



Cardio Técnica

Fabrica Argentina de Equipamiento Hospitalario



User Manual

Electrocardiograph RG6XX

Versión 1.0

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1 Introduction

1. Introduction

ALERT: It is the duty of the Responsible Organization and the User to Read and Understand this Manual before using the RG6XX Electrocardiograph for the first time, mainly the Safety chapter.

1.1 About this manual

This document, the RG6XX Electrocardiograph User Manual, is an integral part of the product and should be kept with the equipment.

The use of this manual is a fundamental requirement to guarantee the functionality and safety of the equipment.

The RG6XX Electrocardiograph User Manual is intended for Responsible Organizations and Users, describes the use of the RG6XX Electrocardiographs, and contains detailed information about their performance, specifications and operation.

The institutions and people mentioned in this manual are:

1.1.1 Responsible Organization

Institution or Health Professional, owner of the RG6XX Electrocardiograph, responsible for the administration of use, conservation and maintenance.

1.1.2 User

Healthcare professional who operates the RG6XX Electrocardiograph, electrically connects the patient and records the ECGs.

1.1.3 Patient

Person who connects to the patient circuit of the RG6XX Electrocardiograph to record the ECG.

1.1.4 Maker

Maker:

CARDIOTÉCNICA SRL -
Av. Reservistas Argentinos 443
Ciudad Autónoma de Buenos Aires - Código Postal C1408All
Buenos Aires - Argentina.

Tel/Fax: (5411) 4643-9436 / (5411) 4643-9482

Web: cardiotecnica.com.ar

E-mail: info@cardiotecnica.com.ar; ventas@cardiotecnica.com.ar

1.1.5 Representative

Company or Person who, with a representation contract with Cardiotécnica SRL, markets and distributes the RG6XX Electrocardiographs.

1.1.6 Technical service

Company or Trained Person, with authorization from Cardiotécnica SRL, to carry out repairs on the RG6XX Electrocardiographs.

1.2 Expected use

The Electrocardiographs manufactured by CardioTécnica are electromedical equipment designed to carry out complementary studies for the clinical diagnosis of cardiac conditions, capable of recording the action potentials of the cardiac tissue, one patient at a time, using a patient cable.

It has been designed to be used in neonatal, pediatric and adult patients in hospitals, hospital-type centers. The use of the equipment is intended for health professionals or institutions.

- Electrocardiographs must be operated in person and attended by health professionals trained in the operation of electrocardiographs, with the supervision of a specialist in cardiology.
- Connected exclusively to the electrical network installation of class 2A medical environments, in accordance with Regulation 90364-7-710 of the AEA, or the IEC 60364-7-710 standard; or battery.
- Supported on flat, stable surfaces with an inclination of less than 5°.

The air of the environment of use of the device:

- must be free of anesthetic gases,
- must be free of flammable gases,
- must not be enriched with oxygen,
- it must have a temperature between 10°C and 40°C,
- must have a non-condensing relative humidity between 25% and 95%,
- It must have an atmospheric pressure between 700hPa and 1060hPa.

1.3 Restrictions

The RG6XX Electrocardiographs must be used in a stable position, properly supported on a flat horizontal surface.

They are not designed to be used:

- as a patient monitor,
- as devices with category AP or APG,
- in environments with flammable anesthetic mixtures with air,
- in environments with flammable anesthetic mixtures with oxygen,
- in environments with flammable anesthetic mixtures with nitrous oxide,
- connected to more than one patient simultaneously,
- with other devices with electrical connection on the patient,
- in the vicinity of MRI or CT equipment.

There is no risk or restriction on the use of the RG6XX Electrocardiographs in patients with pacemakers or other implanted stimulators.

1.4 Function and Purpose of the Electrocardiograph

Electrocardiography detects and graphs the electrical potentials generated by the cells of the heart tissue; that precede and give rise to the systolic and diastolic mechanical activity of the heart.











Cardiac electrical activity generates weak ionic currents physiologically conducted to the surface of the skin, where they are sensed with contact electrodes, at different points on the body surface.



















The sensed cardiac signals vary between 100 μ V and 5mV, and are amplified and conditioned to represent them temporarily on a Cartesian graph called an electrocardiogram or ECG.

The particularities of the waveform of the cardiac electrical signal represented in the ECG depend on the sensing point and the adopted reference.

