CARDIOLINE

ECG100L - ECG200L

User manual

CE
1936

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CARDIOLINE

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Table of Contents

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.

The code relating to this manual is listed below.

Language	Code
ENGLISH	36510212_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 ECG100L and its power supply are classified as ME Equipment, since the power supply is considered an integral part of the device.
- The ECG200L device is classified as Electromedical equipment.
- 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.
- When performing ECG acquisition, ensure the USB port is completely covered by the plastic lid.
- 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.
- 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 11.2 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 11.2 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 11.2 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 electro surgery 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.
- 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 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.
- 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 10 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 show a message “Lead fail”. When the ECG is printed the device will add the indication of inoperable device on the printout.
- As defined by the IEC 60601-1 and IEC 60601-2-25 safety standards, the device is classified as follows:
    - ECG100L: Internal Power equipment - class I on external AC/DC power supply.
    - ECG200L: Internal Power equipment - class I.
    - 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 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.
- ECG100L has the following power supply features:
  - 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 hPa to 1060 hPa

- 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.

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. 11.2 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 device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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 ECG100L/ECG200L is intended to operate in the electromagnetic environment specified below. The customer or the user of the ECG100L/ECG200L must guarantee that it is used in this environment.

Emission test	Compliance	Electromagnetic environment – guidance
Radiated radio frequency emissions (RF) CISPR 11	Class B Group 1	The ECG100L/ECG200L 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.
Conducted radio frequency emissions (RF) CISPR 11	Class B Group 1 (for 200L) Class A Group 1 (for 100L)	The device is suitable for use in all establishments other than domestic environments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics emissions IEC 61000-3-2	Class B (200L) Class A (100L)	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

3.2. Guidance and Manufacturer's declaration - Electromagnetic immunity

The ECG100L/ECG200L is intended for use in the electromagnetic environment specified below. The customer or the user of the ECG100L/ECG200L assure that it is used in such an environment.

Immunity test	Conformity	Compliance level	Electromagnetic Environmental Information
Electrostatic discharge (ESD) IEC 61000-4-2	in contact +/- 8 kV airborne +/- 15 kV air	in contact +/- 8 kV airborne +/- 15 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 lines +/- 1 kV for	+/- 2 kV for power lines +/- 1 kV for	Mains power quality should be that of a typical commercial or hospital environment.

	input/output lines	input/output lines	
Surge IEC 61000-4-5	+/- 0.5, 1 kV line-to-line +/- 0.5, 1, 2 kV between phase and earth	+/- +/- 0.5, 1 kV line-to-line +/- +/- 0.5, 1, 2 kV between phase and 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 ECG100L/ECG200L requires continued operation during power mains interruptions, it is recommended that ECG100L/ECG200L be powered from an uninterruptible power supply or a battery.
Power frequency and magnetic field (50/60 Hz)	30 A/m at a frequency of 50 and 60 Hz	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 ECG100L/ECG200L is intended for use in the electromagnetic environment specified below. The customer or the user of the ECG100L/ECG200L 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 With amplitude modulation 80% 1 kHz sinusoidal waveform	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the ECG100L/ECG200L, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**: $d = \left[\frac{3.5}{3Vrms}\right]\sqrt{P}$
Radiated R IEC 61000-4-3 (for RF wireless communications equipment 385 ÷ 5785 MHz	See table in the standard	Complies with all test levels	
Radiated R IEC 61000-4-3	3 V/m From 80 MHz to 2.7 GHz Modulation amplitude sinusoidal waveform 80% 1	3 V/m	$d = \left[\frac{3.5}{3V/m}\right]\sqrt{P}$ From 80 MHz to 800 MHz

	kHz (Professional facilities) 10 V/m From 80 MHz to 2.7 GHz (Homecare Facilities)		$d = \left[\frac{7}{3V/m}\right]\sqrt{P}$ From 800 MHz to 2.5 GHz 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: 

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 ECG100L/ECG200L is used exceeds the applicable RF compliance level above, the ECG100L/ECG200L should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ECG100L/ECG200L.

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 ECG100L/ECG200L

The ECG100L/ECG200L is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ECG100L/ECG200L can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ECG100L/ECG200L 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.

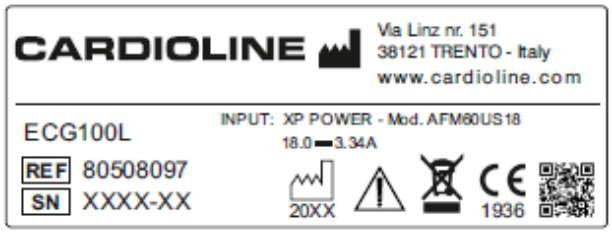
4. SYMBOLS AND LABEL

4.1. Explanation of the symbols

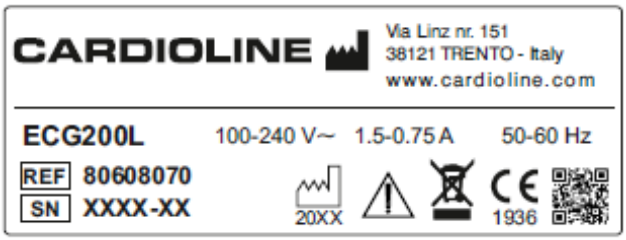
Symbol	Description
	Comply with the instructions in the use manual
	CE marking – compliance with the European Union directives
	Manufacturer
	Reference number (product code)
	Serial Number
	Lot number
	Year of manufacture
	Type CF equipment
	Separate collection of electrical waste and electronic equipment
	Consult instructions for use – placed beside the input connector for the power supply
	Temperature variation
	Humidity variation
	No latex
	Keep dry

4.2. Device label

ECG100L



ECG200L



5. INTRODUCTION

5.1. Purpose of the manual

This manual deals with the ECG100L/ECG200L device.
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)
- Device upgrading. (Section 9)
- Troubleshooting and electrocardiograph maintenance. (Section 10)

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

ECG100L/ECG200L is a 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 USB, print the 12 lead ECG in automatic or manual mode by means of its built-in thermal printer.

ECG100L/ECG200L 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.
ECG100L/ECG200L 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 pediatric 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, fully diagnostic electrocardiograph which displays, acquires, prints and stores ECG tracings, for adults and children, together with its measurements..

ECG100L and ECG200L respectively have a convenient 5" and 7" colour touch screen display used to manage all operations easily. A smart user interface guides the user through the different steps necessary to acquire the electrocardiogram. Various messages on the screen inform the user of the ongoing operations and warn him in case of errors (for example in case of lead fail).
The device is equipped with USB to export the ECG stored in the device memory.

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 provides full ECG interpretation in short or extended form, including infant, paediatric and acute ST elevation myocardial infarction detection.
For further information on the resting ECG interpretation algorithm, refer to the Guide for doctors for applications on adults and children (supplied with the device).
The guide contains specific information on the interpretation algorithm, the measurements it takes, and the criteria it uses. As such, it should be used to properly understand the information provided by the interpretive algorithm.

The device is battery or mains operated.
It prints in the following formats: standard or Cabrera 3, 3+1, 3+3, 6 or 12 (ECG200L only) channels in automatic mode, and 3, 6 or 12 printout channels in continuous mode, as well as printout of the rhythm strip.

