rely on. The new algorithm for artefact reduction SENSA (**S**tress **E**CG **N**oise **S**uppression **A**lgorithm) has been developed in collaboration with the National Research Centre and University of Pisa. Based on the redundancy of the Electrocardiographic signal in all patient leads, it offers a clean and stable signal without altering the true ECG Waveform/Activity.

Lightweight, wireless and robust device, comfortable for patient and ease of use for technician

Connectivity and Data Workflow

Patient information can be uploaded from worklists through the HIS or manually entered and the final report exported in PDF format (DICOM, HL7, GDT or Cardioline ECGWebApp).
Additionally, the whole test can be stored in raw data format, enabling physicians to review, edit and print data remotely, for maximum efficiency in your stress lab.

A step by step intuitive interface

The large touch screen display allows for easy and intuitive navigation through the exercise test procedure. Large touch-buttons are provided on screen to quickly move from pre-exercise resting ECG, through the different stages of the stress protocol, to the recovery phase, or to immediately stop the exercise should it be required.
The large screen shows important information organised into multiple windows during the stress test, such as: 12/15 lead online ECG, single lead full disclosure ECG, 12/15 lead average reference complexes, augmented max ST lead, ST profile, Trends and captured arrhythmias.
All of the data within the windows can be individually modified or the windows can be minimised, providing a totally customisable user interface.

Scalable configuration

Cubestress is a highly configurable system you can design to your personal needs by choosing from different screen formats, thermal and/or laser printer options, automatic NIBP or NIBP/SPO2 monitors, electrode suction systems or the inclusion of an isolation transformer.
In conjunction with the Cardioline ECGWebApp, the report is available for everyone who has access rights to the ECGWebApp platform.

HD+ Acquisition unit

- Robust wireless Bluetooth transmission through Cardioline Dongle and optionally via USB cable
- Lightweight (90 grams) for patient comfort
- IP24 and drop proof protection
- ECG resolution: 500/1000 samples/second/channel (user selectable)

System Specifications

- 12/15 lead Stress Test System
- Secure, dedicated Bluetooth connection through Cardioline Dongle or via USB cable
- Configurable TTL and analogue outputs, an integral part of the dongle to connect with third party systems
- Pre-set protocols for bike, treadmill, pharmacological and generic (tilt test). Ability to add user defined protocols
- Patient demographics entered directly or from a worklist (DICOM, HL7, GDT or Cardioline ECGWebApp)
- Large color touchscreen for stress test visualisation. Customizable user display
- User selectable windows: real time ECG 12/15 lead, full disclosure ECG single lead, reference 12/15 lead, averaged 12/15 lead with ST real time measurements, zoomed lead, with max ST changes, ST profile, trends and captured arrhythmias
- Automatic arrhythmia capture
- Derived indexes: Framingham and Duke treadmill risk scores, Heart rate recovery index, Functional Aerobic Impairment
- Automatic or continuous ECG printing on thermal or laserjet printers
- Full exercise review and replay
- PDF report export (as option: DICOM, HL7, GDT or Cardioline ECGWebApp)

Analysis

- Automatic channel selection for best beat detection
- Automatic Arrhythmia detection and classification
- ST level and slopes (all channels)
- ST/HR, Double Product, QT/QTc trending
- METS
- Indexes: Duke, Framingham, FAI%, Heart Rate Recovery
- Automatic BP and SPO2 measurements via connected external devices (Tango, BL6, bike ergometer)

Alerts

- Rapid systolic BP elevation, Systolic BP drop
- HR drop, ST depression and rapid ST elevation, HR over target
- Arrhythmia
- Technical faults