The ECG allows the cardiology specialist to detect anomalies in the cardiac signal waveform, correlate them with possible pathologies, and, with complementary tests, confirm them by analyzing characteristic symptoms and signs, to establish a clinical diagnosis and an associated treatment.

1.5 Symbology Used

Symbol	Reference
	Indicates protective earth. IEC 60417-5019 symbol.
	Alert signal that indicates the need to refer to the reading of the instructions that accompany the equipment. ISO 7000-0434A symbol.
	Applicable part type CF protected against defibrillation. IEC 60417-5336 symbol.
	Symbol that indicates that waste must be collected in a different way. Symbol of Directive 2002/96 / CE.
	Symbol that indicates that the manual should be read before operating the equipment. ISO 7010-M002 symbol.
	Serial number.
	Lot Number
	Keep dry
	Degree of Protection provided for the enclosure.
	DC.

Symbol	Reference
	Alternating current.
	USB port
	Signal output
	Produced by
	Date of production
	Standby (On / Off Key)
	Lead Selector, Left and Right
	Record Paper Advance
	Work Mode Selector
	Amplitude selector
	Access to Internal Memory
	Calibration Signal
	Copy function of the Last Study
	Menu Navigation Controls
	Internal Battery Operation Indication
	Indication of Equipment Charging the Internal Battery
	Indicates that the SD Card is inserted, a cross indicates its absence.
	It indicates the connection with the PC, with a cross indicates the lack of connection.

1.6 Environmental conditions

The RG6XX Electrocardiographs must be transported, stored and used respecting the following environmental conditions:

Characteristics:	Functioning	Transportation and Storage
Temperature	5°C a +40°C	-10°C a +70°C
RH	25% a 95% (not condensed)	10% a 95% (not condensed)
Atmospheric pressure	700hPa a 1060hPa	500hPa a 1060hPa
Maximum stowage	No weight on equipment	5 Units

The RG6XX Electrocardiographs must be connected exclusively to the electrical network installation of class 2A medical environments, in accordance with the AEA Regulation 90364-7-710, or the IEC 60364-7-710 standard; or used on battery.

The RG6XX Electrocardiographs comply with the immunity and interference requirements required by the IEC60601-1-2 standards with the modifications provided in the IEC60601-2-25.

WARNING:

The equipment must not be used if the transport or storage requirements indicated on the packaging and in this manual have not been observed.

The RG6XX Electrocardiographs

- They are not suitable for surgery in MRI or CT settings.
- They are not suitable for working with anesthetic gases. They are not AP or APG category.
- They should not be used in environments with a risk of explosion.
- In the room of use there must be extinguishers for fire of electrical origin.

1.7 General Warnings and Precautions

The RG6XX Electrocardiographs must not be disposed of with household waste; They must be treated as electronic waste and respect the applicable legislation.

The batteries of the RG6XX electrocardiographs must be treated as electronic waste and respect the applicable legislation. If they are disposed of improperly, they pollute the environment.

Connectors and accessible conductive parts of the equipment should not be improperly connected.

Do not connect the patient, directly or indirectly, to the equipment's protective earth input.

The RG6XX Electrocardiographs are not designed to be used in conjunction with other electrically connected equipment on the patient. The electrical connection of the patient simultaneously with other equipment must be evaluated and authorized by a technical manager.

Only the models of patient cables recommended by Cardiotécnica SRL, listed in the accessories chapter, should be used. The use of inappropriate patient cables can

compromise patient safety.

The defibrillation protection of the RG6XX electrocardiographs is integrated into the patient cable. In the event of defibrillation, the device must be manually re-started to record the patient's ECG.

The Responsible Organization must manage the maintenance of the RG6XX Electrocardiographs, complying with the requirements determined by Cardiotécnica SRL, indicated in this manual.

Maintenance of the RG6XX Electrocardiographs must only be carried out by personnel with written authorization issued by Cardiotécnica SRL.

The equipment must be operated exclusively by health professionals specialized in electrocardiography, under the supervision of a doctor specializing in cardiology.

In the event of external electromagnetic interference, it may happen that the display restarts, but the equipment will continue to operate without user intervention, or the display turns off so the operator must restart the equipment. When the equipment is restarted there is no risk to the patient or the user.