The device includes:

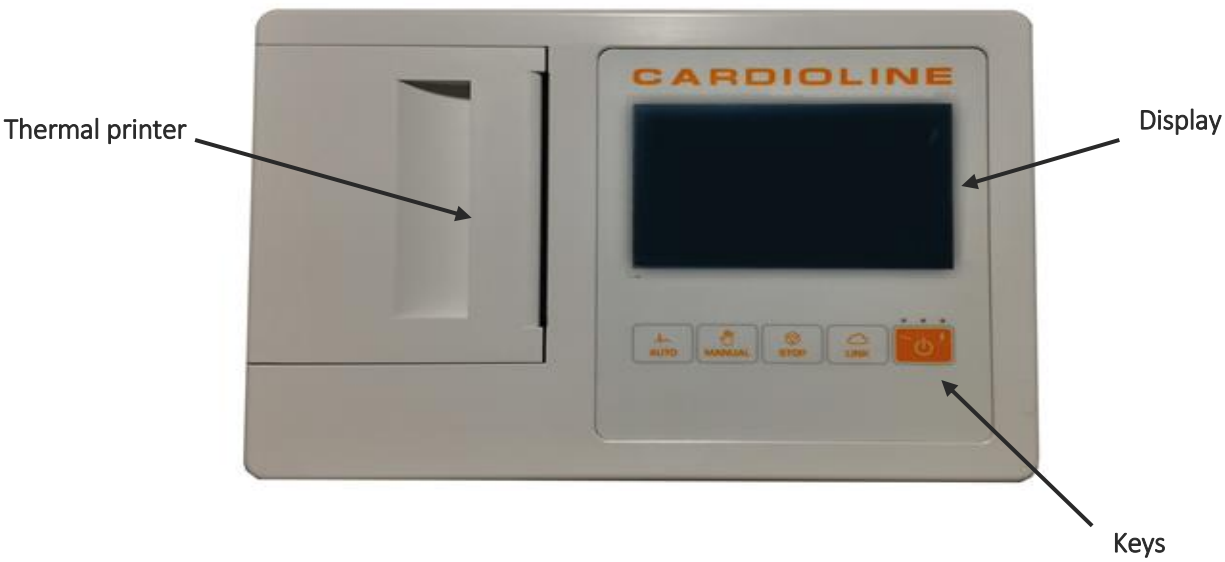
1. Patient cable
2. ECG100L: Power supply

   ECG200L: Power supply cable
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) (only if the device comes with the Interpretation option)
7. User manual

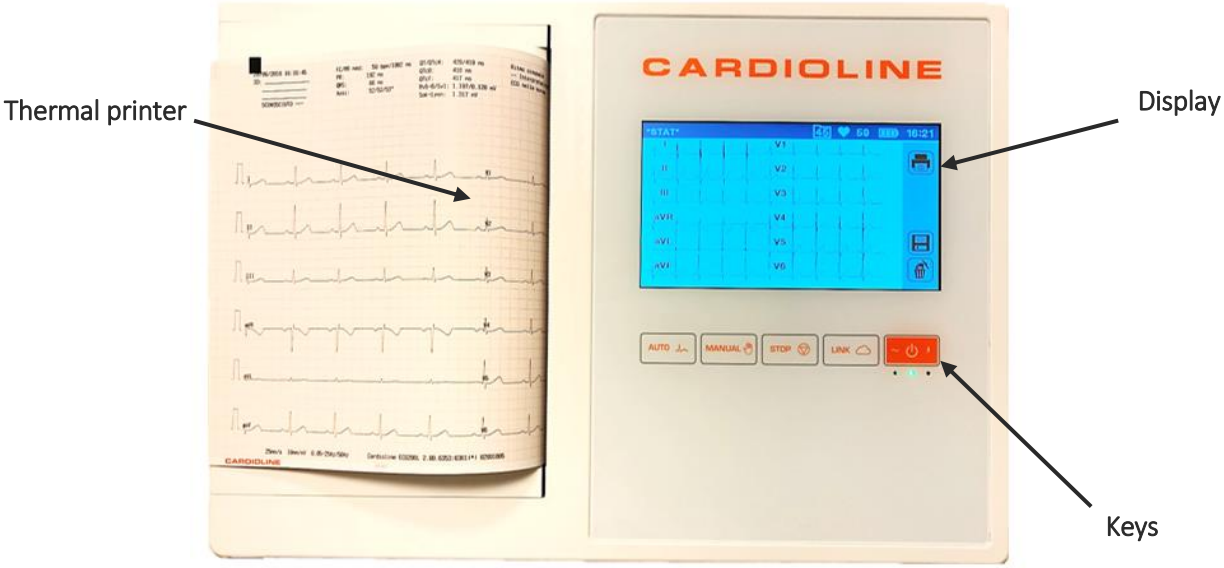
5.4.1. General overview

Front view:

ECG100L

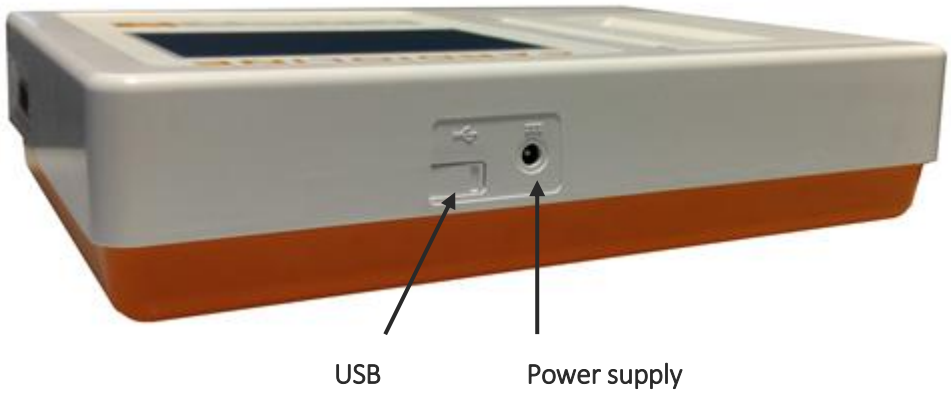


ECG200L

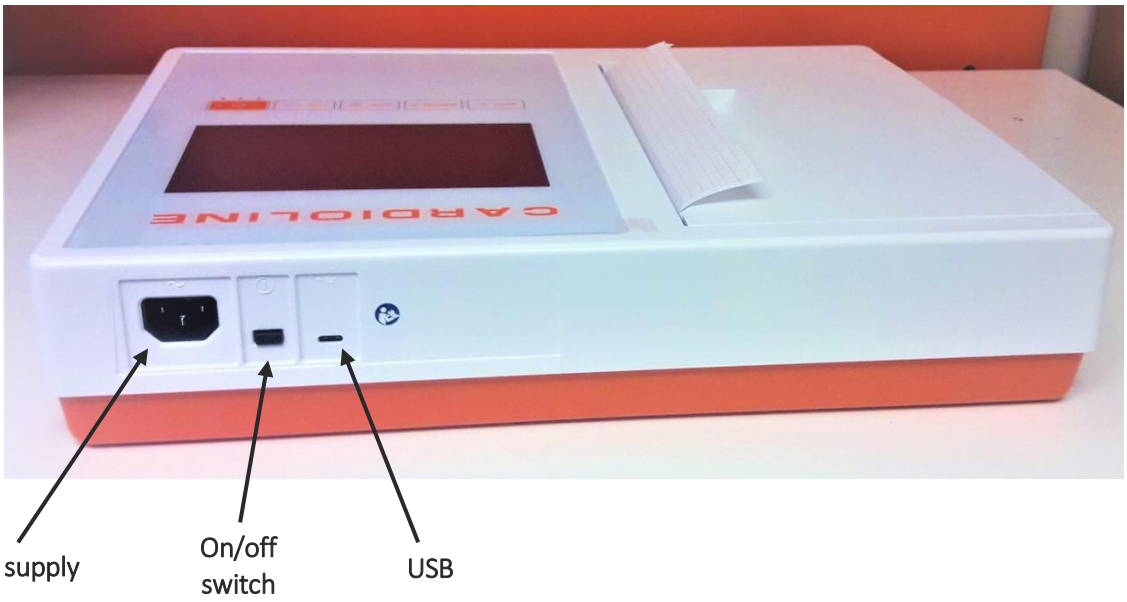


Rear view:

