

CARDIOLINE

**ECG100+ - ECG200+
ECG100S - ECG200S**

User manual

CE
1936

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CARDIOLINE

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1. GENERAL INFORMATION

This manual is an integral part of the device and should always be available as support material to the clinical practitioner or the operator. Strict compliance with the information contained in this manual is an essential prerequisite for a proper and reliable use of the device.

Have the operator read the manual thoroughly as the information related to the different chapters is only described once.

1.1. Other important information

This manual was written with the utmost care. Should you find any details which do not correspond to those contained in this manual, please inform Cardioline SpA who will correct such inconsistencies as soon as possible.

The information contained in this manual is subject to change without notice.

All changes will be in compliance with the regulations governing the manufacturing of medical equipment.

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No part of this manual may be reprinted, translated or reproduced without the manufacturer's written authorisation.

The code relating to this manual is listed below.

Language	Code
ENGLISH	36510210_ENG

2. SAFETY INFORMATION

Cardioline SpA will be held responsible for the safety, reliability and functionality of the devices only if:

1. the assembly operations, modifications or repairs are carried out by Cardioline SpA or by its Authorised Service Centre;
2. The device is used in compliance with the instructions provided in the use manual.

Always contact Cardioline SpA should you wish to connect any devices not mentioned in this manual.



Warnings

- This manual provides important information on proper use and safety of the device. Failure to comply with the described operating procedure, improper use of the device, ignoring the specifications and recommendations supplied, may cause severe physical injuries to the operators, patients and bystanders, or may damage the device.
- No modification of this equipment is allowed.
- The device captures and presents the data that reflects the physiological condition of the patient; this information can be examined by specialist medical staff and will be useful in providing an accurate diagnosis. In any event, the data cannot be used as the only means to make an accurate diagnosis of the patient.
- The operators for whom this device is intended must have the required competence regarding medical procedures and the treatment of patients. They must also be sufficiently trained in using the device. Have the operator carefully read and understand the contents of the operator manual and the other annexed documents before using the device for clinical applications. Inadequate knowledge or training could be at a greater risk for the physical safety of operators, patients and bystanders, or could damage the device. In case the operators are not trained in using the device, we recommend to contact Cardioline or its Authorised Distributors to plan adequate training courses.
- The device and its power supply are classified as ME Equipment, since the power supply is considered an integral part of the device.
- US Federal law restricts this device to sale by or on the order of a Physician.
- To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.
- If in doubt regarding the integrity of the external earth conductor, use the device with its inner battery.
- The positioning of the device must be such as to don't make difficult the operation of disconnection from main supply when an external power supply is used. The plug of the main supply is the main switch used to disconnect the device from the main supply. Please, be sure to keep it near the device.

- All input and output signal connectors (I/O) are intended to be used only for connection to appropriate devices which comply with IEC 60601-1 standards or further IEC standards (e.g. IEC 60950). Connecting additional equipment to the device could increase leakage current to the chassis and/or patient. To avoid endangering the safety of the operator and patient, keep in mind the requirements of IEC 60601-1:2005+A1 clause 16 and measure the leakage current to confirm that there is no risk of electric shock.
- For the correct operation of the device and for the safety of the operators, patients and bystanders, the device and the accessories must be exclusively connected as outlined in this manual. Do not connect telephone lines to the LAN connector.
- To maintain immunity from potential interference of electromagnetic signals, a system must be used with shielded cables when connecting the device to the mains.
- To guarantee the safety of the operator and of the patient, the equipment connected to the same line as the device must comply with IEC 60950 or IEC 60601-1 standards.
- The power cable shielding (when present) must be connected to an earthing system appropriate for the area where the device is used. This will avoid electric shocks caused by different earth potentials which could exist between the various points of an electricity distribution system, or else by failures of the external equipment connected to the mains.
- The safety of the patient and the operator is guaranteed if the peripheral units and the accessories that can come into direct contact with the patient comply with the UL 60601-1, IEC 60601-1 and IEC 60601-2-25 standards. Only use spare parts and accessories supplied with the device and available from Cardioline SpA. Refer to section 12.2 for the list approved accessories.
- The patient cables to be used with the device are defibrillation-proof. Check the patient cables for ruptures or cracks before use.
- Conductive parts of the patient cable, electrodes and associated connections of type CF applied parts, including the neutral conductor of the patient cable and electrode, should not come into contact with other conductive parts, including earth ground.
- Defibrillation protection of the ECG relies on the use of the provided ECG cable and the use of any other ECG cable may impair the safe use of the equipment leading to electric shock for the patient and operator. Refer to section 12.2 for the list approved accessories.
- To prevent death or any serious personal injuries during defibrillation, avoid contact with the device or patient cables. It is furthermore necessary to properly position the defibrillation pads with respect to the electrodes in order to minimize patient skin burns.
- This device is designed to be used only with the electrodes specified in this manual. Strictly follow the correct clinical procedures to prepare the skin before the application of the electrodes and monitor the patient in order to avoid any irritation, inflammation or other skin reactions. The electrodes are designed for short-term applications and must be promptly removed once the examination is complete. Refer to section 12.2 for the list approved accessories.
- The ECG electrodes may cause skin irritation; check the skin for any irritations or inflammations.
- To prevent any infections, use the disposable components (e.g. the electrodes) only once. To ensure safety and use efficiency, do not use electrodes after their expiration date.
- The quality of the signal produced by the electrocardiograph may be adversely affected by the use of other medical equipment such as defibrillators and ultrasound machines.

- The device is intended for external use and is not intended for direct cardiac application.
 - There is a risk of explosion. Do not use the device in the presence of flammable anaesthetics.
 - There is no safety hazard if other equipment, such as pacemakers or other stimulators, is used simultaneously with the device; however, disturbance to the signal may occur.
 - The device is not designed for use with high-frequency (HF) surgical equipment, and does not provide any protective means against hazards to the patient.
 - The operation may be adversely affected by the presence of strong magnetic fields such as those produced by electrosurgery equipment.
 - The use of the device is not recommended in the presence of medical diagnostic imaging equipment such as the Magnetic Resonance Imaging (MRI) or Computerised Axial Tomography (CAT) in the same environment.
 - The following equipment may cause interference with the RF channel: microwave ovens, diathermy units with LANs (spread spectrum), amateur radios, and government radar.
 - Only use the recommended batteries. Using other types of batteries may cause danger of fire or explosion.
 - The internal rechargeable battery is hermetically sealed NiMH and requires no maintenance. Should the battery be faulty, contact Cardioline's technical assistance service.
 - The low battery warning is designed for the recommended batteries only. Using other types of batteries may lead to a lack of indication resulting in device failure. If the battery is low, connect the device to the electrical mains.
 - This device can be equipped with a wireless LAN (WLAN) module for transmitting ECG records. Device labeling will indicate if the device is equipped with such a module. If so equipped, the WLAN identification can be found on a label on the bottom of the device:
 - Shenzhen Kexian Technology KX-WUL150 (model subject to change without notice)
 - Use of the WLAN module may interfere with other equipment operating in the vicinity. Check with local authorities or spectrum management officials in your facility to determine if restrictions apply to the use of this feature in your area.
 - The WLAN modules complies with applicable RF safety standards including standards and recommendations for the protection of public exposure to RF electromagnetic energy that have been established by governmental bodies and other qualified organizations, such as the following:
 - Directives of the European Community
 - Directorate General V in Matters of Radio Frequency Electromagnetic Energy
 - To ensure compliance with current regulations limiting both maximum RF output power and human exposure to radio frequency radiation, a separation distance of at least 20 cm must be maintained between the device's antenna and the head and body of the user and any nearby persons at all times. To help prevent degradation of RF signal and to avoid excess RF energy absorption, do not touch the device during data transmission.
 - The device is not intended as a general purpose storage device, thus no files should be stored except from those automatically created by the device itself. Using the electrocardiograph as a general purpose storage device may results in unwanted radio frequency emissions.
-

- Do not clean the device or the patient cables by submersing them in liquid, autoclaving, or steam cleaning. This may cause serious damage to equipment or reduce its lifespan. Using non-specific detergents/disinfectants, failure to comply with the recommended procedures or contact with non-specific materials may cause additional risks to operators, patients or bystanders or may damage the device. Do not sterilise the device or the patient cable with ethylene oxide gas (EO). Refer to Section 12 for instructions on proper cleaning and disinfection.
- Do not leave the patient cable unattended in the presence of children as they could be accidentally strangled.
- Do not leave the electrodes unattended in the presence of children as they could cause suffocation if accidentally swallowed.



Attention

- To prevent any damage to the keyboard do not use sharp or heavy objects to press the keys, only use your fingertips.
- The device and the patient cable should be cleaned before use. Check the connections for any damage or excessive wear before each use. Replace the patient cable should it present any damage or be excessively worn.
- Do not pull or stretch patient cables as this could result in mechanical and/or electrical failures. Patient cables should be stored after forming them into a loose loop.
- There are no user-serviceable parts inside the device. The device can only be dismantled by qualified service personnel. Any malfunctioning or defective device must be excluded from use and be checked/repaired by qualified service personnel before being reused.
- The device does not require any calibration or special instrumentation for correct use and maintenance.
- When it is necessary to dispose of the device, its components and accessories (e.g.: batteries, cables, electrodes) and/or packaging material, comply with local standards for waste disposal.

Notes

- The movements of the patient may generate excessive noise and affect the quality of the ECG tracing or the correct analysis of the device.
- An appropriate preparation of the patient is important in order to guarantee a proper application of the ECG electrodes and the correct operation of the device.
- The incorrect positioning of the electrodes for the detection of the algorithm depends on the normal physiology and on the order of the ECG leads and tries to identify the most likely exchange. However, it is recommended to check the positioning of the electrodes of the same group (limbs or chest).

- If the electrodes are not properly connected to the patient, or one or more patient leads are damaged, the display will indicate a lead failure. When the ECG is printed, these leads will come out on paper as a square wave.
- As defined by the IEC 60601-1 and IEC 60601-2-25 safety standards, the device is classified as follows:
 - IP class equipment (internal power ME) - class I on external AC/DC power supply
 - Defibrillation-proof Type CF applied parts.
 - Ordinary equipment.
 - Not suitable for use in the presence of flammable anaesthetics.
 - Continuous operation

NOTE: From a safety view point, the external power supply is declared "Class I" based on IEC 60601-1 standard. A three-pole plug is used to guarantee earthing together with the power lines. The earth terminal of the power cable is the only point where the unit is earthed. Exposed metal parts which are accessible during standard operation have a double insulation from the power lines. The internal earth connections are a functional earthing.

- Accuracy of measurements taken with the device is compliant with IEC 60601-2-25.
- Power Supply has the following characteristics:
 - Model: AFM60US18
 - Manufacturer: XP Power Limited
 - Rated Input: 100-240 VAC, 50-60 Hz, 1.5-0.9 A
 - Rated Output: 60 W, 18 V, 3.34 A
 - Protection Class: I
 - Degree of Protection: IP20
- The device is a Class IIa in compliance with Directive 93/42/EEC.
- The device is a prescription device according to FDA regulation
- In order to prevent damage to the device during transportation and storage (when still in its original packaging), comply with the following environmental conditions:

Ambient temperature 5°C to 40°C
 Relative humidity 20% to 90%
 Atmospheric pressure 700 mBar to 1060 mBar

- The device is intended for use in hospitals or doctor's offices and should comply with the following environmental requirements:

Ambient temperature +10°C to 40°C
 Relative humidity 50% to 90%

Atmospheric pressure 700 hPa to 1060 hPa

- After using the device on battery power, always reconnect the power cable. This will guarantee that the batteries are recharged automatically the next time the device is used.

2.1. Wireless Data Transmission

The device can be equipped with an optional wireless data transmission module (WLAN mobile), that uses radios to transmit data to an application that can receive them.

Due to the nature of radio transmissions, it is possible that, due to the characteristics of the environment where the device is located, some other RF sources may interfere with the transmission generated by the device.

Cardioline SpA has tested the coexistence of the device with other devices that can interfere such as devices using WLAN, Bluetooth radio and/or cell phones. Although the current technology allows a very successful rate of transmission, it is possible that in some rare occurrences, the system may not perform at its best resulting in a “failed transmission”. When this occurs, patient data will not be erased from the device nor stored in the receiving application, ensuring that partial or corrupted data are not made available to the receiving station. If the failure mode persists the user should move to a position where the RF signals may propagate better and allow successful transmissions.

2.2. Wireless Option

Wireless options transmit at 2.4 GHz. Other nearby wireless devices may cause interference. If possible, move or turn off other devices to minimize potential interference.

The following table shows the channels allocated in different geographic areas in the world. Please consult with your IT personnel in order to set the device on the proper channels.

Specification	Description
Technology	Compliant with IEEE 802.11n, IEEE 802.11g and IEEE 802.11b standards
Interface Type	USB2.0/1.1
Security	64/128bit WEP encryption WPA/WPA2 and WPA -PSK/WPA2-PSK encryptions Wi-fi Protected setup(WPS)
RF Frequency	2,412 to 2,462MHz (North America) 2,412 to 2,472MHz (Europe) 2,412 to 2,484MHz (Japan)
Operating Frequency	FCC 2412-2462MHz (Ch1-Ch11) ETSI 2412-2472MHz (Ch1-Ch13)
RF Power	11n mode: 13dBm 11g mode: 15dBm 11b mode: 18dBm

In order to achieve the best transmission rate, it is necessary that the facility where the device is operated can provide good area coverage. Please consult the IT personnel of the facility to verify the proper WLAN availability in the area where the device will be used.

RF wave propagation may be blocked or reduced by the environment where the device is used. Most common areas where this may occur are: shielded rooms, elevators, underground rooms. In all the above situations, it is recommended to move the device to a proper location and verify with the IT personnel of the facility the areas where the WLAN signals are available.

3. ELECTROMAGNETIC COMPATIBILITY (EMC)

This device requires particular precautions regarding Electromagnetic Compatibility. It must therefore be installed and commissioned in compliance with the information on Electromagnetic Compatibility contained in this manual.

Portable and mobile radio communication equipment can affect operation of the device.

Using accessories, transducers or cables different than those specified in par. 13.3 can increase the emissions or decrease the immunity of the appliance.



Warnings

- This device is only intended to be used by professional healthcare personnel. This device could generate radio interference or disturb operation of the equipment in the vicinity. Therefore it could be necessary to take measures to mitigate these effects, such as re-directing or repositioning the device or shielding the room.
- The use of accessories and cables other than those recommended by Cardioline may cause an increase in emissions or a lowering in the protection of the system.
- The device must not be used near or superimposed to other equipment. If necessary, check that the device works according to its standard operation.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ME EQUIPMENT, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. Where ME EQUIPMENT stands for the respective models, ECG100+, ECG200+, ECG100S and ECG200S accordingly.

Notes

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Electromagnetic compatibility during the use of the device is required with the surrounding devices.

An electronic device can generate or receive electromagnetic interference. The electromagnetic compatibility test (EMC) has been carried out on the electrocardiograph in compliance with the international EMC directive for medical equipment (IEC 60601-1-2). This IEC standard has been adopted as a European standard (EN 60601-1-2).

Fixed, portable and mobile equipment for RF communication may affect the protection of the medical equipment. See par. 3.4 for the recommended separation distance between the radio equipment and the device.

The purpose of the device is the acquisition of ECG signals and the presentation of ECG reports for diagnostic purposes, as defined in IEC 60601-2-25.

Electromagnetic disturbances can cause disturb or degradation of the acquired ECG signal, resulting in misdiagnosis or delayed treatment.

3.1. Guidance and Manufacturer's declaration - Electromagnetic emissions

The ECG100+/ECG100S is intended to operate in the electromagnetic environment specified below. The customer or the user of the ECG100+/ECG100S must guarantee that it is used in this environment.