PRECAUTIONS:

- Do not loosen the cabinet screws, or disassemble the equipment using other methods; There are dangerous voltages inside the equipment.
- Use only the recommended grounded power cord.
- Do not use adapters, slippers or any bypass device in the electrical power supply of the equipment.
- Do not spill liquids on the equipment, immerse it, get it wet, or expose it to abrasive atmospheres or sunlight.
- Do not touch, press, scratch or damage the surfaces of the equipment with hard objects.
- Check the proper state of integrity of the connection cables (patient cable, derivations, transmission, power supply, ground connection) before using the equipment.
- Keep equipment and accessories clean and disinfected.
- Periodically check the operation.
- Carry out annual preventive maintenance (verification, adjustments and calibration), through the official technical service. Since the safety and reliable operation of the electrocardiograph are important, maintenance is vital.
- If it is necessary to electrically connect a patient to more than one equipment, a technical manager must evaluate and authorize the operation of the complete system, analyzing the new particular risks of the system, analyzing the recognized risks specific to each equipment, and respecting the IEC60601-1 standards. and IEC60601-1-1. Bear in mind that the total patient leakage current of the system is not the direct (algebraic) sum of the leakage currents particular to each equipment.
- Place the electrodes in the correct position, on the skin, without contact with mucous membranes, body fluids, injured tissue, oil, villi or dirt.

IMPORTANT

- The information presented on the equipment display is for guidance only. All measurements and analyzes must be performed on paper printing.

1.8 Warranty

Cardiotécnica SRL assumes, before the warranty holder, the economic costs of repair or exchange due to defects or manufacturing faults of the RG6XX Electrocardiographs.

The warranty has a validity period of 12 months from the date of delivery of the equipment, it is non-transferable and does not cover costs for damages or lost profits.

The warranty holder is the Responsible Organization (institution or health professional) that purchases the RG6XX Electrocardiograph through authorized representatives or the manufacturer.

The warranty is not valid if:

- the recommendations in this manual were not followed,
- the inscription label and / or the serial number are altered,
- the warranty certificate card available at the end of this manual was not completed and sent to the authorized service center,

Or when the failure or defect is a consequence of:

- A use other than the intended use detailed in this manual.
- Accidents, negligence, abuse or improper use of the equipment.
- Incorrect installation of the equipment.
- An incorrect connection with other equipment.
- Repairs, modifications or alterations made without written and signed authorization by the Manufacturer.

To make use of this guarantee, the Responsible Organization (institution or health professional) must:

- Contact the manufacturer to report the defect or failure.
- Request written and signed authorization from the manufacturer.
- Coordinate the shipment of the equipment with the manufacturer.
- Send the device in its original packaging, freight and taxes paid at origin.

If you require our professional service, contact:

<p>CARDIOTECNICA S.R.L. Av. Reservas Argentinos 443 - C.A.B.A. Buenos Aires - Argentina - (C1408All) TE/FAX (5411) 4643-9436 / (5411) 4643-9482 E-MAIL: fabrica@cardiotecnica.com.ar ventas@cardiotecnica.com.ar</p>

2 RG6XX Electrocardiograph

2.1 General description

The Electrocardiographs manufactured by CardioTécnica are electromedical equipment designed to carry out complementary studies for the clinical diagnosis of cardiac conditions, capable of recording the action potentials of the cardiac tissue, one patient at a time, using a patient cable.

They should not be used as a patient monitor.

The RG6XX Family of Electrocardiographs are units with internal rechargeable batteries, which record 12 leads of cardiac electrical activity, and present them with direct printing on thermal paper, in several simultaneous channels, using a high definition thermal matrix printer.

The applicable part is type CF with defibrillation protection. The patient connection circuit has an electrical isolation greater than 3KV with respect to the low voltage electronic stage.

The different keyboard options allow you to manage all the use and configuration menus.

Menus, configuration parameters, device operating status, and the heart signal being recorded are displayed on the screen.

In the models with memory storage for records it is possible to save the data of 250 studies and recall them later.

The data connection port allows log information to be transmitted to the PC.

The electrocardiographs meet the immunity and interference requirements required by the IEC60601-1-2 standards with the modifications provided in the IEC60601-2-25.