ECG100L

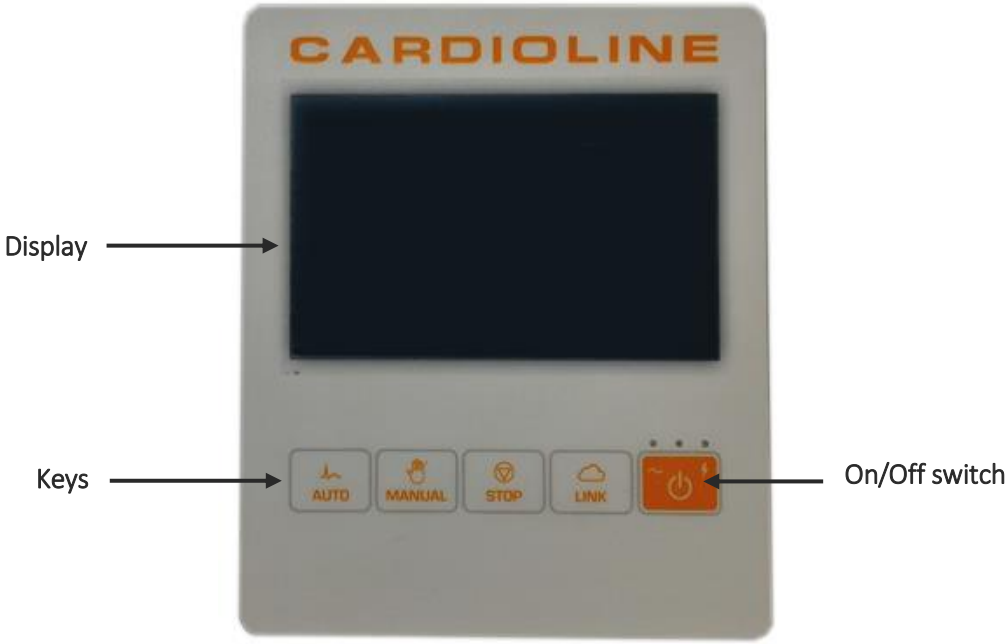


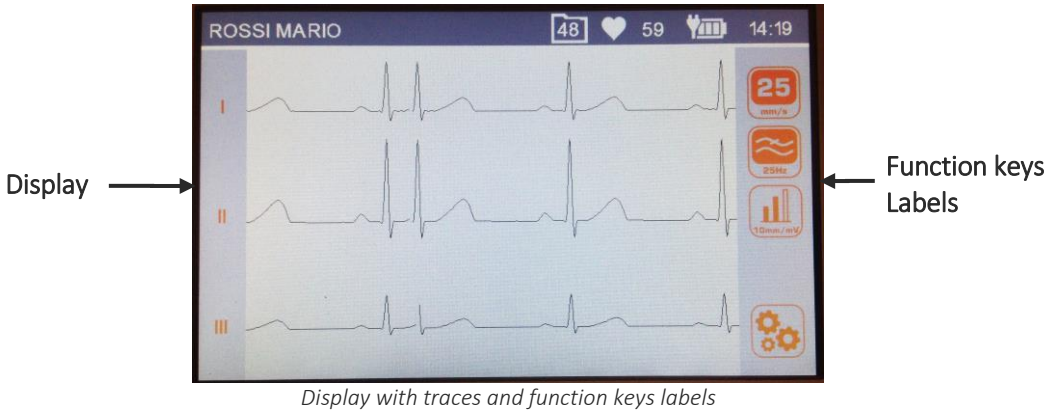
ECG200L



Side view:

Display and keys:





Display with traces and function keys labels

5.4.2. Keyboard

Data entry and commands entry are provided by means of soft keys implemented via touch-sensitive area on the display (see par.5.4.4) and by means of the keys in the picture below.

Keys

Keys

ECG100L/ECG200L has five keys that, depending on the duration of the pressure, will activate the primary function or the secondary feature, with the exception of the power button. The user shall keep the key pressed for more than 2s to trigger the secondary function. Below are the available functions:

Key	Description	
	ECG100L: switches the device on/off. ECG200L: switches off the device.	
	**Short key pressure:** Resting ECG acquisition in AUTO mode	**Button long-press:** adds the STAT ECG tag to the test
	**Short key pressure:** Start of continuous print/change of leads	**Button long-press:** Starts Rhythm printing
	**Short key pressure:** Stop continuous printout	**Long key pressure:** N/A
	**Short key pressure:** Export to USB key	**Long key pressure:** N/A

Note: by selecting Russian in the settings menu (see Par. ***Errore. L'origine riferimento non è stata trovata.****), the eyboard is automatically set in Russian.*

5.4.3. Display

ECG100L is provided with a 5" backlit LCD display with a resistive touch screen panel. ECG200L is provided with a 7" backlit LCD display with a capacitive touch screen panel.. 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. Press the Speed command icon 

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. Press the Gain command icon 

to modify the gain to 5 mm/mV, 10 mm/mV, 20 mm/mV.
- **Filter:** step-by-step filter applied to the tracings. Press the Filter command icon 

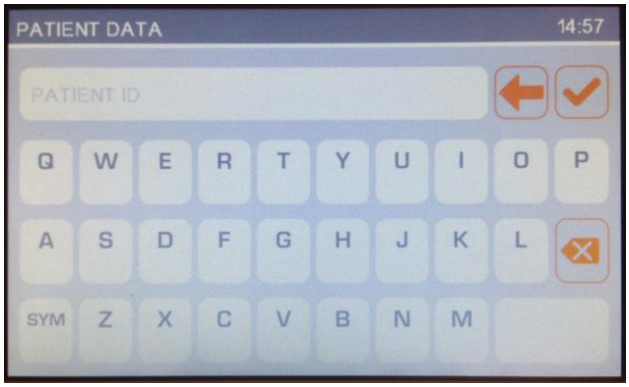
to modify the filter applied between off, 25 Hz, 40 Hz.
- **Battery charge:** indicates the level the battery is charged.
- **Time:** indicates the time of the device
- **Free memory:** number of ECGs left to fill memory (50 = memory empty, 0 = memory full)
- **Messages:** electrode failure popup message and other messages (if present).