Emission test	Compliance	Electromagnetic environment – guidance
Radio frequency (RF) emissions CISPR 11	Group 1	The ECG100+/ECG100S uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Radio frequency (RF) emissions CISPR 11	Class A	The ECG100+/ECG100S is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes, because the emission level is low enough to not affect nearby equipment.
Harmonics emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

The ECG200+/ECG200S is intended to operate in the electromagnetic environment specified below. The customer or the user of the ECG200+/ECG200S must guarantee that it is used in this environment.

Emission test	Compliance	Electromagnetic environment – guidance
Radio frequency (RF) emissions CISPR 11	Group 1	The ECG200+/ECG200S uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Radio frequency (RF) emissions CISPR 11	Class A	The ECG200+/ECG200S is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes, because the emission level is low enough to not affect nearby equipment.
Harmonics emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

3.2. Guidance and Manufacturer's declaration - Electromagnetic immunity

The ECG100+/ECG200+/ECG100S/ECG200S is intended for use in the electromagnetic environment specified below. The customer or the user of the ECG100+/ECG200+/ECG100S/ECG200S should assure that it is used in such an environment.


Immunity test	Conformity	Compliance level	Electromagnetic Environmental Information
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical Fast Transient/Burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV line(s) to line(s) +/- 2 kV line(s) to earth	+/- 1 kV line(s) to line(s) +/- 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruption and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (60% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (60% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ECG100+ requires continued operation during power mains interruptions, it is recommended that ECG100+ be powered from an uninterruptible power supply or a battery.
Power frequency and magnetic field (50/60 Hz)	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the AC mains voltage prior to the application of the test level.

3.3. Guidance and Manufacturer's declaration - Electromagnetic immunity

The ECG100+/ECG200+/ECG100S/ECG200S is intended for use in the electromagnetic environment specified below. The customer or the user of the ECG100+/ECG200+/ECG100S/ECG200S should assure that it is used in such an environment.

Emission test	IEC 60601 test level	Compliance level	Electromagnetic Environmental Information
Conducted RF IEC 61000-4-6	3 V rms From 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the ECG100+, including cables, than the recommended separation

<p>Radiated RF IEC 61000-4-3</p>	<p>3 V/m From 80 MHz to 2.5 GHz</p>	<p>3 V/m</p>	<p>distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:</p> $d = \left[\frac{3.5}{3V/m} \right] \sqrt{P}$ $d = \left[\frac{3.5}{3V/m} \right] \sqrt{P} \quad \text{From 80 MHz to 800 MHz}$ $d = \left[\frac{7}{3V/m} \right] \sqrt{P} \quad \text{From 800 MHz to 2.5 GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a), should be less than the compliance level in each frequency range (b). Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
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NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ECG100+/ECG200+/ECG100S/ECG200S is used exceeds the applicable RF compliance level above, the ECG100+/ECG200+/ECG100S/ECG200S should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ECG100+/ECG200+/ECG100S/ECG200S.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

3.4. Recommended separation distances between portable and mobile RF communications equipment and the ECG100+/ECG200+/ECG100S/ECG200S

The ECG100+/ECG200+/ECG100S/ECG200S is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ECG100+/ECG200+/ECG100S/ECG200S can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ECG100+/ECG200+/ECG100S/ECG200S as recommended below, according to the maximum output power of the communications equipment.

Maximum rated power output of the transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 KHz to 800 MHz	800 MHz to 2.5 GHz	800 MHz to 2.5 GHz
	$d = [\frac{3,5}{V_1}] \sqrt{P}$	$d = [\frac{3,5}{E_1}] \sqrt{P}$	$d = [\frac{7}{E_1}] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

















3.5. Transmission frequencies

Frequency [MHz]	Channel	EIRP Power [mW]	EIRP Measured [dBm]	ERP = EIRP/1.64 [Mw]	ERP = EIRP/1.64 [dBm]	Standard	Modulation
2.412	1	8.43	9.26	5.14	5.64	802.11B	CCK, OFDM, BPSK, GPSK, 16-QAM, 64Q-AM
2.437	6	13.30	11.24	8.11	6.85	802.11B	CCK, OFDM, BPSK, GPSK, 16-QAM, 64Q-AM
2.480	13	11.67	10.67	7.12	6.50	802.11B	CCK, OFDM, BPSK, GPSK, 16-QAM, 64Q-AM
2.412	1	6.20	7.93	3.78	4.83	802.11G	CCK, OFDM, BPSK, GPSK,

							16-QAM, 64Q-AM
2.437	6	9.27	9.67	5.65	5.89	802.11G	CCK, OFDM, BPSK, GPSK, 16-QAM, 64Q-AM
2.480	13	9.64	9.84	5.87	6	802.11G	CCK, OFDM, BPSK, GPSK, 16-QAM, 64Q-AM
2.412	1	11.53	10.62	7.03	6.47	802.11N	CCK, OFDM, BPSK, GPSK, 16-QAM, 64Q-AM
2.437	6	4,48	6.51	2.73	3.96	802.11N	CCK, OFDM, BPSK, GPSK, 16-QAM, 64Q-AM
2.480	13	3.31	5.20	2.02	3.17	802.11N	CCK, OFDM, BPSK, GPSK, 16-QAM, 64Q-AM

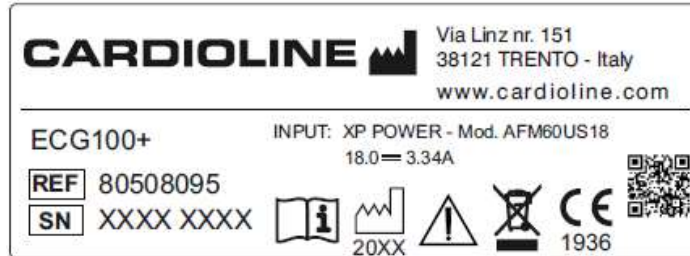
4. SYMBOLS AND LABEL

4.1. Explanation of the symbols

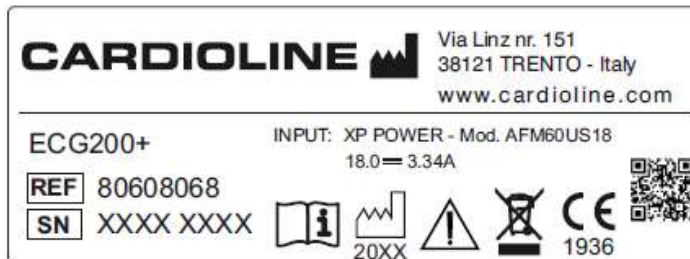
Symbol	Description
	Comply with the instructions in the use manual
	CE marking – compliance with the European Union directives
	Manufacturer
	Reference number (product code)
	Serial Number
	Lot number
	Year of manufacture
	RF transmitter (if present)
	Type CF equipment
	Separate collection of electrical waste and electronic equipment
	Read instruction for use
	Consult instructions for use
	Temperature variation
	Humidity variation
	No latex
	Keep dry

4.2. Device label

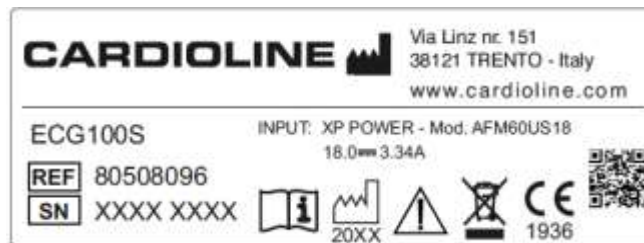
ECG100+



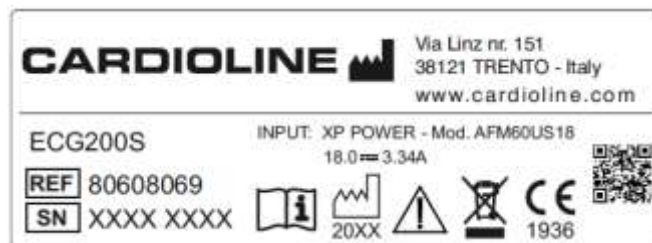
ECG200+



ECG100S



ECG200S



RF Symbol beside the connectors in the rear part of the device (see par. 5.4.1).

5. INTRODUCTION

5.1. Purpose of the manual

This manual deals with the ECG100+/ECG200+/ECG100S/ECG200S devices.

The manual represents a guide for the execution of the following operations:

- Reasonable use of the electrocardiograph, of the function keys and of the sequence of menus.
- Preparation of the device for use. (Section 6)
- Acquisition, printing and storage of ECG tracing. (Section 7)
- System settings. (Section 8)
- Connectivity and transmission of ECG tracings. (Section 10)
- Device upgrading (Section 11)
- Troubleshooting and electrocardiograph maintenance. (Section 12)

5.2. Recipients

This manual is intended for professional healthcare operators. They are therefore presumed to have specific knowledge of medical procedures and terminology, as required by clinical practice.

5.3. Intended use

ECG100+/ECG200+/ECG100S/ECG200S is a high-performance, multi-channel, interpretative resting electrocardiograph.

The ECG signal is acquired with a 10-wires patient cable and is displayed in real time on a LCD screen integrated in the device. The electrocardiograph can analyse and store the ECG traces, send them to an external peripheral via Internet or via USB, print the 12 lead ECG in automatic or manual mode by means of a thermal printer.

The device is intended for assessment and diagnosis of cardiac functions. In any case the results of analysis performed by the electrocardiograph must be validated by a Physician.

The device is intended for use in hospitals, in medical clinics and doctor's offices of any size.

- The device is indicated for use to acquire, analyse, display and print electrocardiograms.
- The device is intended to provide the physician with an automatic interpretation of the ECG to be reviewed by a physician.
- The device is indicated for use in a clinical setting, by a physician or by trained personnel who are acting on the orders of a licensed physician. It is not intended as a sole means of diagnosis.

- The interpretations of ECG offered by the device are only significant when used in conjunction with a physician over-read as well as consideration of all other relevant patient data.
- The device is indicated for use on adult and paediatric populations.
- The device is not intended to be used as a vital signs physiological monitor.

5.4. Description of the device

The device is a 12-lead diagnostic electrocardiograph which displays, acquires, prints and stores ECG tracings for adults and children. It also calculates the main overall ECG parameters.

The device can be supplied with the optional 12-lead Glasgow resting ECG interpretation algorithm, with specific criteria by age, sex and race. If this option is enabled, the algorithm can provide an over-reading physician with a second opinion generating diagnostic messages in the ECG report.

For further information on the resting ECG interpretation algorithm, see the Guidance for the physician on the application on adults and children (see accessories list)

The device can be configured with a larger memory, with two-way connectivity (LAN/WiFi) and with DICOM® functionality in the case of models ECG100+/ECG200+.

The device can be powered by battery or the electrical mains.

The printing formats supported include: standard or Cabrera 3, 3+1, 3+3, 6 or 12 (only ECG200+/ECG200S) channels in automatic mode and 3, 6 or 12 (only for ECG200+) channels rhythm strip printing.

The device includes:

1. Patient cable
2. Power supply
3. Paper
4. Pack of electrodes
5. Banana/clip adapter set
6. Guidance for the physician on the application on adults and children (with interpretative key)
7. User manual

5.4.1. General overview

Front view:

ECG100+



ECG200+



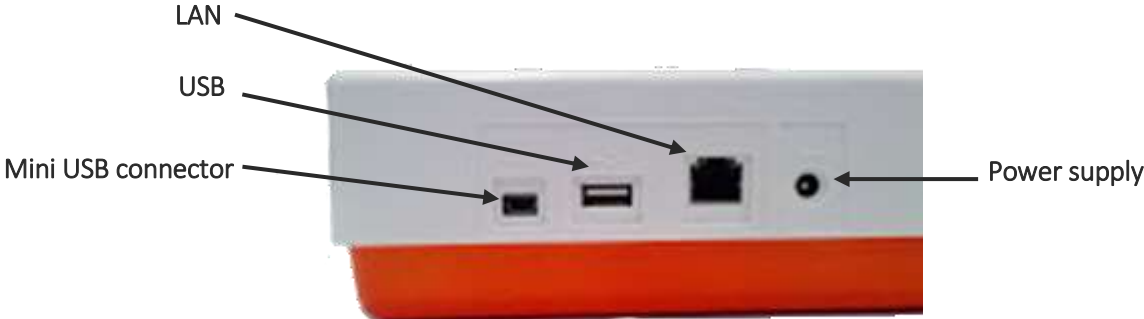
ECG100S



ECG200S



Rear view:

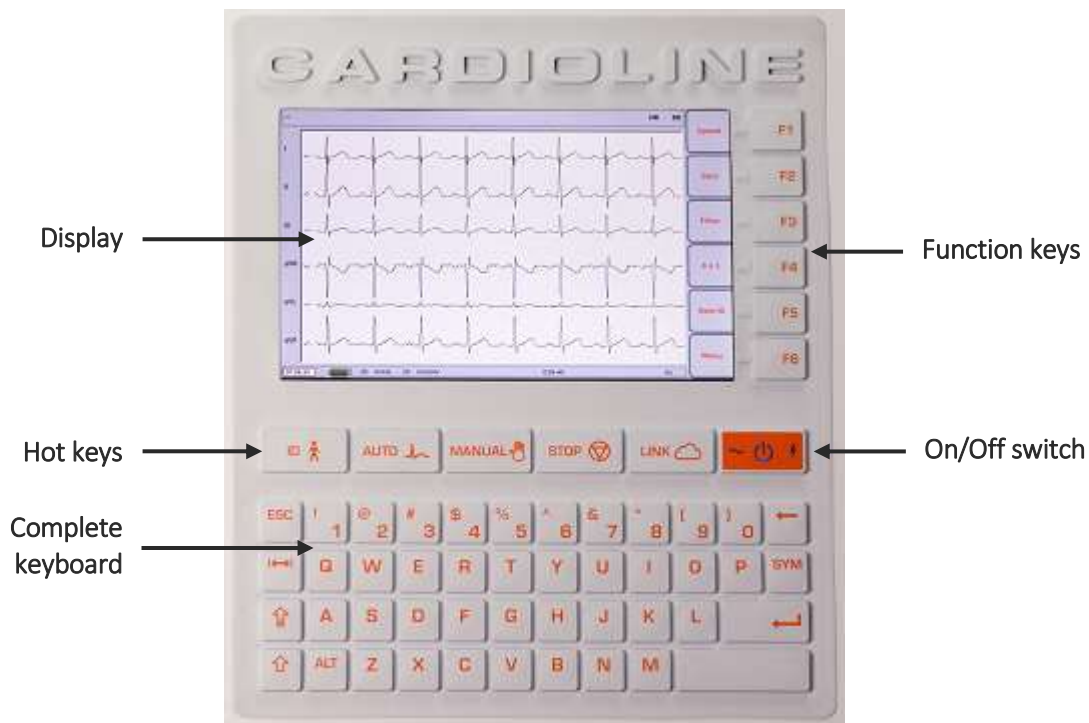


Side view:



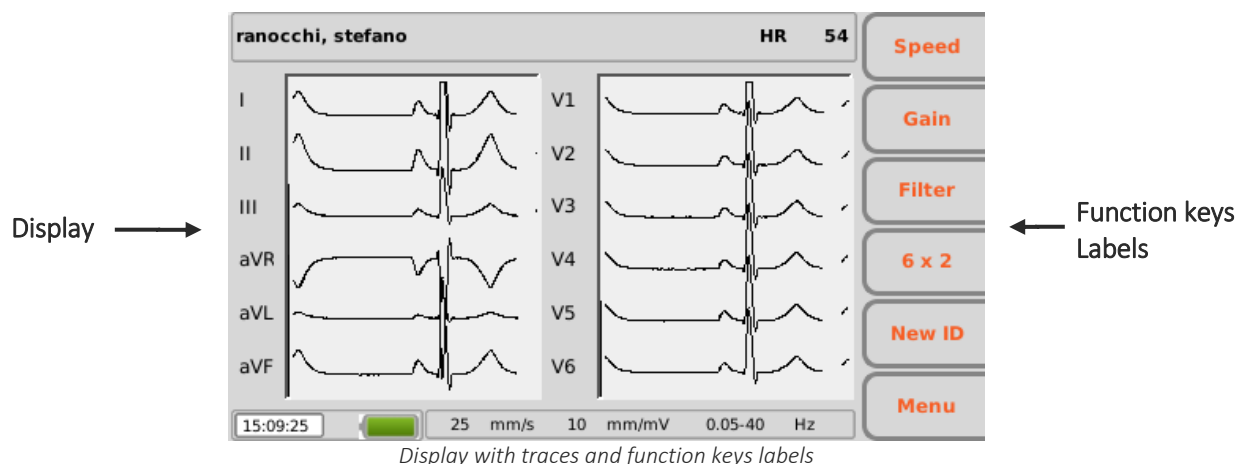
Display and keyboard:

ECG100+/ECG200+



ECG100S/ECG200S










5.4.2. Keyboard

The electrocardiograph is equipped with a complete alphanumerical keyboard for entering numbers, characters and symbols. The keyboard also has hot keys, to easily activate the main operations, and some function keys.