WARNING: Electrocardiographs are NOT designed to be used in conjunction with other electrically connected equipment on the patient. The electrical connection of the patient simultaneously with other equipment must be evaluated and authorized by a technical manager.

WARNING: The defibrillation protection of the RG6XX Electrocardiographs is integrated into the patient cable. In the event of defibrillation, the device must be manually re-started to record the patient's ECG.

2.1.1 Parts Applicable to the Patient

The equipment has applicable parts, namely:

Patient Cable with all ten leads. Of these, 4 are connected to Limb Electrode and the other 6 to Suction Electrodes.

Patient Cable



Limb Electrodes



Suction Electrodes



2.2 Family's description

RG-603: Electrocardiograph up to 3 channels with 50mm thermal printer, 4.3 "TFT graphic display with touch screen, storage memory for records and port for connection to PC.

RG-601 PC: Electrocardiograph with storage memory for records and port for connection to PC.

RG-601 PC Ergo: Electrocardiograph with storage memory for records, Ergometry Module and port for connection to PC.

RG-606: 6-channel electrocardiograph with 80mm thermal printer, 4.3 "TFT graphic display with touch screen, storage memory for records and port for connection to PC.

The RG-603 and RG-606 print on 50 and 80mm paper respectively. All records include study date and time, print speed, amplitude, activated filters, heart rate, and printed lead. If the option has been configured, print the patient's data, these must be edited from the keyboard that appears on the screen.

2.3 Unpacking

The RG6XX Electrocardiographs must be received with the original factory protective packaging for transport and storage.

Before opening the packaging, check that the box is not open or damaged.

When unpacking the equipment, verify the existence of:

- 1 RG6XX Electrocardiograph.
- 1 Quick Use Guide.
- 1 Power cord.
- 1 10-wire patient cable.
- 4 Limb electrode holder forceps.
- 6 Precordial suction electrodes.
- 1 Roll of 50mm x 30m thermosensitive paper (RG603).
- 1 Roll of thermosensitive paper of 80mm x 30m (RG606).
- 1 Equipment bag.

When removing the items from the box, verify that the content is: full, dry, and in good condition (no bumps, scratches or tears).

WARNING: The equipment must not be used if the transport or storage requirements indicated on the packaging and in this manual have not been observed.

Keep the original packaging to use it in future transport, technical services, returns or storage.

Fill in the warranty certificate card (available at the end of this manual) and send it to the Authorized Service Center.

2.4 Useful life

The RG6XX Family Electrocardiographs manufactured by CardioTécnica have a stipulated useful life of 5 years, as long as the conditions of use, transport and maintenance established in this manual are respected.

2.5 Final disposal of waste

RG6XX Electrocardiographs and accessories must be disinfected before being discarded.

The batteries must be sent to the manufacturer, or collected by authorized institutions for the collection and final disposal of batteries.

RG6XX Electrocardiographs and accessories should be considered and treated as electronic waste. To dispose of them, the current local legislation must be respected.

2.6 Unit Description

The RG6XX Electrocardiographs are assembled on a plastic cabinet.

Front



Left side



Right side



lower



2.6.1 Keyboard

The RG6XX EKG keyboard contains three sets of keys; the power keys, the menu navigation keys, and the function keys.

2.6.1.1 On / Off

With the equipment off, pressing it turns on the equipment. If the equipment is on, press, when releasing the button the equipment turns off. The display shows a Warning during shutdown.

2.6.1.2 Navigation Keys

The navigation keys allow you to access the menus, modify the configuration options and accept or cancel the changes.

2.6.1.3 Shortcut Keys

The function keys allow executing a device function immediately.

The available functions are:

- Registration change between Manual mode, Automatic mode and Rhythm mode.
- Amplitude change of the plotted signal.
- Calibration signal printing on the register in Manual mode.
- Access to memory studies
- ECG signal recording start.

2.6.2 Printing machine

The RG-603 Electrocardiograph has a 50mm thermal head printer.

The RG-606 Electrocardiographs have a printer with an 80mm thermal head.

The RG-601PC RG-601 PC Ergo Electrocardiographs do not incorporate a printer.

The printing system of the RG6XX Electrocardiographs works with a resolution of 8 dots per mm; it supports recording at speeds of 5mm / s, 10mm / s, 12.5mm / s, 25mm / s or 50mm / s.