5.4.4. Data entry

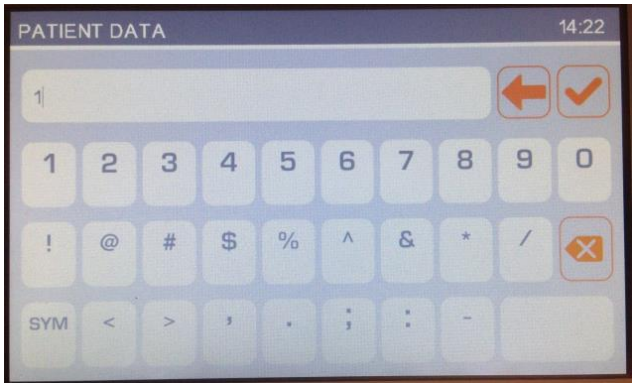
Whenever necessary, the device will display a software keyboard for patient data entry.

The Data Entry Screen consists in a virtual (QWERTY) keyboard, with provision for numerical data entry (NUM/SYM keyboard).

The Screen is activated every time the user needs to enter some data, whether it is patient information or Settings.



Main QWERTY



Symbols QWERTY

6. PREPARATION FOR USE

6.1. Initial startup

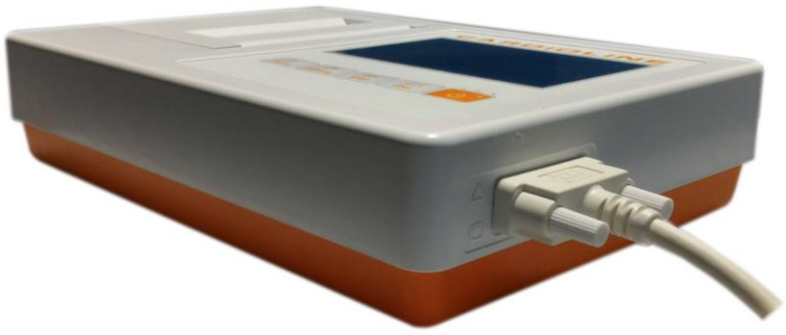
The first time the device is used, the basic configurations of the electrocardiograph should be set.
Therefore, when using the device for the first time, it is recommended to go to the settings screen and set the following parameters:

- Language
- AC filter
- Date and time
- Date format (if different from DD-MM-YYYY)

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.



Patient cable plugged in

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.

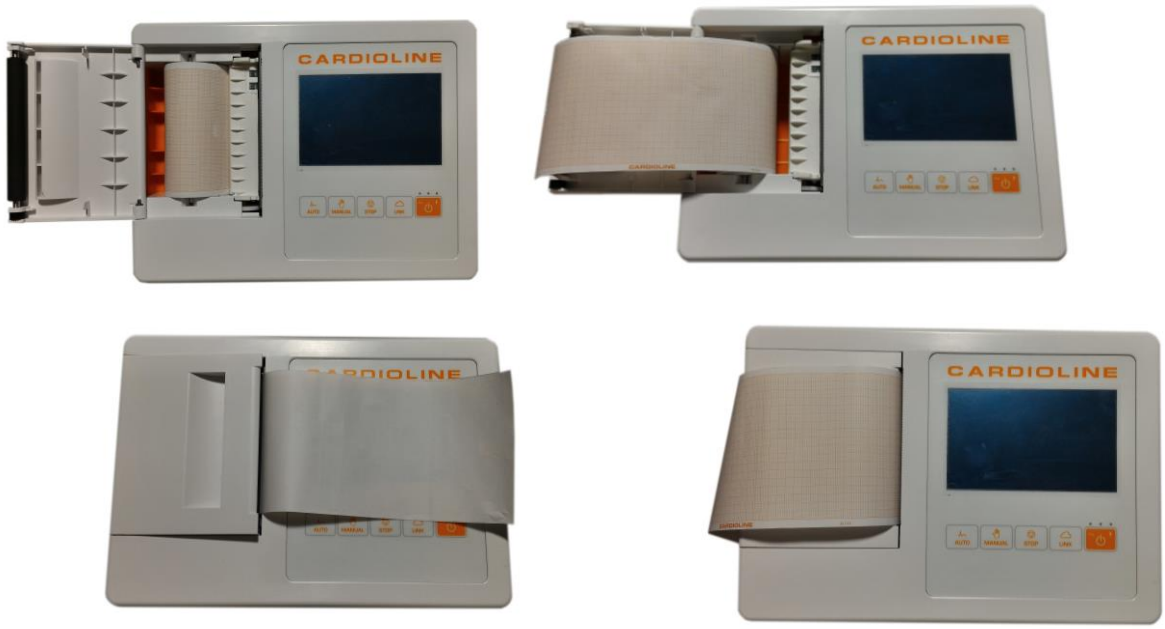
6.3. Loading the paper

ECG100L works with roll paper.
ECG200L can work with both roll paper and z-fold paper. The paper format to be used can be selected in the system settings, as described in par. Errore. L'origine riferimento non è stata trovata..

6.3.1. Roll paper format

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 roll of thermal paper into the drawer of the printer so that the side of the paper grid faces upwards.
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.

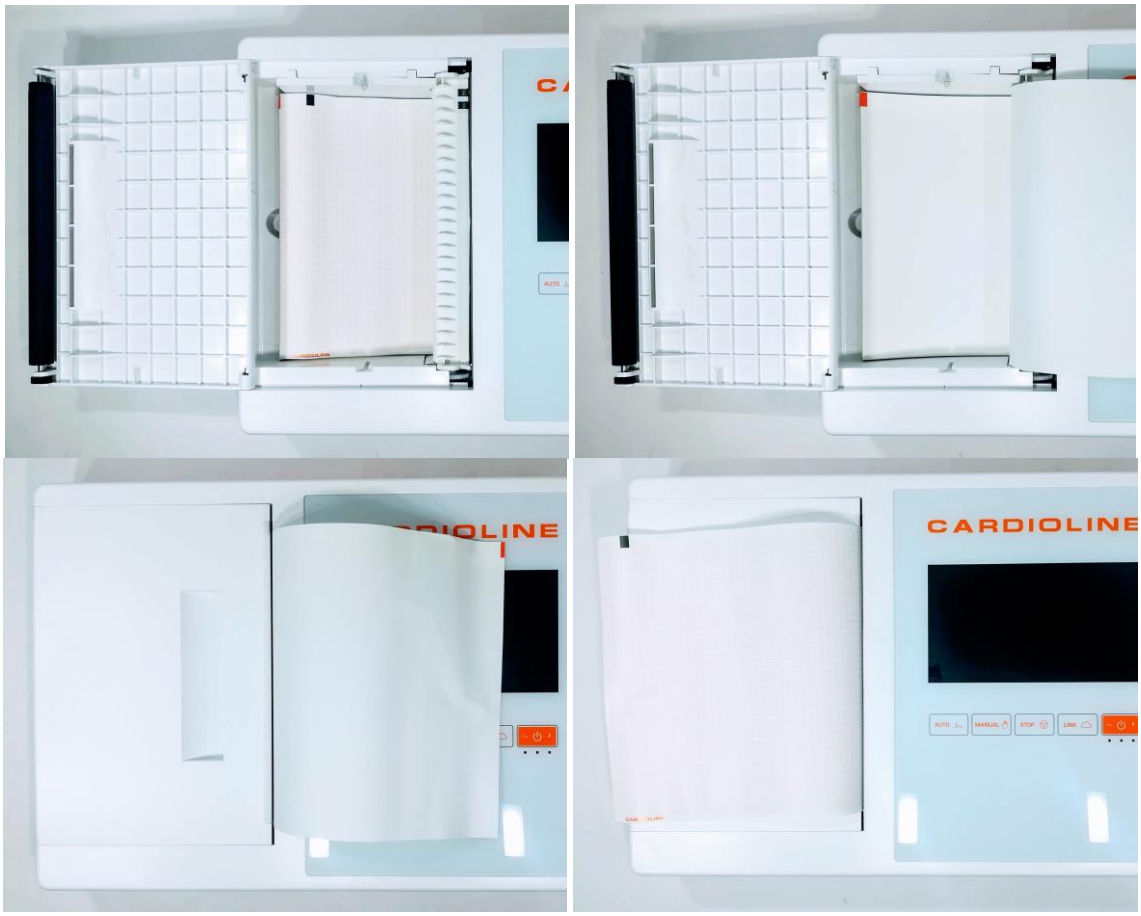


Sequence for loading paper

6.3.2. Z-fold paper format

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 printer's 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. Switching the device ON/OFF