Hotkeys

The electrocardiograph has 5 hot keys to activate the following functions:

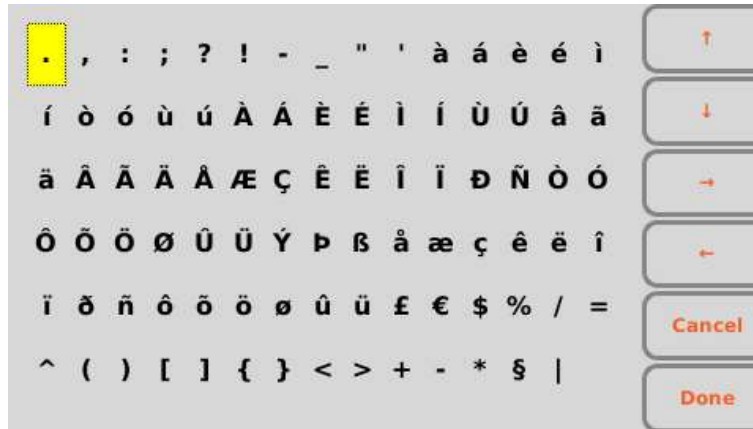
Hot Key	Description
ID 	Entering patient data.
AUTO 	ECG tracing acquisition in automatic mode.
MANUAL 	ECG tracing acquisition in manual mode.
STOP 	Suspend ECG tracing acquisition in manual mode.
LINK 	ECG test transmission and worklist download

Function keys

The function keys (F1 – F6) activate the functions indicated in the corresponding boxes on the right-hand side of the display. The functions change according to the screen displayed. If the box corresponding to a key is not displayed, that key is not active on that screen.

Special symbols and characters

Pressing “SYM”, when a text field is selected, grants access to the special symbols and characters menu.



Symbols and special characters menu

Using the function keys is possible to move between characters and select them:

- F1 (↑) to move up.
- F2 (↓) to move down.
- F3 (→) to move right.
- F4 (←) to move left.
- F5 (Cancel) to close symbols menu without choosing any character.
- F6 (Done) to close symbols menu choosing the selected character.

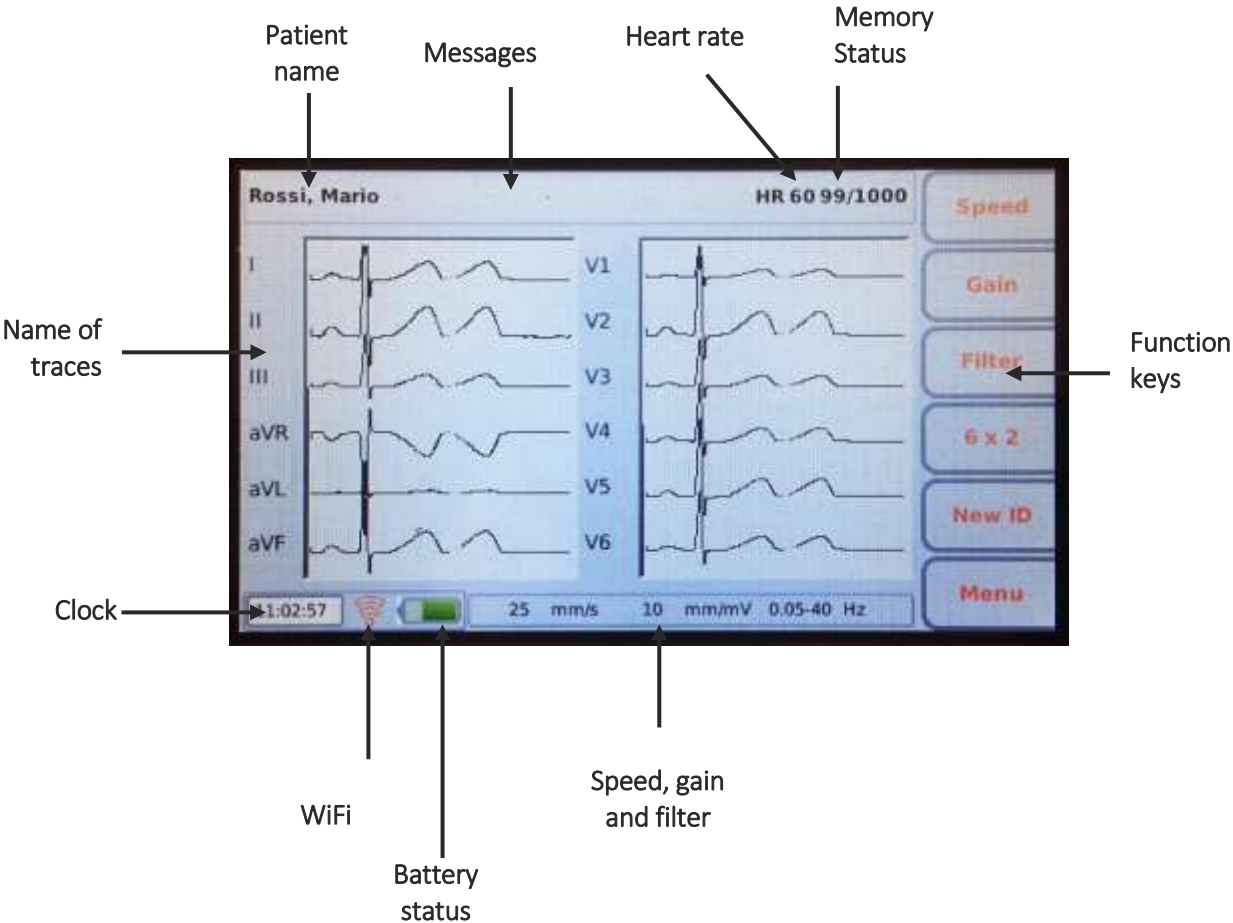
Key combinations

- ALT + z: move left
- ALT + x: ,
- ALT + c: .
- ALT + V: ;
- ALT + B: :
- ALT + n: /
- ALT + m: move right
- Shift + F1: page down
- Shift + F2: page up

5.4.3. Display

ECG100+/ECG100S is supplied with a 4.3” colour LCD monitor, ECG200+/ECG200S is supplied with a 7” colour LCD monitor. When acquiring an ECG tracing, the display shows the following main information:

- **Surname, Name:** surname and name of the patient being examined, if entered.
- **Heart Rate (HR):** when a patient is connected to the device, his/her HR is viewed in real time.
- **Speed:** rate of the tracings in mm/s. Use the F1 key to modify speed to 5 mm/s, 10 mm/s, 25 mm/s or 50 mm/s.
- **Gain:** amplitude of the waveform in mm/mV. Use the F2 key to modify the gain to 2.5 mm/mV, 5 mm/mV, 10 mm/mV, 20 mm/mV.
- **Filter:** step-by-step filter applied to the tracings. Use the F3 key to modify the filter applied between off, 25 Hz, 40 Hz, 150 Hz.
- **Battery charge:** indicates the level the battery is charged.
- **Time:** indicates the time of the device
- **WiFi connection:** indicates the quality of the WiFi connection
- **Messages:** electrode failure indicator and other messages (if present).
- **Memory:** the number of tests that can still be saved in memory (archive size, 100 or 1000, minus the number of tests already saved)
- **Access mode:** an open/closed padlock icon indicates the active access mode (anonymous or full access), see par. 9.2.



6. PREPARATION FOR USE

6.1. Initial startup

The first time the device is used, the basic configurations of the electrocardiograph should be set. Therefore, when using the device for the first time, it's recommended to go to the settings screen and set at least the following parameters:

- Language
- AC filter
- Unit of weight and height
- Date and time

See Section 8 to perform the required configurations.

6.2. Patient cable connection

Connect the patient cable terminal plug to the connector on the side of the electrocardiograph. The connector is so designed that the patient cable can only be inserted one way, with the "Cardioline" logo on the plug facing upwards.

Should the plug of the patient cable not go into the connector, do not force it but try to turn it over.

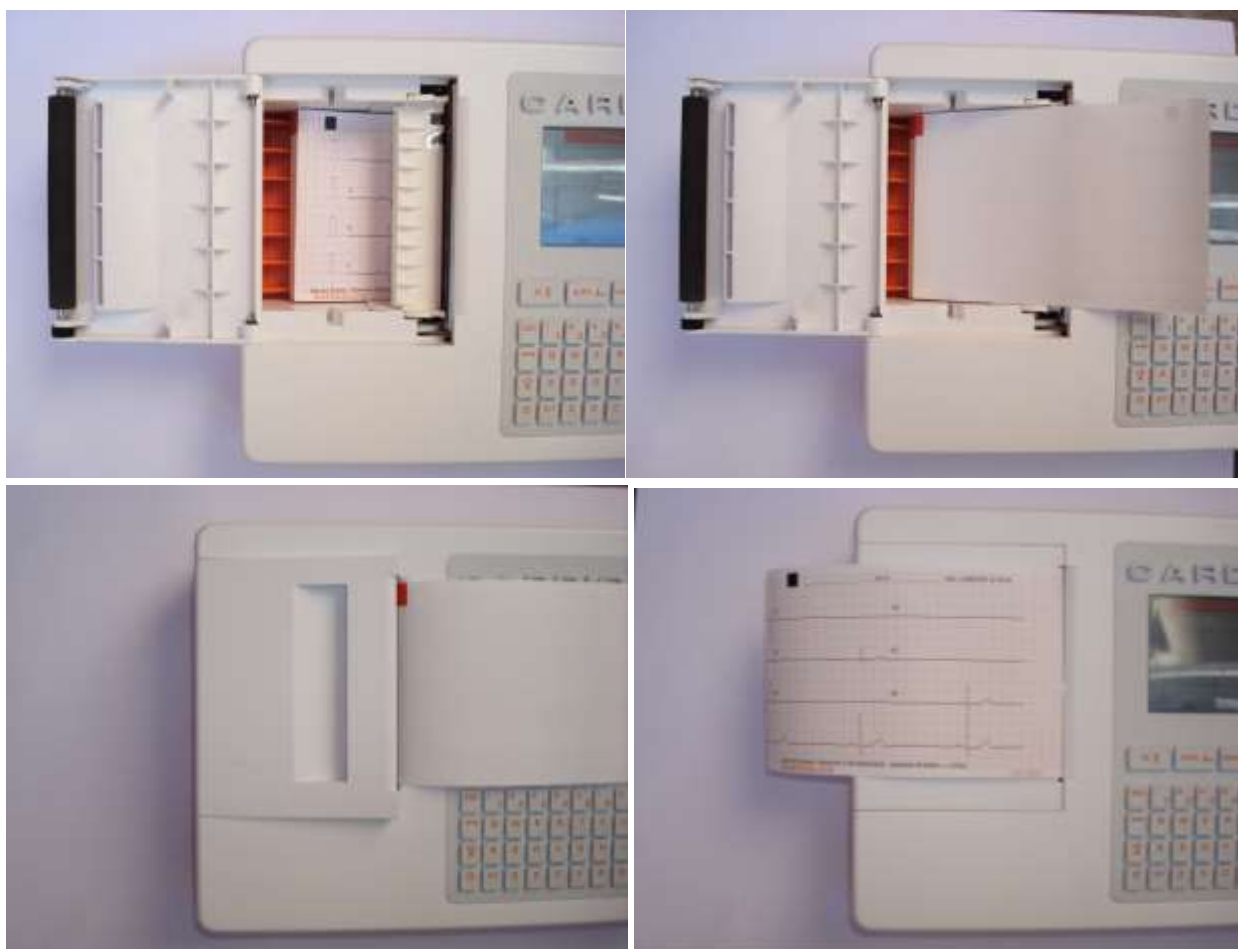


NOTE: to prevent the patient cable from breaking when disconnecting it from the electrocardiograph, remove it from the connector by grasping the plug, avoid straining the terminations.

6.3. Loading the paper

Load paper in the electrocardiograph as follows:

1. Remove the outer packaging of the ream of paper.
2. Open the printer compartment, lifting the panel and turning it anticlockwise around its pivot.
3. Slip the ream of thermal paper into the drawer of the printer so that the side of the paper grid faces upwards and the paper advancement sign (a small black rectangle) is at the top left.
4. Lift the first edge of paper, flip it over (so that the unprinted part faces upwards) and push it to the right so that the edge rests on the right-hand side of the drawer.
5. Close the panel so that the edge of the sheet comes out on the right. The panel clicks when closed properly.



Sequence for loading paper

WARNING: Risk of injuring fingers while handling the paper panel of the printer or the roll control mechanisms.

NOTE: after printing it is important that the paper is cut by pulling it to the right instead of to the left. If the paper is pulled towards the left the door may accidentally open, thus causing problems with any subsequent prints.

NOTE: For the best performance of the thermal printer, use the thermal paper recommended by Cardioline.

6.4. Power connection

The electrocardiograph can also be powered by battery, disconnected from the mains.

Make sure that the power supply is connected to an earthed electrical socket.

If powered by electrical main the plug of the main supply is the main switch used to disconnect the device from the main supply. Please, be sure to keep it near the device to simply disconnect the device from main supply.

When the electrocardiograph is not working, it should be plugged in to charge the battery.

The on/off switch has three led lights, indicating whether and how the device is powered:

NOTE: The first time it is used, the battery must still be fully charged, connecting the electrocardiograph to the power supply.



Model on/off button + (to the left) and model S (to the right)

Led Light	Description
	Green – Lights on if the device is connected to the electrical mains
	Blue – Lights on while device is connected to the electrical mains and battery is charging. Lights off when battery is completely charged or the device is not connected to the electrical mains.
	Blue – Lights on when the device is switched on.

NOTE: There are specific settings which make it possible to extend the life of the battery (see Section 12.5). Appropriate use and maintenance also extend its life.

NOTE: The device should be connected to the mains using only the XP Power - AFM60US18 adaptor supplied.

6.5. Battery operation







When the electrocardiograph is not plugged in, it is powered by battery.

When the device is switched on the "unknown level" icon is displayed until the actual battery level is measured.

The device switches off automatically when the battery reaches the minimum allowed level. When the device detects that the battery voltage has discharged almost to this point, the message "Battery depleted" appears for 30 seconds before the device switches off automatically. During the shutdown the display turns gray and the message "Battery depleted" is shown on the screen for 3 seconds.

If you try to switch on the electrocardiograph in battery mode when the battery is depleted, the device turns on but the display turns gray and the message "Battery depleted" is shown on the screen. After 3 seconds the device switches off automatically. Plug the unit in before turning the unit on again.

The battery symbol at the bottom right corner of the display indicates the battery charge level:

Symbol	Description
	Battery fully charged (over 70% total capacity)
	Battery charged (between 30% and 70% total capacity)
	Battery low (less than 30% total capacity)
	Battery depleted. The device initiates an automatic shutdown after at least 60 seconds. The device will report a warning message on display.
	Battery charging
	Battery level unknown. Displayed when the application starts up while it is reading the battery status.

NOTE: The first time it is used, the battery must still be fully charged, connecting the electrocardiograph to the power supply.

NOTE: When the electrocardiograph is not working, it should be plugged in to charge the battery.

NOTE: if you use the device in battery mode, always remember to recharge the battery completely after use in order to be sure that the unit is ready for use.