2.6.3 Screen

The RG-603 and RG-606 have a 4.3 "TFT graphic display with touch screen, while the RG-601PC and RG601 PC Ergo do not have a display.

The RG6XX system of the Electrocardiographs allows to display, on screen, the navigation of the menus, the configuration states, and the ECG signals.

IMPORTANT

The information presented on the equipment screen is for guidance only. All measurements and analyzes must be carried out on paper printing.

2.6.4 Connectors

WARNING: The connectors and accessible conductive parts of the equipment must not be improperly connected.

WARNING: Do not connect the patient, directly or indirectly, to the protective earth input of the equipment.

WARNING: The RG6XX Electrocardiographs are not designed to be used in conjunction with other electrically connected equipment on the patient. The electrical connection of the patient simultaneously with other equipment must be evaluated and authorized by a technical manager.

2.6.4.1 Mains Power Input

The AC inlet is the connector base located on the left side of the equipment cabinet. Connect the electrical network using the detachable power cable provided with the equipment, or with an analogous cable recommended by CardioTécnica SRL. The base of the connector must only be connected to a fixed socket, of an IT electrical installation, of a class 2A medical use environment, in accordance with AEA Regulation 90364-7-710, or the IEC 60364-7-710 standard.

CAUTION: Do not place adapters between the detachable power cord and the fixed outlet of the electrical installation.

2.6.4.2 Earth Connector

The protective ground connector is the tab located on the left side, next to the base of the connector. It should only be used as a reinforcement of the protective earth connection of the electrical installation.

Connect the end of the banana plug of the protective earth cable to the protective earth connector of the equipment, and the crocodile tip of the other end to the protective earth of the installation.

CAUTION: Do not connect the protective earth to ducts, faucets, etc. This connection should be supervised by the technical manager of the IT installation.

CAUTION: Use only the protective earth cable optionally provided by CardioTécnica SRL.

2.6.4.3 Data Communication Port - RS232

RS232 Serial Port

The connection of the Electrocardiograph to a PC, through the serial port, allows, by installing a specific software, to record and present on the PC screen, the studies stored in the internal memory of the equipment.

CAUTION: The serial cable is not supplied with the equipment. Only use cables with the characteristics indicated in the ACCESSORIES chapter.

CAUTION: Only connect the computer port to a serial port or through a Serial / USB adapter. The connection of other devices (monitors, pendrive, headphones, etc.) can damage the equipment and compromise electrical safety.

2.6.4.4 Signal Output Connector

This connector is reserved for future functions.

2.6.4.5 SD card / USB port

The use of the SD card and the USB port are reserved for the use of technical personnel.

2.6.4.6 Input Patient Circuit

The patient circuit connector is a female DB15 plug, located on the right side of the equipment.

The patient circuit connector has the compatible configuration, for the use of 10-electrode patient cables, with protection against defibrillation and Connection Code No. 1 (usually European), as established in the IEC-60601-2-51 Ed1 standard.

The isolation of the patient circuit is of the CF type, according to the specifications of the IEC-60601-2-25 Ed1.1, and has an electrical isolation greater than 3KV with respect to the low voltage electronic stage.

The patient circuit allows the patient to be connected, through the patient cable and the electrodes provided with the equipment, to acquire the ECG signals.

WARNING: Only the patient cable models recommended by Cardiotécnica SRL, listed in the accessories chapter, should be used. The use of inappropriate patient cables can compromise patient safety.

2.6.5 Fixation piece

The RG6XX electrocardiographs have a insert at the bottom, with a 1/8 "female thread of 6mm depth, which allows to fix the equipment cabinet to the work surface using a screw.

2.6.6 Installation

The RG6XX Electrocardiographs must be installed in a suitable enclosure, and on a work surface that allows the operation of the equipment.

Before installing the RG6XX Electrocardiograph, it must be confirmed that the chosen enclosure meets the environmental requirements for use established in the Environmental Conditions heading of this manual.

The surface assigned to safely locate the RG6XX Electrocardiograph must be stable, flat, support the weight of the equipment, have an inclination of no more than 5° and a minimum surface area of 0.25m x 0.35m.

