

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.

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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

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- 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

Ports

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

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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
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Other classifications

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

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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/AgCl
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+

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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