NOTE: The device should be connected to the mains using only the XP Power - AFM60US18 adaptor supplied.

7. EXECUTION OF AN EXAM

7.1. General procedure

To acquire an ECG proceed as follows:

1. Prepare and connect the patient (as described in Par. 7.2)
2. Check the display to verify the quality of the tracings and to make sure there are no error messages (as described in Par. 7.3).
3. Fill in patient demographic, if necessary (as described in Par. 7.4)
4. Press the **AUTO** hot key for an automatic ECG acquisition or the **MANUAL** hot key for a manual ECG acquisition (as described in Par. 7.5).

***NOTE:** If the work flow allows it, it is good practice to connect the patient to the device and to enter his/her ID data before recording a tracing. This minimises artefacts on the tracings introduced during connection of the patient and positioning of electrodes.*

7.2. Before acquisition

7.2.1. Preparing the patient

Ensure that the patient fully understands the procedure and knows what to expect before connecting the electrodes.

- Privacy is very important to allow the patient to be relaxed.
- Reassure the patient that the procedure is painless, and that he/she will only feel the electrodes on the skin.
- Make sure that the patient is relaxed and in a comfortable position. If the table is narrow, insert the hands of the patient under the buttocks to ensure the muscles are relaxed.
- Once the electrodes are connected, ask the patient to remain still and not to talk. Explain that this is important to ensure a good ECG acquisition.

A proper cleaning of the skin is of the utmost importance. There is a natural electrical resistance on the skin surface, generated by sources such as hair, sebum, and dry or dead skin. Adequately prepare the skin to minimize the aforementioned effects and optimize the quality of the ECG signal.

To prepare the skin:

- If necessary, shave the skin area where the electrode must be applied.
- Wash the area with hot soapy water.

- Dry the skin vigorously with an abrasive pad, such as a 2x2 or 4x4 gauze, to remove dead skin cells and fat.

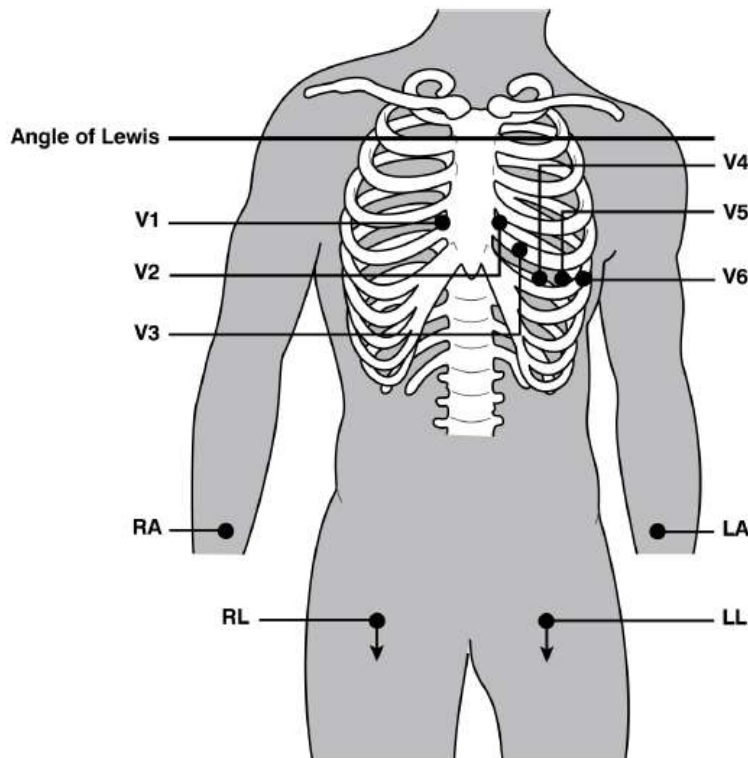
NOTE: Pay attention not to cause abrasions, discomfort or bruises on the skin. Always observe the utmost clinical discretion when preparing the patient.

7.2.2. Connecting the patient

It is important to position the electrodes properly in order to acquire a good electrocardiographic signal. Indeed a low impedance ensures a better waveform, reducing noise. Quality electrodes should be used.

Connect the electrodes as follows:





















1. Expose the arms and legs of the patient to connect the relevant leads.
2. Position the electrodes on the flat and fleshy parts of the arms and legs.
3. If a limb is not available, position the electrodes on a blood-supplied stump.
4. Attach the electrodes to the skin as indicated in the figure below. Test the correct adherence, and therefore the good contact, by pulling the electrode. If the electrode moves freely, replace it. If the electrode does not move easily, a good electrical contact is ensured.



Correct positioning of the electrodes

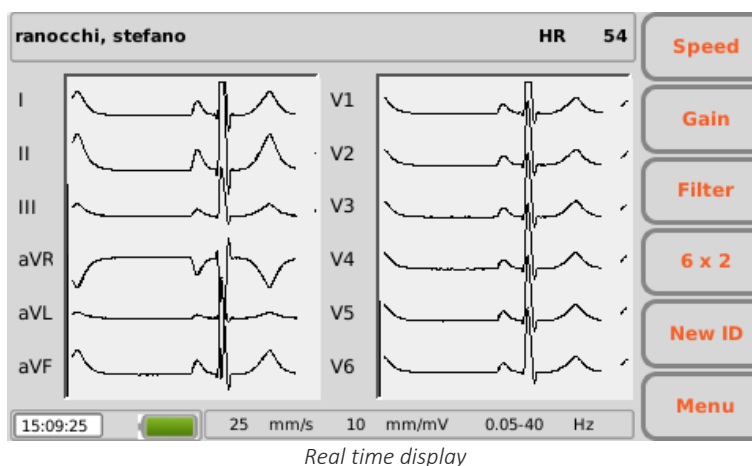
NOTE: It is important to locate the fourth intercostal space for an accurate positioning and monitoring of the precordial leads. It is possible to locate the fourth intercostal space starting from the first intercostal space. Given the variable conformation of the patient, palpating the first intercostal space accurately can be difficult. Therefore, it is advisable to locate the second intercostal space by first palpating the small bone protrusion known as the Angle of Louis, formed by the junction of the manubrium and the body of the sternum. This protrusion of the sternum identifies the junction point of the second rib, and the space immediately below it corresponds to the second intercostal space. Palpate and count following the trunk until the fourth intercostal space is located.

Table 1: Reference table for the connection to the patient

IEC lead			AAMI lead			Position
C1		Red	V1		Red	Fourth intercostal space to the right of the sternum.
C2		Yellow	V2		Yellow	Fourth intercostal space to the left of the sternum.
C3		Green	V3		Green	Midway position between electrodes V2/C2 and V4/C4.
C4		Brown	V4		Blue	Fifth intercostal space at midclavicular line.
C5		Black	V5		Orange	Between electrodes V4 and V6.
C6		Violet	V6		Violet	Level with electrode V4 at left midaxillary line.
L		Yellow	LA		Black	On the deltoid muscle, the forearm and wrist.
R		Red	RA		White	On the deltoid muscle, the forearm and wrist.
F		Green	LL		Red	On the thigh or the ankle.
N		Black	RL		Green	On the thigh or the ankle.

7.3. Viewing the ECG

The electrocardiograph starting screen is the real time display.



Display and function keys

The display shows ECG traces in real time, some basic information (name and surname of the patient, heart rate, speed, gain, filter and battery charge, as indicated in Par. 5.4.3) and the active function keys:

- F1 (**Speed**): to modify the display speed of the tracings (5, 10, 25, 50 mm/s)
- F2 (**Gain**): to modify the amplitude of the displayed tracings (5, 10, 20 mm/mV)
- F3 (**Filter**): to select the low-pass filter to apply to the displayed tracings (off, 150, 40, 25 Hz)
- F4 (variable label): to modify the display format of the tracings (12x1 (only ECG200+/ECG200S), 6x2, 6x1 1st, 6x1 2nd, 6x1 3rd, 3x2 1st, 3x2 2nd, 3x1 1st, 3x1 2nd, 3x1 3rd, 3x1 4th, 3x1 5th). The label corresponds to the current display format.
- F5 (**New ID**): to create a new patient with a new ID and delete the previous one
- F6 (**Menu**): to access to the Settings pages (Chap. 8)

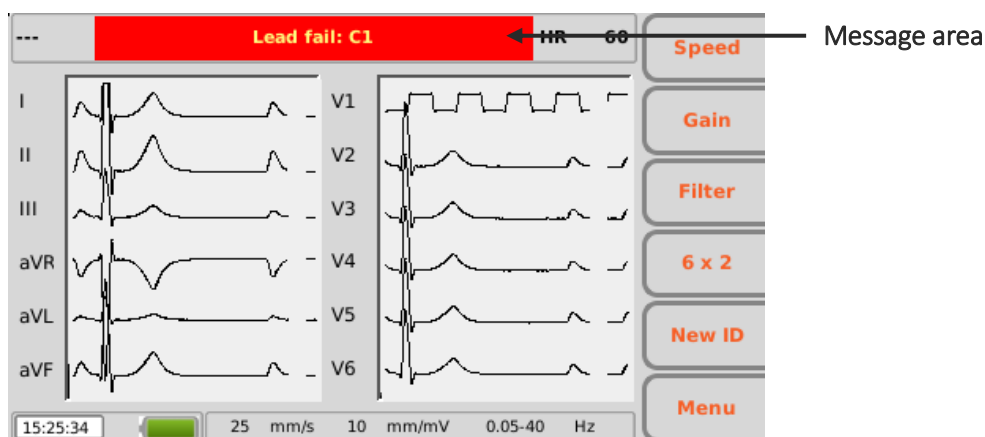
Hot keys

The active hot keys on the real time display screen are:

- **ID**: to enter or change patient data (see Par. 7.4);
- **AUTO**: to start automatic acquisition of ECG (see Par.7.5.1);
- **MANUAL**: to start manual printing of ECG (see Par.7.5.2).

The display also shows messages regarding tracing failures and errors. Messages are displayed on the top of the screen, as shown in the picture below. See par. 12.8 for the complete list of messages.

WARNING: *lead fail, overload and saturation are represented as square waves on the screen.*



7.3.1. Disconnection of the leads

If one or more electrodes are disconnected the message “Lead fail” followed by the list of leads in fail is displayed. The waveforms corresponding to the leads in fail are shown as square waves (see picture above).

In case all the leads are disconnected all the ECG traces are shown as square waves and the message “Lead fail: all” is displayed. Similarly, if the lead in fail is N/RL the message “Lead fail: all” is displayed and all the traces are shown as square waves.

If the patient cable is disconnected from the device front end connector, the ECG traces are shown as flat traces.

NOTE: if the setting “LF mask” is disabled (Off), the setting “automatic interpretation” is enabled (On) and the leads are disconnected, if the acquisition of the examination is forced (see par. 7.5) the print reports the warning “Caution: the quality of the ECG may affect the interpretation”.

NOTE: if the setting “LF mask” is disabled (Off) and the leads are disconnected, the print in the footer shows the writing “-- OL --”.

NOTE: the messages displayed in the event of electrode disconnected remain even if the setting “LF mask” is disabled (Off).

7.4. Entering patient data

Patient data can be entered before or after acquiring an ECG tracing by pressing the ID hot key. The data can be entered manually or automatically by selecting the patient from a work list.

Patient data can also be automatically loaded by selecting an ECG from the archive, as described in par. 8.3.

Screen for patient data input.

NOTE: make sure patient data are cleared and retyped before acquiring an ECG for a new patient, as they are not automatically reset after an exams. Patient data are automatically cleared only when the device is turned off or use function key **New Id – F5**

7.4.1. Manually entering the patient's data

Display and function keys

The fields available for patient data are:

- ID (identification code for the patient)
- First Name
- Last Name
- Gender
- Date of Birth (DoB) and age – Age field is calculated automatically if a valid date of birth is entered. Age is expressed in years (if older than 25 months), in months (if older than 12 weeks), in weeks (if older than 30 days) or else in days.
- Race – Race field appears depending on the chosen settings. If it is invisible, its default value is "unknown".
- Height and Weight
- Blood Pressure (BP) – systolic and diastolic
- Drugs
- Note
- Technician

To shift among the fields of the page, use the arrows corresponding to the following function keys:

- F1 (↑) to move up.

- F2 (↓) to move down.
- F3 (→) to scroll the list of the possible items associated with a field (such as sex and race).

The other function keys allow you to:

- F4 (**Worklist**) open a work list
- F5 (**Cancel**) cancel data insertion and go back to the initial screen
- F6 (**Done**) save the entered data and go back to the initial screen

NOTE: If the age is not entered before acquiring an ECG, it will be interpreted by default relative to a 50-year-old male. The message "Interpretation made without knowing patient's age" will be added to the interpretation text.

NOTE: If age zero (0) is used, it will be interpreted by default relative to a 50-year-old male. The message "Interpretation made without knowing patient's age" will be added to the interpretation text.

7.4.2. Automatically entering the patient's data

If the connectivity option (standard or DICOM) is enabled in the electrocardiograph, patient data can be loaded automatically by selecting them from a work list.

Use the F4 function key (**MWL**) on the **ID** screen to view a work list.

Name	ID	Location /	Exam date	
von Hötzen...	ID000001	Room02	17/07/15 ...	↑
Pennacchi...	ID000004	Room06	21/07/15 ...	↓
Diaz,Arma...	DZARM74E05H096M	Room13	17/07/15 ...	
Tarso,Paolo	22	Room2	20/07/15 ...	Details
Pippo,Franco	1	Room2	20/07/15 ...	
Cuccarini,L...	55HLBWRWEFS12	Room2	20/07/15 ...	
Parisi,Heater	44	Room2	20/07/15 ...	
Galileo,Pietro	33	Room2	20/07/15 ...	
01/04/1981 (→), Male, ACC0902			1/8	Select
				Back

Worklist screen

Function keys

You may scroll the list using the function keys:

- F1 (↑) to move up,
- F2 (↓) to move down,
- F3 (**Details**) to view details regarding the selected order.

The other function keys allow you to:

- F5 (**Select**) load the selected order and to go back to the initial screen
- F6 (**Cancel**) go back to the initial screen without loading any data

NOTE: if the order contains the fields *VisitID* and *ReasonForStudy*, these are automatically saved in the file SCP of the examination performed starting from that order, even though they are not visible from the ECG machine.

7.5. Acquisition of an ECG

ECGs can be acquired both in automatic and in manual mode.

Using the automatic mode you can acquire a 10 s ECG, which can then be saved and printed as an exam.

Using the manual mode you can print continuously an ECG of variable duration (no saving is allowed).

7.5.1. Automatic acquisition of an ECG (AUTO)

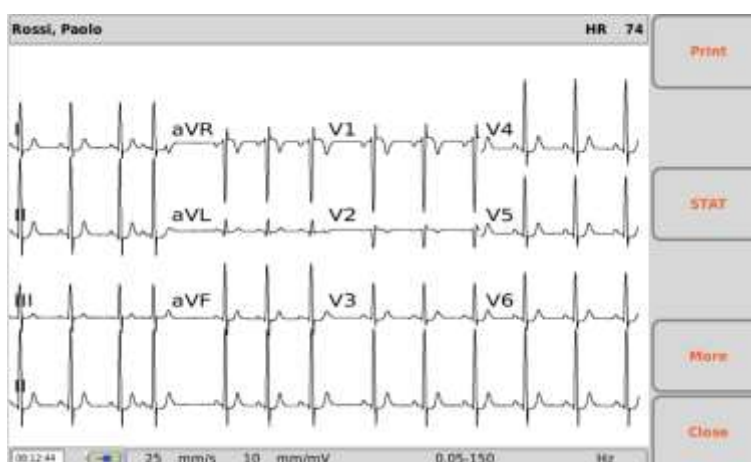
10 s of tracing can be acquired in automatic mode by pressing the **AUTO** hot key on the real time display screen.

When the **AUTO** key has been pressed, the electrocardiograph gathers 10 s of valid data and records them automatically.

During acquisition, the display shows the number of seconds remaining until completion. If the signal is lost, the device restart the acquisition process.