It is recommended that the area assigned to install the equipment:

- It has a comfortable surface for use, greater than the minimum specified, that allows to support accessories and work elements,
- has a suitable height for use (sitting in a chair; high bench or standing),
- have a nearby electrical outlet to connect the power cord,
- is at an adequate distance from the stretcher to connect the patient circuit,
- is at a suitable distance from the PC,
- allow access to the power and patient circuit connectors.

If it is necessary to tack the RG6XX Electrocardiograph, screw a 1/8 "screw over the fixing pad to secure the cabinet to the work surface.

After placing the RG6XX EKG machine on the work surface:

- connect the detachable power cord to the connector base of the computer,

- connect the detachable power cable to the base of the fixed mains socket,
- If it is necessary to reinforce the protective earth connection, request the intervention of the technical manager of the IT electrical installation. The technical person responsible for the installation must connect the banana plug of the protective earth cable to the protective earth connector of the equipment, and the crocodile plug of the protective earth cable to the assigned protective earth connector of the IT installation.
- if you want to connect the equipment to the PC,
- connect the DB15 male plug of the patient cable to the DB15 female connector of the patient circuit and tighten the fixing screws.
- place the thermal paper,

If the equipment does not turn on, with the supervision of the technical person in charge of the medical equipment of the Responsible Organization, check again the network power connections, protective earth, and USB port, and the status of the IT electrical network.

If the problem persists, contact the commercial representative of Cardiotécnica SRL, or the authorized Technical Service.

3 Generalities

To use the RG6XX Electrocardiographs, correct operation, cleaning and disinfection must be ensured, meeting the Maintenance requirements.

To avoid cross contamination, it is recommended:

- handle without the use of gloves: the RG6XX Electrocardiograph, and the trunk end of the patient cable;
- Handle with disposable gloves: the patient, the ten wires of the patient cable, the limb electrode, and the precordial electrodes.

Before connecting the patient and operating the equipment, the user must verify:

- that the RG6XX electrocardiograph is correctly installed, resting on a suitable surface,
- that the RG6XX electrocardiograph is clean and disinfected,
- that the patient cable is the original or one of the replacement cables recommended by CardioTécnica SRL,
- that the patient cable is in good condition, clean and disinfected,
- have the computer turn on, and communicate with the PC (if applicable).

The RG6XX Electrocardiographs should not be used:

- in motion during patient transfer,
- as a patient monitor,
- connected to more than one patient simultaneously,
- in MRI or CT settings,
- with anesthetic gases, they are not category AP or APG,
- in environments with risk of explosion,
- in environments with flammable anesthetic mixtures with air, neither with flammable anesthetic mixtures with oxygen, nor with flammable anesthetic mixtures with nitrous oxide,

The RG6XX Electrocardiographs comply with the immunity and interference requirements required by the IEC60601-1-2 standard with the modifications established by the IEC60601-2-25.

The RG6XX Electrocardiographs are not designed to be used in conjunction with other electrically connected equipment on the patient. The electrical connection of the patient simultaneously with other equipment must be evaluated and authorized by a technical manager.

3.1 Use of Defibrillators

RG6XX Electrocardiographs are protected against defibrillator shocks. Defibrillation protection is partially integrated into the patient cable.

WARNING: When a defibrillator shock occurs, with the patient connected to the electrocardiograph, the cardiac signal will be correctly reset within 10 seconds of the shock.

WARNING: Only the patient cable models recommended by CardioTécnica SRL, listed in the accessories chapter, should be used. The use of inappropriate patient cables can

compromise patient safety.

When using a defibrillator on the patient, the following precautions should be taken:

- Do not make connections of any kind between the Electrocardiograph and the Defibrillator. The RG6XX Electrocardiographs do not have a defibrillator sync input.
- Do not touch the patient or equipment while unloading.
- Do not perform direct discharges on the electrodes, it may overload the inputs.
- Correctly place the conductive gel on the defibrillator paddles, spillage can cause unwanted leaks.

3.2 Color TFT display

These models incorporate a 4.3 "color TFT graphic screen in which it presents the configuration data, the system messages, the different menus for the configuration of the electrocardiograph, the status of the Battery, the heart rate and in the presentation of work until 12 electrocardiographic signals.

It has a touch keyboard with which you can operate the equipment, its configuration options and load the data of the studies to be printed at the end of it.

IMPORTANT

The information presented on the equipment screen is for guidance only. All measurements and analyzes must be carried out on paper printing.

