CARDIOLINE

HD+

General Information

Product name	HD+
Generic name	HD+
Product code	81018027
Manufacturer	Cardioline Spa Head Office and Production: Via Linz, 19-20-21 Zona Ind. Spini di Gardolo 38121 Trento Italy Sales Office: Via F.lli Bronzetti, 8 20129 Milan Italy
Description of Device	HD+ is a digital portable acquisition device which can acquire the physiological electrocardiographic signal of 12 standard leads. The HD+ transmits the acquired data wireless and in real-time to a computer/device (i.e. PC or Tablet) where one of the compatible CARDIOLINE software is installed. HD+ uses a standard Bluetooth data transmission technology to transmit 12-lead ECG data over a proximity range, providing perfect electrical insulation and freedom of movement for the patient. HD+ guarantees the acquisition of an ECG signal, meeting the most severe standards used in clinical and diagnostic applications (AAMI, ANSI, AHA, ACC). HD+ is light and compact, comfortable to wear, minimizing motion artefacts caused by traditional electrodes and patient cables. A LED indicator allows to easily monitor 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 allows to send macro commands to the receiving system (i.e. acquire an ECG). Low-power technology allows continuous usage of the device for more than 10 hours (from full battery charge).
Intended use	The device function consists of acquiring and wirelessly transmitting ECG signal for displaying, processing and presenting ECG signal for the purpose of supporting the diagnose of patient conditions. HD+ is a wireless acquisition device, to be primarily used as common ECG front-end for PC/tablet (Windows/MAC OS/other) standard platforms, both for Resting ECG and Stress ECG applications. The device implements the wireless communication via Bluetooth wireless technology. Connected with a receiver via Bluetooth, HD+ sends the data to the host, without making any analysis or filtering. HD+ is not intended to control or analyse heart function and/or to diagnose the patient's health status. The analysis program on the host is a separate product. The results of the analysis must always be validated by qualified, trained medical personnel. ▪ HD+ uses standard 12 lead ECG cable to acquire the physiological signal to the patient. ▪ HD+ allows the patient to be ambulatory. ▪ HD+ is intended to be used on adult and all paediatric patients.

- HD+ is intended for use in a medical environment (hospitals, clinics and medical practices), in homecare or in an emergency environment (ambulances).
- HD+ is intended for use by qualified, trained nurses and physicians.

Technical specifications

ECG acquisition

ECG leads	12-leads (I, II, III, aVR-L-F, V1-6)
Patient cable	10 leads replaceable wire
CMRR	115dB
DC input impedance	100MΩ
A/D converter	24 bit, 32000 samples/second/channel
Sampling rate of the input stage	32000 samples/second/channel
Sampling rate for signal analysis and storage	1000 samples/second/channel
A/D conversion	20 bit
Resolution	<1 µV/LSB
Dynamic range	+/- 400 mV
Bandwidth	0.05-300 Hz
Pacemaker detection	Hardware detection coupled with digital convolution filter
De fibrillation protection	AAMI/IEC standard
Front-end performance	ANSI/AAMI IEC 60601-2-25:2011
Data transfer	Bluetooth 2.0+ EDR with “secure pairing”
Lead-fail detection	Independent for all leads
Compatible devices	Cardioline **touch**ecg, Cardioline **cube**stress.

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
Humidity	25% - 95%

Pressure	700hPa - 1060hPa

Storage Environmental Specifications

Temperature	0°C - +40°C
Humidity	25% - 95%
Pressure	700hPa - 1060hPa

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	K150289
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	IP (internal power ME)
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)	1211755/R

Applicable standards

EN 980	Symbol for use in the labelling of medical devices

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
EN ISO 15223	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

Product codes

Accessories

63050105	HD+ 10 wires IEC plugs patient cable
63050104	HD+ 10 wires IEC snap patient cable
63030105	Set of 4 colored periph. ECG electrode clamps, Ag/Agcl
63030106	Set of 4 peripheral ECG electric clamp Ag/Agl
63030107	4 peripheral ECG electric clamp pediatric
63030163	6 chest ECG electric suction type Ag/agcl
66030031C	ECG Disposable electrodes, snap, 50 units
66030037C	ECG Disposable electrodes, banana model, 60 units
66030036C	ECG Disposable electrodes neonatal, 25 units
66030039	ECG Disposable electrodes, tab, 100pcs
66030032C	Stress Test disposable electrode, snap, 50 pcs
66020008	Univ. adapter plug 4mm 10pcs.
66020002	ECG electrode gel, 260 ml
63090236C	Set of 10 snap adapters for 4mm plug
67040211	HD+ Stress Belt (strap with bag for HD+)
67040212	HD+ Safety Shell (protective silicone shell for HD+)
63090295	BT/USB adapter for PC