The user can force acquisition of the tracing by pressing the **AUTO** key a second time. This way the electrocardiograph will save an ECG based on the data acquired up to that moment.

When the acquisition is complete, the traces appear on the display as a printing preview.



Printing preview of an acquired ECG.

Printing and saving the exam

If the automatic printing option (Par.8.6.2) is enabled, the examination is printed automatically at the end of the acquisition. In the same way, if the automatic saving option (Par. 8.6.2) is enabled, the examination is saved automatically at the end of the acquisition.

If these options are not enabled, the examination can be printed and saved using the function keys as described below.

Function keys

The function keys allow you to:

- F1 (**Print**) to print the ECG (or reprint it if automatic printing was enabled),
- F2 (**Save**) to save the ECG (disabled if the automatic saving function is active),
- F3 (**STAT**) to associate the “urgent” status to the ECG (Par. 7.6),
- F5 (**More**) to activate functions for modifying printing formats,
- F6 (**Close**) to go back to the real time display screen.

Hot keys

- **LINK** key allows you to transmit the examination (if the connectivity option is active and correctly set) and export the ECG raw record (SCPECG format) and the PDF to the USB memory stick if inserted.

NOTE: the format of the PDF report is the same as the printing format.

Modifying printing formats

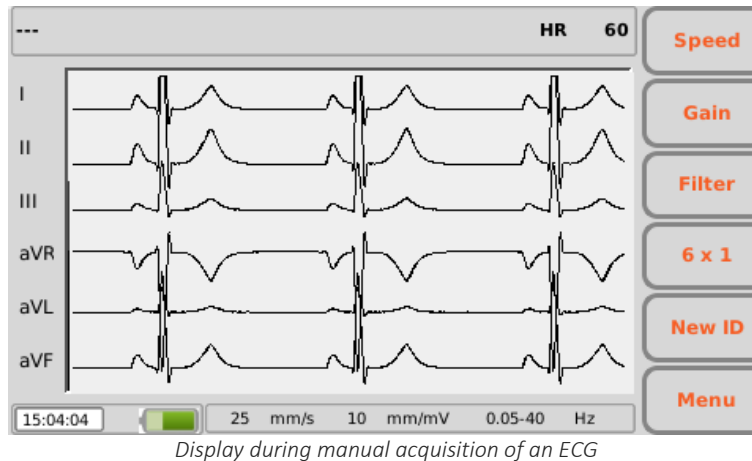
The F5 key (**More**) allows you to activate functions for modifying printing formats:

- F1 (**Speed**) to modify printing speed (25, 50 mm/s)
- F2 (**Gain**) to modify the amplitude of the tracings (5, 10, 20 mm/mV)
- F3 (**Filter**) to select the low-pass filter to apply to the tracings (off, 150, 40, 25 Hz)
- F4 (variable label): to modify the display format of the tracings (12x1 (only ECG200+/ECG200S), 6x2, 3x4+3, 3x4+1, 3x4). The label shows the current display format.
- F5 (**Print**) to print the ECG with the current settings
- F6 (**Back**) to go back to the previous display.

NOTE: To speed up acquisition of the ECG, the electrocardiograph starts acquiring data as soon as the patient is connected. This way, when the “AUTO” key is pressed, the electrocardiograph analyses the data already acquired and, if it finds 10 s of valid data, it saves them without needing to wait a further 10 s of acquisition. Therefore it is important to ask the patient to relax on his/her back to make sure that the ECG is free of artefacts due to inactivity of the patient and, if possible, to follow the work flow described in the previous paragraphs (connecting patient – entering data – acquisition) to give the tracings time to stabilise.

7.5.2. Manual acquisition of an ECG (MANUAL)

Pressing the **MANUAL** key on the real time display screen starts manual acquisition and printing of the ECG tracing.



Function keys

The function keys allow you to modify the printing parameters of the ECG:

- F1 (**Speed**): allows you to modify the printing speed (5, 10, 25, 50 mm/s)
- F2 (**Gain**): allows you to modify the amplitude of the tracings (5, 10, 20 mm/mV)
- F3 (**Filter**): allows you to select the low-pass filter to apply to the tracings (off, 150, 40, 25 Hz)
- F4 (variable label): to modify the format of the trace printed while keeping the number of channels chosen. The label shows the current display format:
 - 12x1: 12x1 (only ECG200+/ECG200S)
 - 6x1: 6x1 1st, 6x1 2nd, 6x1 3rd
 - 3x1: 3x1 1st, 3x1 2nd, 3x1 3rd, 3x1 4th, 3x1 5th

NOTE: to change speed, amplitude and format of the trace printed you must stop printing and start again.

Hot keys

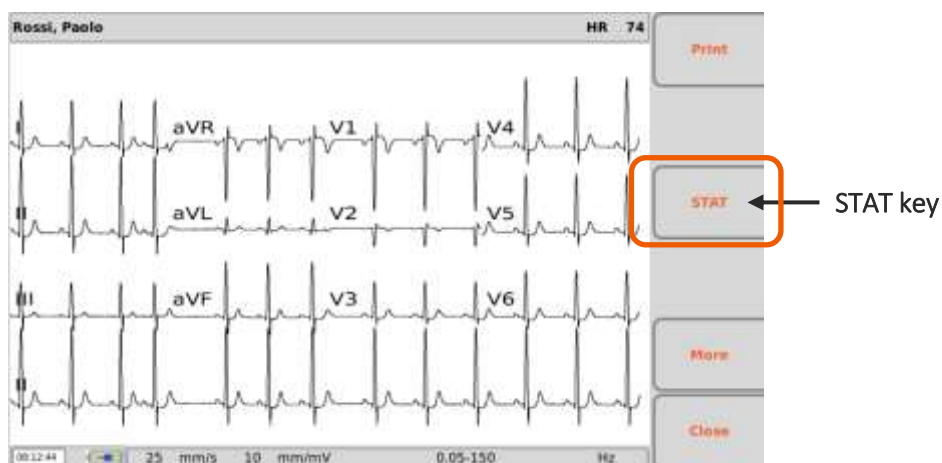
- **MANUAL:** repeated presses, once the printing is started, allow changing the format of the trace printed (12x1 (only ECG200+/ECG200S), 6x1 1st, 6x1 2nd, 6x1 3rd, x1 1st, 3x1 2nd, 3x1 3rd, 3x1 4th, 3x1 5th).
- **STOP:** interrupts manual printing and restores the real time display screen. By pressing the button once, the printing stops and the paper moves at the end of the current page, by pressing two times the printing stops immediately without the paper moving at the page end.

7.6. Identifying urgent ECGs (STAT)

The acquired examinations can be identified as "urgent", for example for flagging as such in Cardioline WebApp or in an archive.

Once the ECG has been acquired it can be given the "urgent" status by pressing the F3 function key (**STAT**). When this key is pressed, the corresponding label and the patient name filed turn **red** and the acquired ECG is given the "urgent" status. Pressing the key again activates/deactivates the "urgent" status.

If the automatic saving option is enabled, the examination is re-saved automatically every time the "urgent" status is modified (namely every time the F3 key (**STAT**) is pressed). If on the other hand the automatic saving option is not enabled, the examination must be saved manually at each modification by pressing the F2 key (**Save**).



If an ECG must be acquired urgently, it can be started without entering the patient's data, but simply by pressing the **AUTO** key on the real time display screen.

The acquired examination can then be printed, saved or transmitted as is without patient data, or the patient's data can be associated to it at the end of acquisition by pressing the **ID** hot key.

NOTE: The word **stat** is an abbreviation of the Latin word *statim*, which has the meaning "instantly/immediately".

NOTE: if **STAT** is selected for an exam activating its "urgent" status, the status is maintained for all the subsequent exams acquired for the same patient ID.

NOTE: To transmit the ECG as urgent, it must be sent after having modified the status.

7.7. Printing an ECG

As described in Par. 7.5.1, if the automatic printing option is enabled, the ECG is printed automatically at the end of acquisition. It is always possible to print or reprint the ECG using the F1 function key (**Print**).

It is also possible to start manual printing by using the **MANUAL** hot key on the real time display screen (Par. 7.5.2).

***NOTE:** the heart rate shown in print is that calculated as the average of the 10 s rhythm printed. It may therefore be different from that shown on the display before printing, which instead corresponds to the rate in real time.*

7.7.1. Printing formats

Format	ECG data
12x1 (only ECG200+/ECG200S)	10 seconds of 12 leads in 12 channel format.
6x2	5 seconds of 6 leads in 6 channel format.
3x4	2.5 seconds of 12 leads in 3 channel format.
3x4+1	2.5 seconds of 12 leads in 3 channel format; the fourth channel is a rhythm strip of 10 second lead defined by the user (Rhythm Lead).
3x4+3	2.5 seconds of 12 leads in 3 channel format plus a strip of 10 second lead defined by the user (Rhythm Lead), in a 3-channel format.

7.8. Storing an ECG

At the end of an "AUTO" acquisition, the exam can be stored.

As described in Par. 7.5.1, if the automatic saving option is enabled, the examination is saved automatically at the end of acquisition. It can also be saved using the F2 function key (**Save**).

The examination will be saved in an SCP file containing:

- Progressive number of the ECG
- Patient's data
- Urgency (yes/no)
- Automatic measurements
- Interpretation (if the electrocardiograph is supplied with the Glasgow Interpretation option)

7.9. Transmitting an ECG

If the device is equipped with LAN or WLAN module and the Standard network or DICOM connectivity are enabled, the device can transmit examinations to an external system.

The examination can be transmitted automatically or manually (using the **LINK** key) at the end of the acquisition, as described in par. 7.5.1, depending on whether the “**Autosave**” function is active in the Settings (par. 8.6.7).

If the “**Autosave**” setting is enabled and transmission fails, the device will try again until it succeeds.

You can always send or re-send an examination from the ECG Archive by selecting the exam in question, open it clicking **Select** and then clicking on **LINK**. From the ECG Archive you can also transmit all untransmitted exams together clicking on **LINK**.

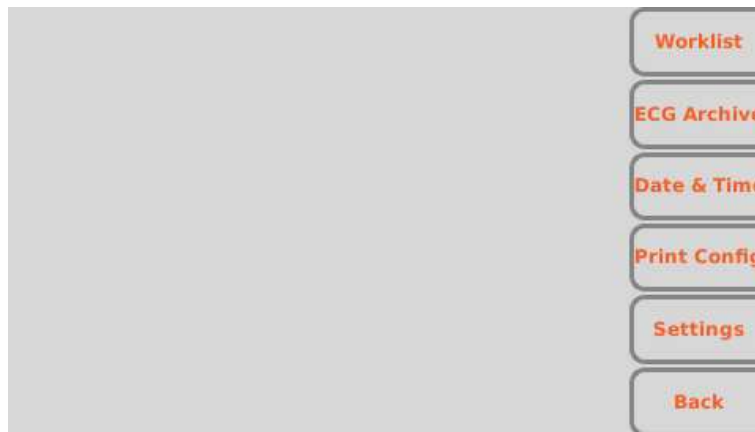
See par. 8.3 for further details about the ECG Archive.

***NOTE:** if you are trying to send a test that has already been sent previously, you will be asked to confirm the operation.*

8. MENU AND DEVICE SETTINGS

8.1. Main menu

The main menu can be accessed by pressing the F6 function key (**Menu**) on the real time display screen.



Main menu screen

Function keys

From the Main menu, you may access the various sections using the corresponding function keys:

- F1 (**Worklist**) to view a work list,
- F2 (**ECG Archive**) to view the archive of the saved ECG examinations,
- F3 (**Date & Time**) to set the date and time of the device,
- F4 (**Print Configuration**) to print the configuration page of the device,
- F5 (**Settings**) to modify the default settings of the device,
- F6 (**Back**) to close the Menu and to go back to the real time display screen.

8.2. Work lists

If the electrocardiograph has the Connectivity option, it is capable of downloading the work lists generated by the server it is connected to.

Name	ID	Location	Exam date
Parisi, Heater	44	Room2	27/05/2015 17:01
Galileo, Pietro	33	Room2	27/05/2015 17:01
Tarso, Paolo	22	Room2	27/05/2015 17:01

01/03/1961 (---), Female, ACC44

Worklist screen

Display and function keys

The work lists are displayed on a specific screen, reached from the Main menu (with the F1 function key (**Worklist**)) or from the patient's data screen (as described in Par. 7.4).

The orders are viewed as a list, indicating for each one:

- Patient name
- Patient ID
- Location
- Planned date and time

It is possible to move within the list, to select an order and to order the list using the function keys:

- F1 (▲) to move to the previous order,
- F2 (▼) to move to the following order,
- F3 (**Details**) to open a pop-up window with patient data details for the selected order (the window closes with the F6 function key (**Back**)),
- F5 (**Select**), only enabled if the work list was opened starting from the patient's data screen; it allows you to select the current order, to load its data or to go back to the page of the patient's data. If the work list was opened from the Main menu page, the (**Select**) key is disabled.
- F6 (**Back**) to go back to the previous screen (Main menu or patient's data screen).

8.3. ECG archive

The electrocardiograph can save up to 100 ECG's (1000 if the extended memory option is enabled). To access the ECG archive, press the F2 key (**ECG Archive**) on the Main menu.

Name	ID	Time	ST	Pr	Tx	
???		26/05/2015 18:06	x			↑
???		26/05/2015 14:45	x			↓
???		26/05/2015 14:43	x			Sort Opt
???		26/05/2015 14:41	x			Delete
???		26/05/2015 14:40				Select
???		25/05/2015 17:42	x			Back
???		25/05/2015 17:41	x			
???		25/05/2015 16:55				
???		25/05/2015 16:54				
???		25/05/2015 16:53				
???		25/05/2015 16:52				
???		25/05/2015 16:52				
(--), Unknown						

ECG archive screen

Display and function keys

The stored examinations are viewed as a list, each including:

- Patient name
- Patient ID
- Date of birth or age
- Date and time of acquisition
- Status: transmitted, printed, urgent

It is possible to move within the list, to select an ECG and to order the list using the function keys:

- F1 (↑) to move to the previous examination,
- F2 (↓) to move to the following examination,
- F3 (**SortOpt**) to order the list, cycling over the sorting criteria: Patient name ascending, Patient name descending, Patient ID ascending, ID descending, acquisition time ascending, acquisition time descending
- F4 (**Delete**) to delete the selected ECG; a confirmation pop-up window appears,
- F5 (**Select**) to open and view the selected ECG. Once an ECG has been opened it is possible to print it, to modify the format of the tracings, to mark it as "urgent", to transmit it, etc. as described in Par. 7.5.1.
- F6 (**Back**) to go back to the Main menu.

Hot keys

The following hot keys are also enabled in the archive screen:

- **LINK**: if the connectivity option of the electrocardiograph is enabled, it allows you to send all of the ECG's not transmitted ("non-transmitted" status flag). Pressing the **LINK** key opens a message window indicating the advancement status; press the F6 function key (**Back**) to close it. If a USB memory stick is inserted in the type A USB port the LINK button also allows you to save the exams (in SCP and PDF formats) on it.

***NOTE:** The cancellation of an examination is definitive and cancelled examinations cannot be recovered.*

8.3.1. Archive full

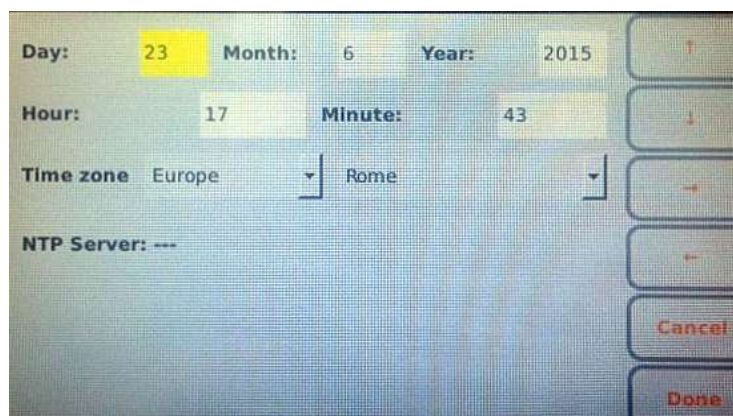
When the archive has reached the limit of 91 exams stored (991 in in the expanded memory version) the device will warn the user that memory is almost full showing the number of exams saved in memory in red colour.