To switch on ECG100L, press the On/Off button under the display (see par. 5.4.1).
Instead, to switch on ECG200L, you must use the switch at the back of the device (see par. 5.4.1).
To switch the device off completely, disconnect the power cable and keep the ON/OFF key pressed. Always perform this operation before proceeding with authorised repairs of the device.
ECG200L can be switched off also by using the switch located on the back of the device.

6.5. Power connection

ECG100L/ECG200L 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 mains 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.

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

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

On/Off switch

Led Light	Description
~	Blue – ON, if the device is connected to the mains power supply OFF – when the device is not connected to the mains power supply.
■	Green – ON when the device is on. OFF – when the device is off
⚡	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.

NOTE: There are specific settings which make it possible to extend the life of the battery (see Section 10.5). Appropriate use and maintenance also extend its life.

NOTE: The device ECG100L should be connected to the mains using only the XP Power - AFM60US18 adaptor supplied.

6.6. 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 grey 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 (red, empty battery icon). The icon represent the state for which the cardiograph will initiate the shutdown after at least 60 seconds have elapsed. 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 deviceECG100L must only be connected to the power supply using the supplied XP Power - AFM60US18 power supply.

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. 7.1);
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;
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. 7.4).

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.

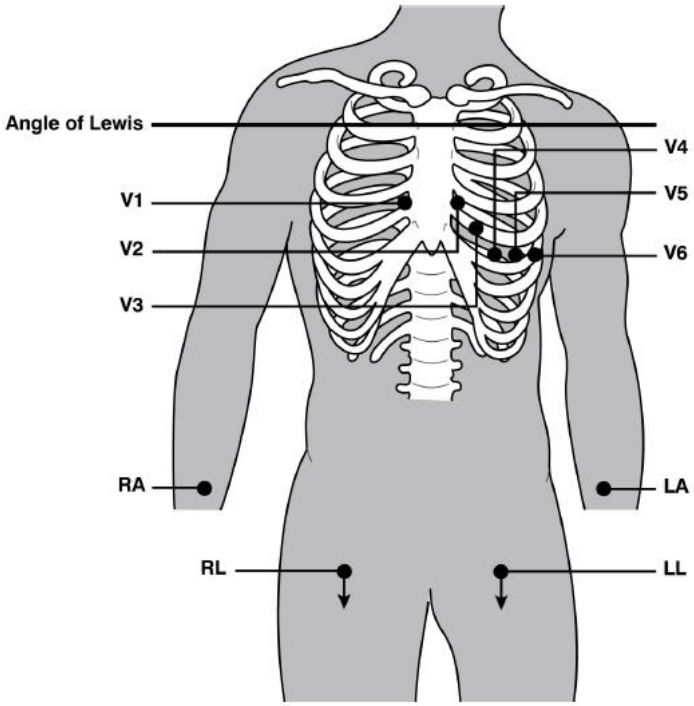
NOTE: Pay attention not to cause abrasions, discomfort or bruises on the skin.
Always observe the utmost clinical discretion when preparing the patient.

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

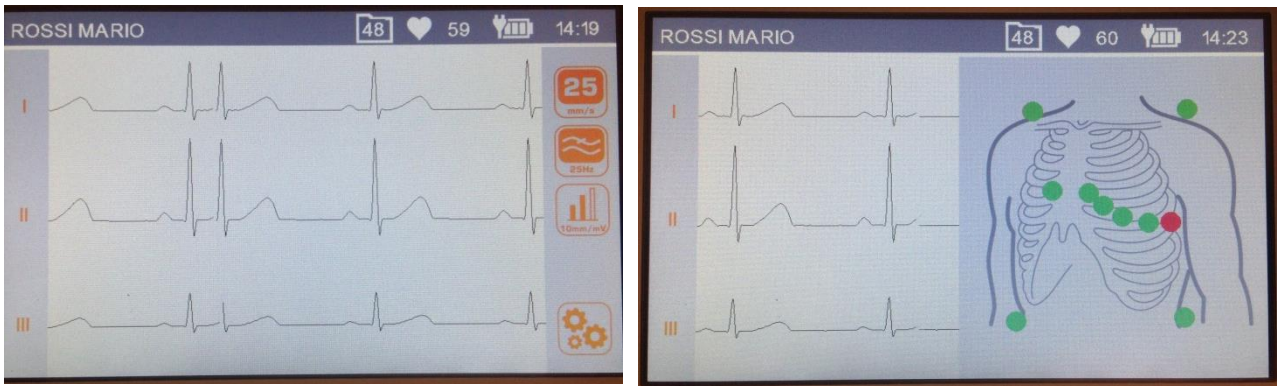
NOTE: It is important to locate the fourth intercostal space for an accurate positioning and monitoring of the precordial leads. It is possible to locate the fourth intercostal space starting from the first intercostal space. Given the variable conformation of the patient, palpating the first intercostal 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	C1	Red	V1	V1	Red	Fourth intercostal space to the right of the sternum.
C2	C2	Yellow	V2	V2	Yellow	Fourth intercostal space to the left of the sternum.
C3	C3	Green	V3	V3	Green	Midway position between electrodes V2/C2 and V4/C4.
C 4	C4	Brown	V4	V4	Blue	Fifth intercostal space at midclavicular line.
C5	C5	Black	V5	V5	Orange	Between electrodes V4 and V6.
C6	C6	Violet	V6	V6	Violet	Level with electrode V4 at left midaxillary line.
L	L	Yellow	LA	LA	Black	On the deltoid muscle, the forearm and wrist.
R	R	Red	RA	RA	White	On the deltoid muscle, the forearm and wrist.
F	F	Green	LL	LL	Red	On the thigh or the ankle.
N	N	Black	RL	RL	Green	On the thigh or the ankle.

7.3. Viewing the ECG

The electrocardiograph starting screen is the real time with torso screen and lead fail indications.



Display in real time and display in real time with Torso screen

Display

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. 0) and the active function keys.

Function keys

- *Touch vertical bar* — **Traces format** — Touch on the vertical grey bar on the left of the screen. Changes the display format of the tracings (12x1, 6x2, 3x4). The label shows the current display format.
- *Touch traces area* — **Torso** — Touch on the left part of the traces area. Shows/hides the Torso screen with the indication of electrodes position.
- 25 mm/s — **Speed** — Changes printing speed (5, 10, 25, 50 mm/s). Affects the next printout request.
- 25 Hz — **Filter** — Selects the low-pass filter to apply to the of the the displayed and printed traces (off, 40, 25 Hz).
- 5mm/mV — **Gain** — Changes the amplitude of the the displayed and printed traces (5, 10, 20 mm/mV).
- **Settings** — Access the settings menu (see par. 8)

Active keys

- AUTO — **AUTO** — Short press: starts automatic acquisition of the ECG (see Par.7.4.1);

  Long press: starts automatic acquisition of the ECG with STAT tag

(see Par. 7.4.4Errore. L'origine riferimento non è stata trovata.).

