

CARDIOLINE

HD+ 12 / HD+ 15

General Information

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| 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 | <p>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.</p> <p>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.</p> <p>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).</p> <p>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).</p> <p>It is light and compact, comfortable to wear, minimizing motion artifact caused by traditional electrodes and patient cables.</p> <p>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).</p> <p>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.</p> |
| Intended use | <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.).</p> <p>HD+ is able to detect the heart rate only for the purpose of generating a synchronisation signal towards NIBP devices or ECHO systems.</p> |

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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

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| 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 | >100M Ω |
| 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 μ V/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

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| 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: <ul style="list-style-type: none">▪ Switching off▪ Switching on▪ Connection▪ Error condition▪ Flat battery |
| Buzzer | Buzzer to indicate: <ul style="list-style-type: none">▪ Switching on |

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- Connection
- Low battery / error condition
- Switching off

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| R-Wave Synch output | TTL output (0 - +5V) |
| Compatible devices | Cardioline touchECG, Cardioline Cubestress. |

Electrical Characteristics

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

Physical Characteristics

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

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

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

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| 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: <ul style="list-style-type: none">▪ 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

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

Environmental storage specifications

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

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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 FDA

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

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

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| Group | 1 |
| Class | B |

Performances (ECG acquisition)

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| Standard | EN 60601-2-25:2011 |
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Other classifications

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

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RDM (Medical Device Catalogue) 2117422/R

Applicable standards

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

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| 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 |