When the memory has reached the limit of 100 saved tests (1000 in the extended memory version), when saving a new test, the device automatically deletes a test from the memory to make room for the new test. The device first eliminates the tests starting from those transmitted, then those printed and then all the others, from the oldest moving gradually to the newer ones.

***NOTE:** To avoid automatic cancellation, periodically check the occupation level of the memory and cancel ECG's manually.*

8.4. Date and time

Device date and time can be changed through the Date & Time screen. Press F3 (**Date & Time**) on the Main menu to open it.



Date and time setting

Display and function keys

You may shift among the fields of the page by using the function keys:

- F1 (↑) to move to the previous field,
- F2 (↓) to move to the following field,
- F3 (→) to increase the value of a field or to select one of the possible items associated,
- F4 (←) to decrease the value of a field or to select one of the possible items associated.

The other function keys allow you to:

- F5 (**Cancel**) go back to the initial screen without saving
- F6 (**Done**) save the changes and go back to the initial screen

The “Timezone” field allows the user to set the time zone of reference.

Automatic synchronisation with a server

The date and time can be set manually or you may choose automatic synchronisation with a server (if the electrocardiograph is provided with a connectivity option and is connected to Internet).

In this second case, the user cannot modify the Date and Time fields and the system automatically considers the address set in the “Time Server” field of Settings (described in par.8.6.5) as the address of the server to which the device must be linked. If automatic synchronisation is enabled, the program automatically updates from Winter Time to Summer Time. Otherwise the time must be updated manually.

8.5. Print configuration

By pressing the F4 function key (**Print Configuration**) on the main menu, it is possible to print one or more pages containing the current values of all the settings together with the following additional information:

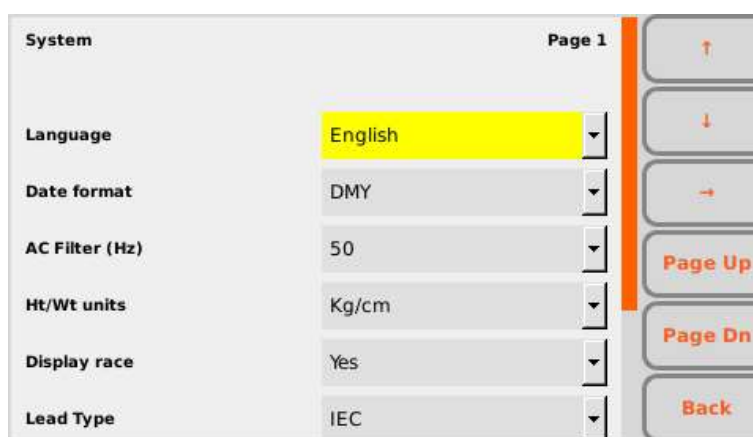
- Device model
- Product code (REF) of the device
- Device serial number
- Active hardware and software options
- Software version
- LAN MAC address
- WLAN MAC address
- Current status of the LAN network (enabled, disconnected, etc.) and information on the network (IP address, subnet mask, gateway and DNS)
- Current status of the WLAN network (connected/disconnected), current RF channel, RF signal power and noise level and/or quality index of wireless connection.
- Battery charge
- Internal memory space occupied

- Number of orders and stored ECG's

8.6. Settings

The settings menu consists of several pages that allow to change the device settings. To move between the pages and between the fields of each page, use the function keys:

- F1 (↑) to move to the previous field,
- F2 (↓) to move to the following field,
- F3 (→) to scroll the possible items associated with a field,
- F4 (**Page Up**) to move to the previous settings page,
- F5 (**Page Dn**) to move to the following settings page,
- F6 (**Back**) to go back to the Main menu page



Settings page

8.6.1. General settings (page 1)

Field	Description	Possible values
Language	Language used for display and printing. If changed, it needs the device reboot to be applied.	
Date format	Format of the dates.	dd/mm/yyyy, mm/dd/yyyy, yyyy/mm/dd
AC filter	Value of the filter to eliminate disturbance introduced by the electrical mains. The value must correspond to the frequency of the electrical line (e.g. 60 Hz in the USA and 50 Hz in Europe).	Off/ 50 Hz/60 Hz
Unit of weight and height	Unit of measurement for weight and height (in kilograms/centimetres or pounds/inches)	Kg/cm or lb/in

Field	Description	Possible values
Display Race	Visibility of the race field in the patient's data and in print.	Yes/No
Accession number	Visibility and editability of Accession Number field.	hidden/not editable/editable
Brightness	Brightness of the screen.	from 10% to 100%
Auto Turn off	Time of inactivity (without any key being pressed and without any acquisition) after which the device switches off automatically, if powered by the battery.	15/ 30/60 minutes
Lead Type	Sets the name of displayed electrodes label depending on the standard used. If changed, it needs the device reboot to be applied.	IEC/AHA
LF mask	Allows turning off the display of the square waves in case of lead fail, so that you can see the real signal. Useful for patients with high impedance or with under-performing electrodes.	On/Off
External DICOM (only ECG100+/ECG200+)	This setting is displayed only if Connectivity Option is DICOM and allows to choose if the DICOM transmission has to be done using an external gateway (Cardioline Gateway), If set to Yes the external gateway is used.	Yes/No
Configuration PIN	Allows to set a 4 digits PIN in order to protect the access to settings. If empty (default) the settings are not protected.	Numeric (4 digits)

8.6.2. Default ECG settings (page 2)

Field	Description	Possible values
Interpretation	Automatic interpretation of the ECG (if the electrocardiograph is provided with the Interpretation option). If "off", the interpretation is not included in the ECG and in the print. if "long", the interpretation text is enriched with additional explanatory statements.	Short/Long/Off
Leads order	Order in which tracings are displayed and printed.	Standard/Cabrera
Leads format	Initial tracings display format. If changed, it needs the device reboot to be applied.	12x1 (only ECG200+/ECG200S)/ 6x2/6x1 1 st /6x1 2 nd /6x1 3 rd /3x2 1 st /3x2 2 nd /3x1 1 st /3x1 2 nd /3x1 3 rd /3x1 4 th / 3x1 5 th
Muscle filter	Initial value of filter for reducing the muscle noise. It is only applied to the displayed tracings and not on the saved data (SCP file). If changed, it needs the device reboot to be	Off/25Hz/40Hz/150Hz

Field	Description	Possible values
	applied. The 150 Hz filter is available only if using a sampling frequency of 1000 Hz.	
Speed	Initial speed of the tracings. If changed, it needs the device reboot to be applied.	50/25/10/ 5 mm/sec
Gain	Initial tracings amplitude. If changed, it needs the device reboot to be applied.	20/10/5 mm/mV
Autoprint	Automatic printing of examination at end of acquisition.	On/Off
Autosave	Automatic saving of examination at end of acquisition.	On/Off
QTcB	Activates the QT corrected calculation of Bazett	On/Off
QTcF	Activates the QT corrected calculation of Fredericia	On/Off

8.6.3. Manual printing settings (page 3)

Field	Description	Possible values
3-Lead 1 st	1 st lead in 3-channel print	From I to V6 (default II)
3-Lead 2 nd	2 nd lead in 3-channel print	From I to V6 (default V1)
3-Lead 3 rd	3 rd lead in 3-channel print	From I to V6 (default V5)
6-Lead 1 st	1 st lead in 6-channel print	From I to V6 (default I)
6-Lead 2 nd	2 nd lead in 6-channel print	From I to V6 (default II)
6-Lead 3 rd	3 rd lead in 6-channel print	From I to V6 (default III)
6-Lead 4 th	4 th lead in 6-channel print	From I to V6 (default VI)
6-Lead 5 th	5 th lead in 6-channel print	From I to V6 (default V2)
6-Lead 6 th	6 th lead in 6-channel print	From I to V6 (default V5)

8.6.4. Automatic printing settings (page 4)

Field	Description	Possible values
Printout format	Initial tracing printing format. If changed, it needs the device reboot to be applied.	12x1 (only ECG200+/ECG200S)/6x2/3x4/3x4+1/3x4+3
Department Header	Name of Department to insert in header	Alphanumerical (30 characters)
Rhythm Lead 1	1 st rhythm lead (3x4+1 e 3x4+3)	From I to V6 (default II)

Field	Description	Possible values
Rhythm Lead 2	2 nd rhythm lead (3x4+3)	From I to V6 (default VI)
Rhythm Lead 3	3 rd rhythm lead (3x4+3)	From I to V6 (default V5)
No. copies	Number of printed copies. If 0, only the original copy is printed, if 1 the original + 1 copy are printed, if 2 the original + 2 copies are printed, and so on.	0 to 5 (default 0)
Record Status	Printing of examination status on report: if set at "Yes" the text "REPORT NOT CONFIRMED" or CONFIRMED is printed by xxxx on xx/xx/xxxx".	Yes/No

8.6.5. Connectivity Settings (page 5)

Different according to options configured in the cardiograph.

ECG100+/ECG200+

Field	Description	Possible values
Connectivity Settings (page 5)		
Cart #	Device identification number.	From 0 to 65535
Department ID	Department identification number.	From 0 to 65535
Time Server	Server address for automatic synchronisation of time (if enabled). If changed, it needs the device reboot to be applied.	Alphanumerical (256 characters)
If Connectivity Option is on (LAN or DICOM) and External DICOM is Yes		
Username	User name for network connection. Empty and disabled if connectivity option is not present	Alphanumerical (24 characters)
Password	Password for network connection. Empty and disabled if connectivity option is not present	Alphanumerical (24 characters)
Connection String	IP address or host server name.	Alphanumerical (256 characters)
If Connectivity Option is DICOM and External DICOM is No		
MWL Address	Address of the server for receiving DICOM worklists (DICOM Modality WorkList).	Alphanumerical (256 characters)
STORE Address	Address of the server for the transmission of DICOM exams (DICOM Storage).	Alphanumerical (256 characters)
Local AE Title	IP address or host server name.	Alphanumerical (16 characters)

ECG100S/ECG200S

Field	Description	Possible values
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Field	Description	Possible values
Connectivity Settings (page 5)		
Cart #	Device identification number.	From 0 to 65535
Department ID	Department identification number.	From 0 to 65535
Time Server	Server address for automatic synchronisation of time (if enabled). If changed, it needs the device reboot to be applied.	Alphanumerical (256 characters)
If Connectivity Option is on (LAN/WLAN)		
Username	User name for network connection. Empty and disabled if connectivity option is not present	Alphanumerical (24 characters)
Password	Password for network connection. Empty and disabled if connectivity option is not present	Alphanumerical (24 characters)
Connection String	IP address or host server name.	Alphanumerical (256 characters)

8.6.6. LAN Settings (page 6)

Field	Description	Possible values
Network Settings (page 6)		
DHCP	DHCP on or off. With DHCP "On", the network automatically and dynamically assigns an IP address to the device and therefore it is not necessary to enter an IP address manually. With DHCP "Off" the device's IP address, Gateway and Sub Net Mask must be entered. If changed, it needs the device reboot to be applied.	On/Off
IP Address	Device IP address. Only editable if the DHCP is Off. If changed, it needs the device reboot to be applied.	XXX.XXX.XXX.XXX
Subnet Mask	Subnet mask (IPv4 format). Only editable if the DHCP is Off. If changed, it needs the device reboot to be applied.	XXX.XXX.XXX.XXX
Gateway	Default gateway address (IPv4 format). Only editable if the DHCP is Off. If changed, it needs the device reboot to be applied.	XXX.XXX.XXX.XXX
DNS	IP address of DNS If changed, it needs the device reboot to be applied.	XXX.XXX.XXX.XXX

8.6.7. WLAN Settings (page 7)

Field	Description	Possible values
DHCP	DHCP on or off. With DHCP "On", the network automatically and dynamically assigns an IP address to the device and therefore it is not necessary to enter an IP address manually. With DHCP "Off" the device's IP address, Gateway and Sub Net Mask must be entered. If changed, it needs the device reboot to be applied.	On/Off
IP Address	Device IP address. Only editable if the DHCP is Off. If changed, it needs the device reboot to be applied.	XXX.XXX.XXX.XXX
Subnet Mask	Subnet mask (IPv4 format). Only editable if the DHCP is Off. If changed, it needs the device reboot to be applied.	XXX.XXX.XXX.XXX
Gateway	Default gateway address (IPv4 format). Only editable if the DHCP is Off. If changed, it needs the device reboot to be applied.	XXX.XXX.XXX.XXX
DNS	IP address of DNS If changed, it needs the device reboot to be applied.	XXX.XXX.XXX.XXX

8.6.8. WiFi security Settings (page 8)

Field	Description	Possible values
SSID (rescan)	Allows to select the available WiFi networks. It has a dropdown list to select (via RIGHT button) the enumerated networks. The label will act as a button (pushed with Enter or Space key) to trigger the network scan. During the scan, a popup will show the operation is ongoing.	Alphanumeric (64 characters)
Security	Allow to choose the security protocol for WiFi.	None / WEP / WPA/WPA2 / WPA-EAP
Passphrase	To set the passphrase for WEP or WPA/WPA2 <i>Visible only if security is WEP or WPA/WPA2.</i>	Alphanumerical (24 characters)
Username	To set the username for WPA-EAP. <i>Visible only if security is WPA-EAP.</i>	Alphanumerical (24 characters)
Password	To set the password for WPA-EAP. <i>Visible only if security is WEP or WPA/WPA2.</i>	Alphanumerical (24 characters)

Field	Description	Possible values
Test	Button to test the wifi connectivity	-
Enable WiFi	Enable/Disable the WiFi antenna of the device and make the WLAN settings page accessible/inaccessible.	On/Off

8.7. Protection of the Settings

You can set a security code (PIN) that allows access to the settings section to be protected. In this way you can prevent the settings from being changed accidentally or by unauthorised personnel.

To enable the protection of the settings set the "Configuration PIN" field to a 4 digits value and save settings.

Subsequent log-ins to the Settings section will require the PIN to be entered, as shown in the figure, which must be entered in the text field shown.



Page for entering the PIN

9. SET THE DEVICE IN ACCORDANCE WITH GDPR (General Data Protection Regulation)

9.1. General information

The electrocardiograph provides a series of features (described in the table below) that can be used by the Data Controller in order to comply with the minimum requirements of EU Regulation 2016/679, known as GDPR (General Data Protection Regulation).

Field	Function
Access control	An advanced access control mode through a NFC badge is foreseen. With this function the device foresees two operating modes: <ul style="list-style-type: none"> ▪ Locked: the device works in anonymous mode, limiting the functions only to the acquisition and sending of ECGs on the net ▪ Unlocked: the complete operating mode is enabled through a NFC badge, so the user has access to the parts containing sensitive data too. After a period of inactivity or at the operator's command, the system returns to the locked state.
Data at rest protection	The data are kept in the internal memory of the cardiograph and are not accessible until the system has been unlocked by the operator through a badge.
Audit trail	Logging of the transactions associated with the users, with association of the operator code if the system is unlocked.
Patient data removal (right to be forgotten)	Foreseen cancellation of the archive.

9.2. Method of anonymous or full access

If the device is equipped with the “Privacy Mode” option, it manages two types of access: anonymous and full access.

In anonymous access mode the user can perform a test, save it and print it but they will not be able to:

- Access the work lists;
- Access the test archive;
- Access the device settings;
- Export the data to a USB;
- Connect the device via USB to a computer to access the archive and folders.

In full access mode the user will have access to all the features of the device.

9. SET THE DEVICE IN ACCORDANCE WITH GDPR (General Data Protection Regulation)

At startup, the device works in anonymous access mode. To enable the full access mode, insert an NFV reader into the USB socket, with which to scan an adequately configured NFC card.

Similarly, after a period of inactivity, the device automatically returns to the anonymous access mode and full access is restored by scanning the NFC card again.