- 

MANUAL — Short press: starts manual printing of the ECG (see Par.7.4.2);
Long press: starts manual printing of the ECG with Rhythm printing (see Par. 7.4.3Errore. L'origine riferimento non è stata trovata.).
- 

LINK — Transfers the ECG (SCP file) to a connected USB pen drive.
- 
ON/OFF — Switches off the electrocardiograph.

The display also shows messages regarding tracing failures. The messages are displayed in the centre of the screen. Refer to par. 10.9 for a complete list of messages.

7.3.1. Disconnection of the leads

If one or more electrodes are disconnected the message “Lead fail” is displayed over the traces. The device draws the Torso screen and the lead in fail is marked with a red dot.
Should all leads be disconnected or the lead in fail is N/RL, the device displays the message “Lead fail: all” and draws the Torso screen.
If the patient cable is disconnected from the device front end connector, the ECG traces are shown as flat traces and the torso screen is drawn with all red dots.

7.4. Acquiring an ECG

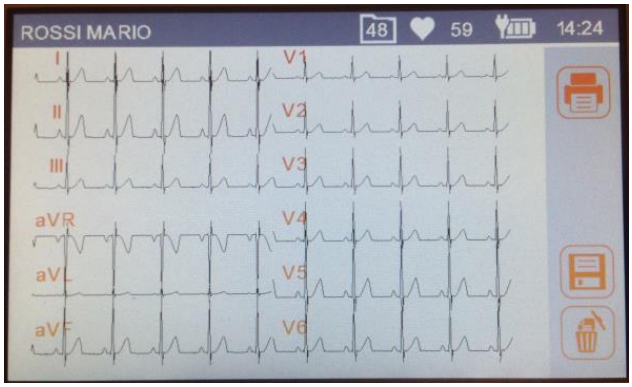
ECGs can be acquired both in automatic and in manual mode.
Using the automatic mode you can acquire a 10 s ECG, which can then be saved and printed as an exam.
Using the manual mode you can print continuously an ECG of variable duration (no saving is allowed).

7.4.1. Automatic acquisition of an ECG (AUTO)

When the operator presses the AUTO button, if the device is provided with the patient’s data already loaded, it asks the user for confirmation to enter a new patient.
If it is a new Patient, the device asks the user to enter the patient’s data: ID, Surname, Name, Age and Gender.
If you want to proceed with the test without entering the data, you can skip this stage by pressing the AUTO button in the patient ID setting screen.
The device displays the surname and name of the patient in the main window.

The device will guide the operator in the process of patient hookup by displaying a torso representation with the indication of both connected and disconnected leads. Once terminated, the system proceeds with completing the acquisition of 10s of ECG signal, displays the acquired traces and prints them using the previously configured layout.

If the device has the Glasgow analysis option, it will print also the automatic interpretation.



Printing preview of an acquired ECG.

Printing and saving the exam

The examination is printed automatically at the end of the automatic ECG acquisition.
After that the user may:

- Edit the trace format by touching the traces displayed on the screen: this change is effective on the display and in any subsequent printout
- print another copy of the test, by pressing **Print**
- save the test in the local storage, by pressing **Save.** The user interface is automatically updated to indicate the estimated number of ECG tests that can still be saved. It is impossible to save the test if the memory is full.
- delete the test by pressing **Bin**
- connect a pen drive and press **LINK** to export all ECGs stored on memory

Function keys

▪ *Touch traces area*	**Traces format**	Touch on the traces area. Changes the display format of the tracings (12x1 (ECG200L only), 6x2, 6+6, 3x4, 3x4+1, 3x4+3). The label shows the current display format.
▪	**Print**	Prints the ECG with the current settings.
▪	**Save**	Saves the acquired ECG in the internal memory.
▪	**Delete**	Discards the ECG and immediately jump to the Real-time Screen for a new acquisition with the current patient data.

Active keys

- 

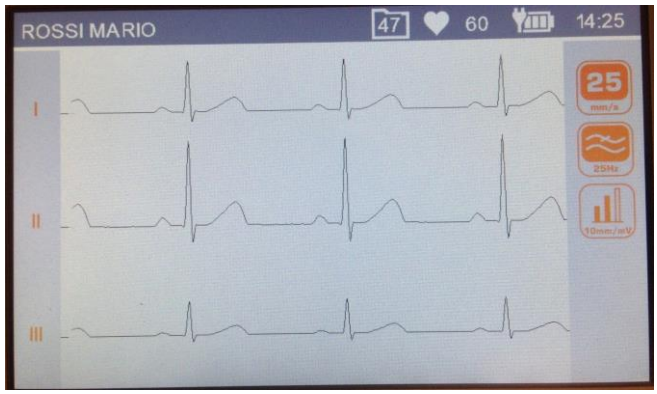
AUTO — Jump to the Real-time Screen for a new acquisition prompting the user whether to keep the same patient data and.
- 

LINK — Transfers the ECG (SCP file) to an inserted USB drive.
- 
ON/OFF — Switches off the device

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.

7.4.2. 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.



Display during manual acquisition of an ECG

Function keys

- *Touch the vertical bar* — Trace format — Touch the grey vertical bar to the left of the screen. Edits the printed and displayed trace format, rotating from among all formats.
- 

Speed — Changes the printing speed (5, 10, 25, 50 mm/s).
- 

Filter — Selects the low-pass filter to apply to the tracings (off, 40, 25 Hz).
- 

Gain — Changes the amplitude of the tracings (5, 10, 20 mm/mV).

Active keys

- 

MANUAL Changes the printed leads, as described above.
- 

STOP Stops the manual printout and restores the real time display screen.
- 
ON/OFF Switches off the device

7.4.3. Manual acquisition of an ECG with Rhythm Printing (MANUAL)

Press MANUAL on the display screen for minimum 2 seconds in real time to start acquisition with Rhythm printing, which provides a compact printout of a long ECG (up to 3 minutes).
It is possible to have two different formats, which can be selected from the Settings menu (see par. 8.3):

- One lead for a 180 s ECG;
- Three leads for a 60 s ECG.

The printing speed is fixed at 5 mm/s and has a muscle filter fixed at 25 Hz, whereas the amplitude used for printing (5, 10 or 20 mm/mV) is defined according to the amplitude of the acquired trace.

Besides traces, rhythm printing shows:

- Heart Rate Graph
- RR Average Interval Graph
- Heart rate parameters: minimum, maximum, Average and standard deviation.

7.4.4. Acquisition of an urgent ECG

ECG100L/ECG200L provides a way to acquire urgent ECG, skipping the patient data entry proposed during the AUTO acquisition.
Urgent (STAT) ECG can be acquired by keeping the AUTO key pressed for 2 seconds.

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

7.5. Printing an ECG

As described in Par. 7.4.1, the ECG is printed automatically at the end of acquisition. It is always possible to print or reprint the ECG using the Print function key.