An open/closed padlock icon indicates the active access mode.

NOTE: *NFC cards must be previously configured in order to be read by the reader and enabled for full access.*

9.3. Audit trail

The device logs the operations performed by the operator on the device itself and saves them in a protected memory area, stored for at least 12 months

The file shows:

- Operator ID ('?' if the operator is anonymous);
- Date and time of the operation (YYYY-MM-DD HH:mm:ss);
- The identification label of the event;
- Additional data, if applicable.

The logged events are:

- User authentication (USRAUTH);
- Work List Opening (WORKLST);
- Archive opening (ARCHIVE);
- Opening of a test in the Archive (OPENEXM): the patient name, patient ID and test date/time are also shown;
- Printing of a test (PRNTEXM): the patient name, patient ID and test date/time are also shown;
- Transmission/sending of a test (LINKEXM): the patient name, patient ID and test date/time are also shown;
- Exporting a test via USB (EXPTEXM): the patient name, patient ID and test date/time are also shown;
- USB connection to a PC (USBCONN);
- Switch to Anonymous Access mode (ANONMOD).

If the same operation (e.g. test transmission) is performed on multiple tests simultaneously, an event is logged for each test.

10. CONNECTIVITY, RECEIVING WORK LISTS AND TRANSMITTING ECG EXAMS

10.1. General

ECG100+/ECG200+/ECG100S/ECG200S electrocardiographs are all equipped with a USB port and they can be optionally equipped with:

- LAN socket;
- WLAN (WiFi) module.

Moreover they can be configured with different communication options:

- USB connectivity (always included)
- Standard Network connectivity (available for devices with LAN or WLAN)
- DICOM connectivity (available for devices with LAN or WLAN) – *only ECG100+/ECG200+*.

10.1.1. Configuring LAN connectivity

In case only the LAN option is enabled, the transmission can take place connecting a LAN cable between the connector on the device and a LAN socket based.

The connection parameters for LAN connectivity must be configured correctly, as indicated in Par.8.6.6.

In particular, if the DHCP is set at “No”, the LAN access point will have a static network setting and the following parameters must be configured in the electrocardiograph:

- IP address
- Subnet Mask
- Gateway

If the DHCP option is set at “Yes”, its LAN access point will have an automatic network setting and the IP address, Subnet Mask and Gateway parameters do not necessarily need to be configured.

In both cases, the Connection String parameter (essential for transmission) must be supplied by the network provider.

The LAN connector has two small LED's to assess the status of the connection and of the data transmission/reception. The left LED on the connector remains on when the network signal is detected (device connected), while the right LED flashes when data packs are transmitted or received or traffic is identified on the network. If neither of the two LED's is on, it means there are problems with connection (see Par. 12.7).

10. CONNECTIVITY, RECEIVING WORK LISTS AND TRANSMITTING ECG EXAMS



LAN connector

10.1.2. Configuring WLAN connectivity

If the WLAN option is enabled the transmission can be wireless.

The connection parameters for LAN connectivity must be configured correctly, as indicated in Par. 8.6.1.

In particular, if the DHCP is set at “No”, the WLAN access point will have a static network setting and the following parameters must be configured in the electrocardiograph:

- IP address
- Subnet Mask
- Gateway

If the DHCP option is set at “Yes”, its WLAN access point will have an automatic network setting and the IP address, Subnet Mask and Gateway parameters do not necessarily need to be configured.

In both cases, the Connection String parameter (essential for transmission) must be supplied by the network provider.

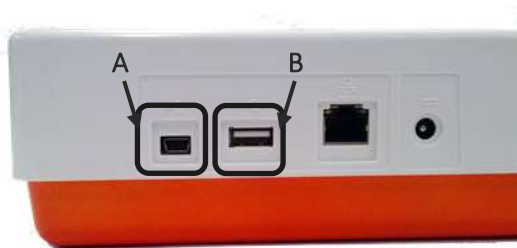
It's also necessary to set the WiFi security settings, as indicated in Par. 8.6.8, in order to set the WiFi network and the related security protocol.

The quality of the WiFi signal is displayed on the screen.

10.2. USB connectivity

All electrocardiographs are supplied with USB connectivity.

Specifically each device is equipped with two USB ports: one mini-USB (A) and one type A port (B).



USB ports of the device

The type A USB port can be used to transfer data from the electrocardiograph to a USB memory stick inserted in the port (as described in par.10.2.1) and for technical assistance.

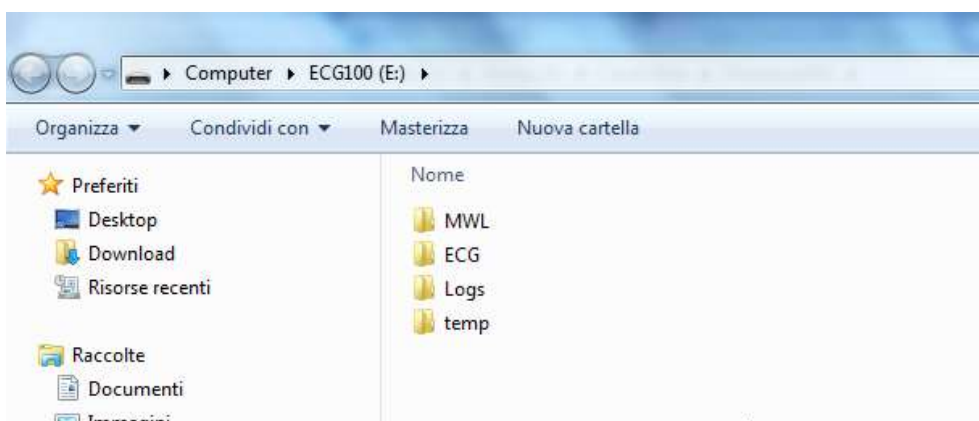
The mini-USB port can be connected to a computer, as described in Par.10.2.2.

10.2.1. Connection to a computer

To connect the electrocardiograph to a computer, connect a USB cable to the USB connector of the device (B) and to a USB connector on the computer. Then make sure the device is on.

Once the electrocardiograph is connected and switched on, it will appear as a device in the folder "This PC" of the computer. Double-clicking the icon opens the folder of the electrocardiograph, consisting of three sub-folders: one containing saved ECG examinations, one with downloaded work lists and one with log files. The latter is read-only and can only be used for troubleshooting.

The user can copy the ECG files on the computer or cancel them. Similarly the user can copy on the computers or cancel the work lists files.



The ECG examinations are saved in SCP format files, the name of which includes the main information of the examination:

```
{TYPE}{STAT}{XMT}{PRT}_{PAT_ID}_{PAT_LAST}_{PAT_FIRST}_{ACQ_DT}_
{SCP_GENDER_CODE}_{DOB}_{AGE}{SCP_AGE_UNIT_CODE}_{LOCATION}_{ACCESSION_NUMBER}
```

10.2.2. Transfer data to a USB memory stick

ECG records in SCPECG and PDF format can be saved in a USB memory stick inserted in the type A USB port. In order to do this, you can use the LINK hot key, that is enabled at the end of an automatic ECG acquisition to export only the current exam file (as described in par.7.5.1) or in the ECG Archive screen to export all the files (as described in par.8.3).

Data is saved in the memory stick in a folder. The folder name begins with the token "ExpECGxxx" followed by the timestamp of the operation

10.3. Standard Network connectivity (LAN)

If the device is equipped with WiFi and/or LAN, the electrocardiograph can transmit ECG traces via the network to an external Cardioline ECGWebApp archive system (as described in Par. 7.5).

It is also possible to download work lists as described in Par. 8.2. The work lists must be constructed based on [DICOM attributes](#) conform to the Modality Worklist Information Model of DICOM PS 3.4, Annex K.6.1.2.

For correct transmission, the connection parameters must be configured correctly, as indicated in Par. 8.6.5.

10.4. DICOM connectivity (LAN / WLAN) – *only ECG100+/ECG200+*

If the electrocardiograph is supplied with the DICOM option and is equipped with the LAN or WLAN module,, it can be connected to a DICOM system to store ECG examinations and to create work lists.

To be able to connect to the server, just set the LAN/WLAN connectivity parameters as described in Par. 10.3.

This will make it possible to transmit acquired ECG tracings (as described in Par. 7.5) and to download work lists (as described in Par. 8.2).

It's possible to choose whether to connect directly to the PACS system or to use an external gateway (Cardioline Gateway).

In the first case, the electrocardiographs sends exams to and receives worklists directly from a PACS system that is connected to its same network. In the second case exams and worklists have to pass through a software gateway, installed on a computer, before reaching the PACS system and the electrocardiograph respectively.

For a direct connection with the PACS set the "External DICOM" settings to "No", for a connection through a gateway set the "External DICOM" settings to "Yes" (see par. 8.6.5).

If External DICOM is set to "No", the following settings must be configured:

- MWL Address: address of the server for receiving DICOM worklists (DICOM Modality WorkList).
- STORE Address: address of the server for the transmission of DICOM exams (DICOM Storage).
- Local AE Title: IP address or host server name.

If External DICOM is set to "Yes", the following settings must be configured:

- Username: user name for network connection.
- Password: password for network connection.
- Connection String: IP address or host server name.

The DICOM protocol structure used is described in the DICOM Conformance Statement attached to the documents accompanying the device.

11. UPGRADING YOUR DEVICE OPTIONS

Activating new options on your device is simple.

First of all, you have to contact Cardioline, or your distributor, to purchase the upgrades you need. Be sure you have the serial number of all the devices you need to upgrade, because they are required to finalize the purchase.

Once you have purchased the upgrade options you will receive files (one for each device), named ARxxxPlusSN.ini and ARxxxPlusSWOpt.ini, that allows you to activate the new options on your device.

To activate the new options follow these steps:

1. Copy the ARxxxPlusSN.ini and ARxxxPlusSWOpt.ini files received on a PC.
2. Connect the electrocardiograph to be updated to the PC (see also Par. **Errore. L'origine riferimento non è stata trovata.**).
3. Copy the ARxxxPlusSN.ini and ARxxxPlusSWOpt.ini files to the electrocardiograph folder.
4. Disconnect the electrocardiograph from the PC and restart it.

The available upgrade options are:

Upgrade option	Description
Extended memory	To extend memory capacity from 100ECGs (Standard memory) up 1000 ECGs (Extended memory).
Glasgow Interpretation	To add automatic interpretation of ECGs (Glasgow interpretation program).
Standard Network Connectivity <i>Only ECG100+/ECG200+</i>	To enable standard network connectivity.
DICOM connectivity <i>Only ECG100+/ECG200+</i>	To enable DICOM connectivity.
Privacy Mode	To allow anonymous or full access to be managed

NOTE: each upgrade file is specific for a particular serial number, thus for a particular device. Be sure you copy the correct file on the electrocardiograph you are upgrading.

12. MAINTENANCE AND TROUBLESHOOTING

12.1. Precautions

- Switch the device off and disconnect it from the patient before inspecting or cleaning it.
- Do not immerse the device in water.
- Do not use organic solvents, ammonia-based solutions or abrasive cleaning agents which could damage the surface of the device.

12.2. Switching off the device

To switch the device off completely, disconnect the power cable and keep the ON/OFF key pressed for 2 seconds. Always perform this operation before proceeding with authorised repairs of the device.

12.3. Regular maintenance

Cardioline suggests to regularly check the device:

- Perform a functional and operation check daily
- Periodically clean the unit and the patient cables
- Periodically clean the printer and the printer head
- Periodically check for continuous electrical safety of the device:
 - leakage current in the patient
 - leakage current in the chassis
 - leakage current to earth
 - dielectric strength (supply line and patient circuits)

NOTE: Frequency depends on local regulatory requirements and use of the device.

12.3.1. Functional check

Check the device daily before putting it into function:

- Check the proper connection of all the cables and connectors.
- Inspect the container and frame for any damage.
- Check the cables and connections for any visible damage.
- Check that the keys and controls work properly and have an appropriate aspect.

- Check battery works properly.

If you notice anything needing a repair, contact an authorised assistance operator to perform it.

12.3.2. Patient cable cleaning

- Before cleaning, remove the cables and terminations.
- For the general cleaning of cables and terminations use a soft lint-free cloth slightly moistened with a mild soap and water solution. Clean and air dry.
- For cable and termination disinfection, clean the outside with a soft lint-free cloth using a Sodium Hypochlorite solution (water and bleach at 10%): minimum dilution 1:500 (minimum 100 ppm of free chlorine) and maximum dilution: 1:10 in compliance with the APIC guidelines for the Selection and Use of Disinfectants.
- Pay attention to the excess liquid as contact with metal parts may result in corrosion.
- Do not immerse the cable terminations. Immersion may result in metal corrosion.
- Do not dry excessively or use forced heat to dry.

ATTENTION: *Keep the liquid from penetrating into the device and do not try to clean/disinfect the device or patients' leads by immersing them in liquid, autoclave and steam cleaning. Protect the leads against strong ultra-violet radiation. Do not sterilise the device or the ECG lead cables with ethylene oxide gas (EO).*

12.3.3. Device cleaning

Unplug the device. Clean the external surface of the device with a damp lint-free cloth, using a neutral detergent diluted with water. Thoroughly dry with a clean cloth or paper napkin after washing.

The cleaning solutions allowed are:

- 90% Ethyl alcohol solution
- 90% Methyl alcohol solution
- 90% Isopropyl alcohol solution - only for plastic parts and not for the display/keyboard area.
- Hydrogen Peroxide Solution at 10V
- Hydrogen Peroxide Solution at 36V
- 2% sodium hypochlorite solution

ATTENTION: *Improper cleaning products and operations may damage the device, render the terminals and cables fragile, corrode the metal and invalidate the warranty. Use caution and adopt the correct procedures when cleaning and checking the device.*

12.3.4. Operation check

After cleaning and checking the device, it is possible to verify the correct operation of the device using an ECG simulator to acquire and print a standard 12-lead ECG of known amplitude. Printing must be clear and uniform on the whole page. The printing head must not show signs of malfunctioning (e.g. interruptions during printing in the form of horizontal stripes). The paper must slide well and uniformly during printing. The tracings must appear normal, with appropriate amplitude and without distortion or excessive disturbances. The paper must stop with the perforations near the tear bar (indicating that the reference sensor works properly).

12.4. Recommendations

Ensuing any type of assistance on the device or should you suspect non-conforming operation, we recommend the following procedures:

- Check that it works properly.
- Perform the checks to guarantee a continuous electrical safety of the device:
 - leakage current in the patient
 - leakage current in the chassis
 - leakage current to earth
 - dielectric strength (supply line and patient circuits)

12.5. Battery maintenance

From the moment the device is installed, the battery lasts approximately 6 months without being recharged. If a low battery is put away for a long period of time, it might not be possible to recharge it.

If the battery does not provide at least 30 minutes of continuous operation, it is recommended to perform a full discharge/recharge cycle.

The battery should be replaced if it does not hold enough power after a full recharge cycle, i.e. the battery does not guarantee at least 20 minutes of continuous operation and the battery level indication drops rapidly to the Low state after a full recharge cycle.

The battery can be replaced by means of a screwdriver. The battery door is on the bottom side of the device, so to replace the battery follow this procedure:

1. Turn the unit upside down to access the battery door
2. Open the battery door using a screw driver
3. Disconnect the battery connector from the electrocardiograph and take the battery out of its compartment
4. Take a new battery and connect it to the battery connector
5. Place the battery in the battery compartment. Make sure the battery is in place.

6. Close the battery door with the screw driver.
7. Turn on the device to check if the battery has been replaced correctly. If the device does not turn on, the battery may have been connected in the wrong way. Open the battery door again and repeat the above procedure.



1. Open the battery door with a screw driver.



2. Disconnect the battery connector.



3. Connect the new battery.



4. Place the battery in its compartment.

It is recommended to plug the device in when possible to charge the battery to a maximum.

In any case the user should try to recharge the battery before the unit indicates the "low battery" condition (namely reduce the battery charging threshold level).

The life of the battery varies based on operating procedures. For better functionality, it is good practice to keep the electrocardiograph plugged in when not used to fully recharge the battery after each use.

When the battery charger reaches the minimum level (10.6V), the device switches off automatically. It takes 4 hours to recharge the battery from its lowest level to 85%. 7 hours are necessary to reach 90%. More time is needed to reach 100%.

The device can be plugged in and used normally even when the battery is charging.

NOTE: every 6 months a full charge/discharge cycle should be performed in order to guarantee a long battery life.

NOTE: Refer to section 12.2 for the reference to the approved battery.

12.6. Cleaning the thermal printer

Periodically, and anyhow whenever the tracing printing is faulty, the printer and thermal head of the device should be cleaned.

12.6.1. Cleaning the printer

- Unplug the electrocardiograph.
- Clean the outside surface of the unit with a moist cloth and a water and neutral detergent solution.
- Dry the unit completely with a clean cloth or paper napkins.

NOTE: Make sure that soap or water do not come into contact with the heads, socket or vents.

12.6.2. Cleaning the thermal head of the printer

- Open the printer cover.
- Rub the printer head delicately with a cloth soaked in alcohol.
- Pass a clean cloth to remove alcohol residue.
- Let the head air-dry.
- Clean the plate using adhesive tape. Apply the tape and lift it up. Turn the roll and repeat the operation until the entire roll is clean.
- Clean the sensor photocell.

12.7. Troubleshooting table

Problem	Cause	Solution
Bad ECG signal	<ul style="list-style-type: none"> ▪ Damaged patient cable ▪ Bad skin-electrode contact ▪ Patient movements 	<p>Verify the patient cable is in good conditions. Try to replace the patient cable.</p> <p>Prepare the patient skin as described in this manual and replace the electrodes. Use gel if electrodes are reusable.</p> <p>Ask the patient to stay calm.</p>
Variations of the isoelectric signal	<ul style="list-style-type: none"> ▪ Use of non-original electrodes ▪ Bad skin-electrode contact ▪ Patient movements 	<p>Change the electrodes or clean them if they are reusable ones.</p> <p>Prepare the patient skin as described in this manual and replace the electrodes. Use gel if electrodes are reusable.</p>

		Ask the patient to stay calm.
Electrical interference	<ul style="list-style-type: none"> ▪ AC filter not or wrongly set ▪ Devices generating electromagnetic noise nearby (X-ray devices, magnetic resonance, etc) ▪ Patient in contact with conductive materials parts or other persons 	<p>Verify AC filter is set to the right AC frequency.</p> <p>Verify there are no devices that can generate interferences nearby.</p> <p>Verify the patient is not in contact with conductive materials (e.g. bed metal parts) or other persons.</p>
Muscular noise	<ul style="list-style-type: none"> ▪ Patient movements ▪ Muscular filter not set 	<p>Ask the patient to stay calm.</p> <p>Verify the muscular filter is correctly set.</p>
Device shutting down unexpectedly	<ul style="list-style-type: none"> ▪ Trying to use or switch on the device in battery mode but the battery is depleted 	If the device is powered in battery mode, plug it in the supply mains and try to switch it on again.
Noisy printer	<ul style="list-style-type: none"> ▪ Door not completely closed 	Open the door and close it firmly.
Paper sliding problems	<ul style="list-style-type: none"> ▪ Non original paper ▪ Paper placed incorrectly 	<p>Verify Cardioline paper is in place.</p> <p>Take out paper and position it as described in this manual.</p>
Device not printing	<ul style="list-style-type: none"> ▪ Paper is finished ▪ Auto-print not set 	<p>Verify paper is in place.</p> <p>If the exam is not automatically printed at the end of the acquisition, try to print it manually. If manual print does not work contact Cardioline customer service.</p> <p>Verify auto-print settings.</p>
Block of the device	<ul style="list-style-type: none"> ▪ Software problem 	Press the On/Off button for at least 10 seconds to restart the device.

12.8. Messages and solutions table

Message	Cause	Solution
General errors		
Battery depleted	Attempt to use or switch on the device in battery mode but the battery is depleted.	Plug the device in the supply mains and try to switch it on again.
Printer initialization error	Error given at the start of the application related to errors in loading/opening the printer driver.	Try to turn off and restart the cardiograph.
Out of paper	The user tried to print an ECG without paper in the paper tray.	Add paper in the paper tray.
Printer door opened	Printer door is opened	Close printer door.
Printer buffer full	Printer buffer is full due to a CPU overflow.	Try to turn off and restart the cardiograph. If the problem is not solved try a hardware shutdown. If the problem still persists contact Cardioline or an

Message	Cause	Solution
		Authorized Distributor.
Printer timeout	The printer does not respond due to software errors.	Try to turn off and restart the cardiograph.
Unknown printer driver error	Unforeseen printer error. The cause is unknown.	Try to turn off and restart the cardiograph.
Depleted battery	Battery is below 30% related charge.	Connect the cardiograph to an AC power source and recharge it.
Electrode fail: list of leads in fail	One or more leads are disconnected.	Check all the leads and make sure they are all connected. If the problem is not solved try a new patient cable. If the problem still persists contact Cardioline or an Authorized Distributor.
Unable to save Configuration data	The system can't save changes to settings and configuration due to a failure in the SD card or other software issues.	Try a hardware shutdown. If the problem persists contact Cardioline or an Authorized Distributor.
Communication errors		
Cannot run command	Communication can't start due to a software error.	Contact Cardioline or an Authorized Distributor.
Cannot write file	The device cannot save the work list due to an error in the internal memory.	Try to connect the cardiograph to a PC via USB and format the storage device (device memory will be completely erased). If the problem persists contact Cardioline or an Authorized Distributor.
Cannot read file to send	Error in opening the file to send.	Try to restart the device. If the problem persists contact Cardioline or an Authorized Distributor.
Cannot connect	Impossible to connect to the server for an unknown network error.	Contact your IT administrator to check for the network.
Remote service not found	The server is reachable but the service is not running.	Contact your IT administrator and check that the Connection String set on the cardiograph is correct. If the string is correct, ask your IT administrator to check if services are running on the server. If the problem persist contact Cardioline or an Authorized Distributor.
Remote host not found	The server cannot be reached.	Contact your IT administrator and check that the server is on and reachable. If the problem persist contact Cardioline or an Authorized Distributor.
Connection failed: Authorization denied	Username and password are not correct.	Try to retype username and password. Make sure capital letters are used appropriately (check that cap-lock is not active). If the problem persist contact your IT

Message	Cause	Solution
		administrator to check for the correct username and password.

13. TECHNICAL SPECIFICATIONS

ECG channels.....	12-lead (I, II, III, aVR-L-F, V1-6)
CMRR	> 100 dB
DC input impedance	No lead-off 100 MΩ
A/D converter	24 bit, 32 kHz
Sampling frequency.....	1000 Hz
A/D conversion	20 bit
Output data resolution	< 1uV/LSB
Bandwidth	Performances equivalent to 0.05 – 300 Hz
Pacemaker detection.....	Hardware detection coupled with convolution digital filtering
Filters	Linear phase digital diagnostic high-pass filter (according to 60601-2-25 2nd ed.) 50/60 Hz AC interference adaptive digital filter Digital low pass filters at 25/40/150 Hz, for display and printing only
Defibrillation protection	AAMI/IEC standards
Front-end performance	ANSI/AAMI IEC 60601-2-25:2011
Safety	EN 60601-1 internal power equipment - class I on external AC/DC power supply ANSI/AAMI ES1 CE1936
Conformance Standards	Certified to AAMI Std. ES 60601-1, IEC Std.60601-2-25 Conforms to CSA Std. No.60601-1, No. 60601-2-25
ECG storage.....	Internal storage 100 ECGs, expansion 1000 ECGs (optional)
Display.....	ECG100+/ECG100S: Backlit, colour LCD display, 4.3" ECG waveform real-time tracing ECG200+/ECG200S: Backlit, colour LCD display, 7" ECG waveform real-time tracing
Thermal printer	ECG100+/ECG100S: 8 dot/mm - 108mm; Z-fold 100x150mm ECG200+/ECG200S: 8 dot/mm - 216mm; A4 Z-fold
Manual print.....	3, 6, 12 (only ECG200+/ECG200S) channels, 5/10/25/50 mm/s
Auto print.....	Standard or Cabrera; 3, 3+1, 6, 12 (only ECG200+/ECG200S) channels Patient Demographic, Global Measurements, Optional Interpretation

(Glasgow University – Prof. MacFarlane)
Adult, Paediatric, STEMI

Keyboard	Mechanical keypad with alphanumeric keys and special function keys
Connectivity	USB device, LAN (optional)
Patient cable	Standard 15D, 10-wires
Data export	SCP (standard format), XML-PDF-GDT (included in standard connectivity option), DICOM (included in DICOM connectivity option), HL7 (optional)
Power supply	Medical grade AC power supply (100-240 VAC 50/60 Hz); internal rechargeable battery (NiMH)
Internal battery	Recharging time: 4 hours to 85% of full charge Duration: more than 500 ECGs (more than 6 hours)
Dimensions	ECG100+/ECG100S: 285 x 204 x 65 mm ECG200+/ECG200S: 396 x 290 x 80 mm
Weight	ECG100+/ECG100S: 1,8 Kg con batteria ECG200+/ECG200S: 2.6 kg con batteria

13.1. Filter features

The device adopts different filtering techniques in order to process the signal and make it easier for the cardiologist to make the diagnosis.

The device implements a high-pass linear-phase filter, with a cutoff frequency of 0.67Hz, to remove the drift of the entirely digital baseline.

The filter effectively reduces the artefacts induced by the respiratory movement without introducing distortions on the reproduction of the ST segment, as specifically recommended in "cf. Paul Kligfield et al., Recommendations for the Standardization and Interpretation of the Electrocardiogram Part I, Circulation. 2007;115:1306-1324":

To reduce artifactual distortion of the ST segment, the 1990 AHA document recommended that the low-frequency cutoff be 0.05 Hz for routine filters but that this requirement could be relaxed to 0.67 Hz or below for linear digital filters with zero phase distortion. The ANSI/AAMI recommendations of 1991, affirmed in 2001, endorsed these relaxed limits for low-frequency cutoff for standard 12-lead ECGs, subject to maximum allowable errors for individual determinants of overall input signal reproduction. These standards continue to be recommended

The high-pass filter meets the requirements set by IEC 60601-2-25 2nd Ed. in terms of low-frequency impulse response:

“A 0,3 mV × s (3 mV for 100 ms) impulse input shall not produce a displacement greater than 0.1 mV outside the region of the impulse.”

The acquisition (sampling and filtering) system of the device complies with AHA recommendations (Paul Kligfield et al., Circulation 2007) for both paediatric and adult ECGs. The high frequency response of the system is 150Hz or 300Hz, depending on the filter applied.

The device also offers the option of applying, only in display and printing mode, digital linear-phase filters with a cutoff frequency of 25Hz or 40Hz, which reduce the bandwidth of the printed signal in order to reduce the effects of high frequency noise ("muscular" noise). As a consequence of the application of these filters, the resulting signal no longer meets the minimum requirements on the high frequency response reported in the above recommendations.

The device can also be configured to selectively eliminate interference induced by the electricity network (50Hz or 60Hz, depending on the country where the device is installed).

The network filter complies with the requirements of IEC 60601-2-25 2nd Ed.

13.2. Harmonised standards applied

STANDARD	DESCRIPTION
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 for 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 requirements - Collateral standard: Usability
EN 60601-2-25	Medical electrical equipment - Part 2-25: Particular requirements for the safety of electrocardiographs.
EN 62304	Medical device software - Software life cycle processes EN 62304:2006/AC:2008

STANDARD	DESCRIPTION
EN 62366	Medical devices - Application of usability engineering to medical devices

13.3. Accessories

CODE	DESCRIPTION
63030105	Set of 4 Peripheral ECG electrodes clamp Ag/AgCl
63030106	Set of 4 peripheral ECG electric clamp Ag/AgCl
63030107	Set of 4 peripheral ECG electric clamp pediatric Ag/AgCl
63030163	Set of 6 chest ECG electric suction type Ag/AgCl
63050025	ECG patient cable IEC, 10 lead, plug 4 mm
63050068	ECG patient cable AHA, 10 lead, plug 4 mm
63050108	ECG patient cable IEC, 10 lead, snap
63050109	ECG patient cable AHA, 10 lead, snap
63050032	ECG patient cable IEC-10 CLIP 4 mt
66030031C	Disposable electrodes ECG, snap, 50 pcs
66030040C	Disposable electrodes ECG, tab, 100 pcs; pack of 10
66030036C	Disposable electrodes ECF neonatal, 25 pcs
66030037C	Disposable electrodes ECG banana, 60 pcs
66020008	Gel bottle for ECG electrodes, 260 ml
63090236	Set of 10 snap adapters for 4 mm plug
66020008	Adapters for tab and button electrodes for 4 mm plug, 10 pcs
66010051C	Z-FOLD 100X150mm Paper 180 sheets (ECG100)
66010052S	Z-FOLD 210x295mm A4 PAPER (ECG200+)
66010053S	Z-FOLD 216x280mm LETTER PAPER (ECG200+)
67010223	Carrying case "Cardioline ECG 100"
67040225	ECG200+/s dust cover
67040224	ECG100 dust cover
63090712	ECG100+/S/L trolley II Edition
63090713	ECG200+/S/L trolley II Edition hospital grade

14. WARRANTY

Cardioline SpA guarantees this equipment to be free of defects in material and workmanship for 24 months from date of purchase of the device and for 3 months for spare parts and accessories. The date of purchase shall be proven by a document, issued upon delivery, which shall be submitted in the case of any claim under the warranty.

The warranty provides for free-of-charge repairing or replacement of the equipment parts with manufacturing or material defects. The possible replacement of the equipment is at the manufacturer's discretion. Extended warranty after repairing is not available.

This warranty does not cover defects resulting from:

- tampering, third party negligence, including servicing or maintenance by unauthorised personnel;
- failure to comply with the usage instructions, improper use or use of the equipment different than that for which it was intended;
- improper operation of the power supplies;
- damages caused by fires, explosions or natural disasters;
- use of non-original consumable parts;
- transportation carried out without any precautionary measures;
- use of software programs not associated with the primary function of the machine;
- other circumstances not attributable to manufacturing defects.

Unless otherwise specified, the removable parts, the accessories and the parts which are subject to normal wear are excluded under the warranty; for example: patient cables, batteries, connection cables, electrodes, glass parts, computer supports, ink cartridges, etc.

Cardioline Spa declines all liability for any damage which may be caused, directly or indirectly, to persons or property as a consequence of non-compliance with all the prescriptions specified in the manual, especially warnings regarding installation, safety, use and maintenance of the equipment, as well as non-operation of the equipment.

In the event of repair and/or replacement of the equipment or its spare parts, take the equipment to the nearest Cardioline Spa authorised service centre or send it to Cardioline S.p.A. All costs of material and labour will be free of charge and transport costs shall be at the customer's expense.

After 24 months from the date of purchase of the equipment and 3 months from the date of purchase of the accessories and spare parts, the warranty becomes void and service will be provided charging for the parts replaced and labour costs according to the current rates.

Any derogation from the present warranty conditions shall be valid only if expressly approved by Cardioline SpA

15. DISPOSAL

Pursuant to Italian Legislative Decree no. 49 dated 14 March 2014 "Implementation of Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE)", the crossed-out "wheeled bin" symbol on the medical device indicates that, at the end of its service life, the product must be collected separately from other wastes. Therefore, when disposing of the product at the end of its service life, the user is required to contact the supplier or the manufacturer.

Suitable differentiated collection to allow for the subsequent recycling of the decommissioned device, with environmentally-compatible treatment and disposal, helps to prevent any negative effects on the environment and health and to promote the recycling of the materials from which the device is made.

The illegal disposal of the product by the user entails the application of administrative sanctions envisioned by Italian Legislative Decree no. 22/1997 (Art. 50 and subsequent to the Italian Legislative Decree no. 22/1997).

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CARDIOLINE