It is also possible to start manual printing by using the MANUAL key on the real time display screen (Par. 7.4.2).

The printing format used is saved for subsequent printing.

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.

7.5.1. Automatic Printing formats

Format	ECG data
12x1 (ECG200L only)	10 seconds of 12 leads in 12 channel format.
6x2	5 seconds of 6 leads in 6 channel format.
6+6	10 seconds of peripheral leads followed by 10 seconds of precordial leads
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.

7.6. Storing an ECG

At the end of an "AUTO" acquisition, the exam will be saved.
As described in Par. 7.4.1, the examination is saved automatically at the end of acquisition, unless discarded by pressing the trashcan icon.

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)

7.7. Exporting an ECG

The device allows the user to export the ECG exams from the internal memory in the following ways.

7.7.1. Exporting to a USB flash drive

After the system automatically analyses the ECG (AUTO or STAT), the ECG preview screen is displayed. This gives you the option to export all the ECG tests to a USB pen drive that was previously connected to the device's USB port (see par. 5.4.1), by pressing LINK.
This empties the internal archive of the cardiograph. This can also be carried out from the Real Time screen.

7.7.2. Transferring ECG to the PC

Whenever the device is connected to a PC using a USB cable, linked between the USB port of the device itself and a USB port on the PC, the device enters the USB connection screen.
Upon entering this screen, the device stops operating as an electrocardiograph and the usual functionalities (such as ECG acquisition/printing or user interface navigation) are not available.

When this screen is active, no key on the device is active.

The screen shows a USB icon indicating that the device is connected via USB.
When the device is disconnected, the message "Device restart..." appears, informing the user that the device is being restarted to re-enable the electrocardiograph functions.

WARNING: when connected via USB the device must always be disconnected from the patient. Once the USB connection is removed, the USB port on the device must be protected and closed with its plastic lid.

8. DEVICE SETTINGS

8.1. 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 soft keys on the display.
Access the settings menu by pressing the **Settings** function key from the ECG's display window (see par. 7.3).

Settings Screen Functions:

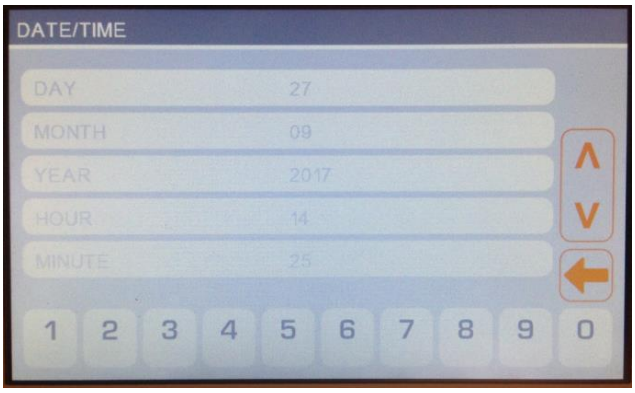
- Vertical Arrow keys (^, v): select the previous or the next setting page;
- Right-oriented Arrow key (>): to select the next enumerate value. Hidden if not applicable;
- Digit keys (0 – 9): to enter the numerical data;
- Touching on a row: to select the row;
- Left-oriented Arrow key (🡐): to exit the Settings screen and return to the real-time screen.

Upon exit, the updated values shall be stored in the device memory and it shall automatically reboot

8.2. Setting date and time

The Date/Time Settings page allows entering the current date/time up to the minute resolution, one line per value (5 values total) as showed in the picture below.

If the inserted value is not correct, it is not possible to move to the next field.



Date and time settings page

8.3. System settings

The system settings page allows the user to choose the following parameters:

Field	Description	Possible values
Date and time	current date and time	N/A
Language	User interface language ***Note**: by selecting Russian, the keyboard is automatically set in Russian.*	
Date Format	Date format	DDMMYY (Default), MMDDYY, YYMMDD
AC filter	AC filter	50Hz(Default)/60Hz/Off
Brightness	Screen brightness control	From 10% to 100%, steps of 10% 80% (Default)
Auto shutdown	Enable the device to switch off automatically after a set period of inactivity (15 or 30 minutes).	OFF / 15 minutes / 30 minutes
LF Window	To enable/disable the Disconnected Electrode Window (Lead Fail – LF) (see Note below)	ON (Default)/OFF
Leads order	Sets the leads order	Standard(Default)/Cabrera
Rhythm Lead 1/2/3	Rhythm Leads used in AUTO printing 3x4+1 and 3x4+3	Lead labels
Rhythm printing duration	To set the duration of the signal that will be acquired for Rhythm printing	60 (Default) or 180 seconds
Paper type *(ECG200L only)*	To select the paper size to be used	A4 / Letter / Roll

***NOTE:** When LF Mask is OFF, the device does not mask the ECG signal when the acquisition detects a LF. This setting is useful in case of patients with high impedance or poorly performing electrodes as it displays/prints the ECG activity (although it might be very noisy). When printing in such conditions, the footer of the printout shows a warning message. Also, the interpretation text generated by the resting ECG analysis algorithm reports that the quality of the signal might be inadequate for performing a diagnosis.*

8.4. Rhythm Leads setting

The Rhythm tracings page allows the user to define the rhythm derivations for AUTO print formats 3x4+1 and 3x4+3:

Field	Description	Possible values
LEAD 1	Default II	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
LEAD 2	Default V1	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
LEAD 3	Default V5	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Rhythm Printing Duration	Default 60	60 or 180 seconds

8.5. Service settings

The Service settings page has the following functions:

- Shows the information regarding the device (firmware version, product code, serial number and software options);
- Enables you to empty the memory (**Empty memory** key);
- Enables you to calibrate the display (**Reset Calibration**).

8.5.1. Memory wipe

To wipe the internal memory of the device, select the Service settings page and then press **Wipe memory**.
After removing all the ECGs, the device will restart and the counter will display the number 50.

8.5.2. Display calibration

The touchscreen can be recalibrated pressing the **Reset calibration** key in the Service settings page.
The device will be restarted and will ask you to repeatedly touch the black circles for calibration.

8.6. Memory management

The internal archive of the device can store up to 50 ECGs.
The free space is displayed in the top bar folder icon.
When there are only 5 ECGs left, the free space icon becomes red.

At any moment you can delete all the contents of the memory by accessing the Service settings pages and selecting **Wipe memory**.

9. 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.
You will receive, for each device to be upgraded, a text file containing the commands to upgrade the devices options.
Then:

- Connect each device to be upgraded to the PC
- Copy the text file to the device memory
- Unplug the device.

The device will print a confirmation whether it upgraded the options successfully.

10. MAINTENANCE AND TROUBLESHOOTING

10.1. 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 that could damage the surface of the device.

10.2. Switching off the device

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

10.3. 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.

10.3.1. 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.

10.3.2. 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).

10.3.3. 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.

10.3.4. 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).

10.4. 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)

10.5. 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.

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 screwdriver.
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.

10.6. Cleaning the thermal printer

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

10.6.1. 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.

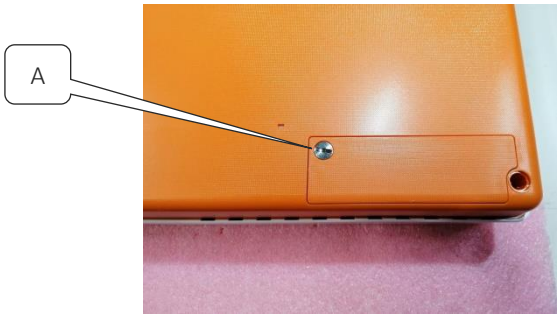
10.6.2. Cleaning the thermal head of the printer

- 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.

10.7. Touchscreen calibration procedure

If the touchscreen does not work properly and it is not possible to access the menu for calibration, proceed as follows:

1. Turn off the device and disconnect the device's power-supply unit or power cable.
2. Undo the fixing screw A and remove the cover on the battery compartment in the base of the device:



3. Disconnect the battery and remove it from the compartment:

4. Leave the device with the battery disconnected for 60 minutes (the time required to reset the touchscreen calibration memory).
5. After 60 minutes, reconnect the battery and put the cover back on the battery compartment.
6. Turn on the device and wait for the touchscreen calibration screen to appear: press a finger on the circle shown in the top left corner of the display and then press a finger on the circle in the bottom right corner.

10.8. Troubleshooting table

Problem	Cause	Solution
Bad ECG signal	▪ Damaged patient cable ▪ Bad skin-electrode contact ▪ Patient movements	Verify the patient cable is in good conditions. Try to replace the patient cable. Prepare the patient skin as described in this manual and replace the electrodes. Use gel if electrodes are reusable. Ask the patient to stay calm.
Variations of the isoelectric signal	▪ Use of non-original electrodes ▪ Bad skin-electrode contact ▪ Patient movements	Change the electrodes or clean them if they are reusable ones. Prepare the patient skin as described in this manual and replace the electrodes. Use gel if electrodes are reusable. Ask the patient to stay calm.
Electrical interference	▪ 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	Verify AC filter is set to the right AC frequency. Verify there are no devices that can generate interferences nearby. Verify the patient is not in contact with conductive materials (e.g. bed metal parts) or other persons.
Muscular noise	▪ Patient movements ▪ Muscular filter not set	Ask the patient to stay calm. Verify the muscular filter is correctly set.

Device shutting down unexpectedly	▪ 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	▪ Door not completely closed	Open the door and close it firmly.
Paper sliding problems	▪ Non original paper ▪ Paper placed incorrectly	Verify Cardioline paper is in place. Take out paper and position it as described in this manual.
Device not printing	▪ Paper is finished	Verify paper is in place. 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. Verify auto-print settings.
Block of the device	▪ Software problem	Press the On/Off button for at least 10 seconds to restart the device.
The touchscreen doesn't work	▪ Probable loss of touchscreen calibration	Disconnect the battery and the mains for at least 2 hours, then connect the battery and turn on the device. The touchscreen calibration procedure will appear on the display.

10.9. Error notifications

ECG100L/ECG200L will display on a popup message error/warning conditions requiring the intervention of the operator as described below.
The popup message may appear in any screen, consistently with the function performed in the screen; the error reported in the popup message may be acknowledged by the operator and thus closed, or it may automatically close if the condition resolves.

Message	Cause	Solution
General errors		
LEAD-FAIL	One or more electrode/channel does not work properly	Restore proper connection, the message will close automatically.
Paper end error	The user tried to print an ECG without paper in the paper tray.	Insert a new paper roll in the paper tray, the message will close automatically.
Printer lid open	Printer door is opened	Close the paper tray, the message will close automatically.
Battery Depleted	Attempt to use or switch on the device in battery mode but the battery is depleted.	Connect the device to the supply mains, the message will close automatically.
Export error	The device does not export	The USB pen drive may not have been inserted

Message	Cause	Solution
	tests onto the USB pen drive	correctly into the connector. Try disconnecting and reconnecting the USB pen drive. If the error persists, try using a different USB pen drive. The message closes if the user confirms the message (touching the popup) or removes the USB pen drive.
HW related fatal error	May be caused by a failure of printer, ECG front-end storage, configuration, SCP files	Reboot the device, the message will close automatically after the reboot.
SW/Configuration related errors	Device not serialized, invalid options.	Contact Cardioline. The message will close automatically if the user acknowledges the message by touching the popup.

11. 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	16 bit, 32 kHz
Sampling frequency	500Hz
A/D conversion	16 bit
Output data resolution	5uV/LSB
Bandwidth	Performance equivalent to 0.05 – 150 Hz
Pacemaker detection	Hardware detection coupled with convolution digital filtering
Filters	Digital high pass linear phase filter, diagnostics (compliant with 60601-2-25 2nd ed) Digital AC interference adaptive filter (50/60 Hz) Digital low pass filter, 25/40 Hz (for printout and display)
Defibrillation protection	AAMI/IEC standards
Front-end performance	ANSI/AAMI IEC 60601-2-25:2011
Safety	ECG100L: EN 60601-1 Internal power supply device – class I on external AC/DC power supply ECG200L: EN 60601-1 Internal power supply device – class I 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 up to 50 ECGs
Display	ECG100L: 5” TFT colour backlit LCD display 800x480 with resistive touch panel ECG200L: 7” TFT colour backlit LCD display 800x480 with capacitive touch panel
Thermal printer	ECG100L: 8 dot/mm - 108mm; roll 100mm x 20m ECG200L: 8 dot/mm - 216mm; roll 200mm x 20m– z-fold A4 295 mm x 210 mm – z-fold Letter 280 mm x 216 mm
Manual print	3, 6, 12 channel, 5/10/25/50 mm/s

Auto print	Standard or Cabrera; 3, 3+1, 6, 12 (ECG200L only) channels Patient Demographic, Global Measurements, Optional Interpretation (Glasgow University – Prof. MacFarlane) Adult, Paediatric, STEMI
Keyboard	Touchscreen plus functional dedicated keys
Connectivity	USB device
Patient cable	Standard 15D, 10-wires
Data export	SCP (standard format). PDF and other formats via external PC software
Power supply	ECG100L: Medical grade AC power supply (100-240 VAC 50/60 Hz); internal rechargeable battery (NiMH) ECG200L: 100-240 V 1.5-0.75 A 50-60 Hz
Internal battery	Recharging time: 4 hours to 85% of full charge Duration: more than 500 ECGs
Dimensions	ECG100L: 270x190x60mm ECG200L: 413x295x80mm
Weight	ECG100L: 1480 g (including battery pack), 1620 g (with roll of paper) ECG200L: 3820 g (including battery pack), 4170 g (with roll of paper)

11.1. Harmonised standards applied

STANDARD	DESCRIPTION
EN ISO 15223-1	Medical devices - Symbols to be used with labels, labelling and information on medical devices 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

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

11.2. Accessories

CODE	DESCRIPTION
63030105	4 Peripheral ECG electrodes clamp Ag/AgCl
63030106	Set of 4 peripheral ECG electric clamp Ag/AgCl
63030107	4 peripheral ECG electric clamp pediatric Ag/AgCl
63030163	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
66030031C	Disposable electrodes ECG, snap, 50 pics
66030034C	Disposable electrodes ECG, tab, 100 pics
66030036C	Disposable electrodes ECG neonatal, 25 pics
66030037C	Disposable electrodes ECG banana, 60 pics
66020008	Set of 10 4mm plug/snap adaptors
66010055	Thermal paper roll 100x2000 mm ECG100L
66010052S	Z-Fold paper A4 210x295mm (ECG200L)
66010053S	Z-Fold paper Letter 210x295mm (ECG200L)

12. 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 60 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

13. 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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