3.3 Battery Operation

The RG-6XX Electrocardiographs are equipped with a recharge control circuit along with a built-in rechargeable lithium battery.

When the RG6XX Electrocardiograph is connected to the mains, the system is powered from the mains and permanently charges the battery, regardless of the on / off state. The equipment has an LED on the keyboard that functions as a connection indicator to the electrical network.





When the RG6XX electrocardiograph is disconnected from the mains, it is powered by the battery. While the equipment is running on battery power, the screen shows the battery icon with the charge divided into four levels. The full charge of the battery ensures an autonomy of operation of at least 4 hours of continuous use.

When the Battery is completely discharged, it will take a time of at least 5 hours to achieve a charge of approximately 90% of the total. To prolong the useful life of the battery, it is recommended not to subject it to charging periods longer than 10 hours continuously; and disconnect the equipment from the electrical network when it is not used for long periods.

If the battery does not charge while the equipment is connected to the mains, or if the full charge of the battery does not ensure a normal operating autonomy, or if an inadequate operation of the battery is perceived, corrective maintenance must be managed.

Battery Status

The current capacity of the rechargeable battery can be identified according to the symbol located in the upper right corner of the TFT screen.

	Full capacity. The full charge of the battery ensures an autonomy of operation of at least 4 hours of continuous use.
	Capacity is limited, and recharging must be taken into account
	The battery is discharged and a warning message will be displayed on the TFT screen. The battery must be recharged immediately.
	The battery is completely discharged, the equipment will shut down to protect them. Connect to the electrical network to recharge them. When the Battery is completely discharged, it will take a time of at least 5 hours to achieve a charge of approximately 90% of the total.

The system permanently monitors the battery charge level, and automatically shuts down when it drops to the minimum level. Prior to this point, when the battery charge reaches the critical level, a visual warning is issued. This indicates that it is necessary to connect the equipment to the network to avoid automatic shutdown due to lack of load

CAUTION: Do not loosen the cabinet screws, or disassemble the equipment using other methods; There are dangerous voltages inside the equipment.

WARNING: The Responsible Organization must manage the maintenance of the RG6XX Electrocardiographs, complying with the requirements determined by Cardiotécnica SRL, indicated in this manual. When the useful life of the battery ends, or a bad smell and leaks have been found, contact the manufacturer or your local dealer to replace the battery.

Only qualified service personnel authorized by CardioTecnica SRL can open the battery compartment and replace it. The battery of the same model and specification provided by the manufacturer should always be used.

Explosion Hazard: Do not reverse the polarity of the Battery

3.4 Use of Paper

The RG6XX Electrocardiographs allow the recording of ECGs on thermosensitive paper. The quality of the printing and the durability of the printer are strongly dependent on the quality of the paper used and the correct placement.

The lack of paper stops the printing system and emits a warning, visual and audible, indicating the need to place a roll.

3.5 System Messages

The RG6XX Electrocardiographs do not emit an alarm signal.

The notices issued by the RG6XX Electrocardiographs are indications to the user about the occurrence of some technical problems that need their attention.

The cessation of the notices indicates that the technical problem has been solved.

The disregard of these notices does not create a danger for the patient, the user, or third parties.

The system also emits sounds such as the key beep and rhythm beep, in order to give confirmation to the user.

The visual and audible warnings issued by the RG6XX Electrocardiographs are the following:

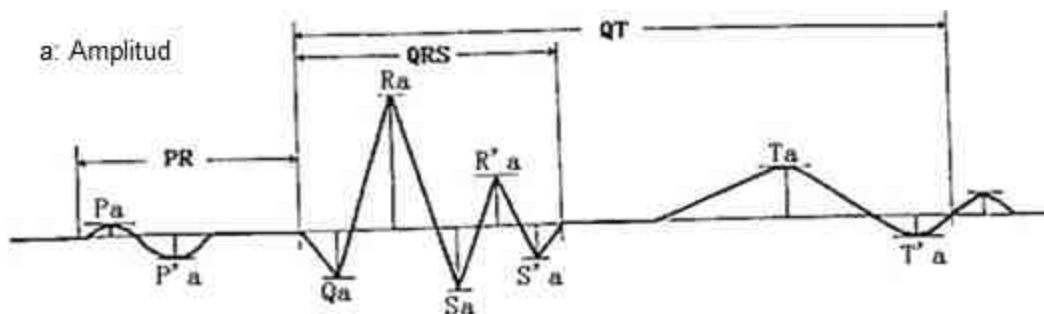
Low battery	Indicates that the battery level has reached a point where it is necessary to connect the equipment to the mains to charge it.
Lack of Paper	It should be checked if the recorder is out of paper. In case of not having a recorder or having paper, the message is informative and transitory due to an external source of noise and does not require operator intervention.
Printing	The equipment is ready to print a study.
Sampling	The equipment is inputting signal to be processed.
Analyzing	The equipment is analyzing the signal to be printed.
CABLE Desc.	Patient cable disconnected
XX Desc.	Patient cable terminal disconnected.
Demo	The EKG machine is in demo mode.
Sending	The equipment is sending studies saved in the internal memory through the communication port.
Full Memory	The number of studies stored in the internal memory is greater than 100.
INOPERABLE	When the preamplifier is saturated by some external condition. This condition is automatically corrected when the amplifier exits clipping. At the time of receiving interference through the power conductors. It is an informative and transitory message and it does not affect the operation of the equipment. The equipment continues to operate without operator intervention.

COMMUNICATION DENIED	Informational message that requires no operator action.
CONNECTION STOPPED	There is no data output through the serial port while the message is on the screen.

3.6 Measurements

A predominant beat is selected from each waveform of the 12 leads. The 12 predominant beats are used to locate the waveform boundaries (the beginnings and ends of the P, QRS, T wave) in the multi-lead ECG signal (the standard 12 leads) and to measure clinically important features (such as the amplitude and duration of the Q, Waves R, S, R' and S', the QT interval, the internal PR).

3.6.1 Measurements of a Heartbeat



Measure	Description	Unit of measurement
Pa	P wave amplitude	mV
P'a	P' wave amplitude	mV
Qa	Q wave amplitude	mV
Ra	R wave amplitude	mV
Sa	S wave amplitude	mV
R'a	R' wave amplitude	mV
S'a	S' wave amplitude	mV
Ta	T wave amplitude	mV
T'a	T' wave amplitude	mV
Pd	P wave duration	ms
P'd	P' wave duration	ms
PR	PR interval	ms
QRS	QRS duration	ms
QT	QT interval	ms

4 ECG setup

The machine has two different types of ECG setup modes, one through the use of shortcut keys and the second through the On-Screen Menu.

The shortcut keys are Mode, Span, and Memory Access. These are changed at any time during the study using them as expressed in the Key Functions point of this manual. Menu settings include less used equipment options and are used to customize the EKG machine for the user. The use of the Menu options is described in the manual under Keys and Menus, Menu part.

4.1 Keyboard Functions



- 1.- On / Off key
- 2.- Right Arrow Bypass Key
- 3.- Left Arrow Bypass Key
- 4.- Manual / Automatic / Rhythm Mode Selector Key
- 5.- Amplitude key
- 6.- File key
- 7.- Mv / Copy key
- 8.- Navigation Keys
- 9.- Alternating Current Presence Indicator
- 10.-Indicator of use with Internal Batteries
- 11.-Internal Battery Charging Indicator

4.1.1 On / Off

With the equipment off, pressing it turns on the equipment. If the equipment is on, press, when releasing the button the equipment turns off. The display shows a Warning during shutdown.

4.1.2 Right Arrow

In Manual Mode, it changes the lead or lead group.

4.1.3 Left arrow

En Modo Manual realiza el cambio de derivación o grupo de derivaciones.

4.1.4 Manual / Automatic / Rhythm

Change the way of use between Manual / Automatic / Rhythm respecting the settings of each mode.

4.1.5 Amplitude

Pressing this button changes the amplitudes of the trace, with each change of amplitude, before the cardiac recording draws a calibration signal. The change of amplitudes can also be done from the on-screen menu.

4.1.6 Mv / Copy

During a paper recording, pressing this button in Manual Mode records one mV according to the AMPLITUDE value being used during cardiac tracing. When not registering, pressing this button makes a copy of the last study carried out (if the equipment is turned off after carrying out the study, the possibility of making a copy of it is lost).

4.1.7 Paper Advance

In Manual Mode, when you press this button, it begins to print the configured leads, the paper advance is stopped by pressing a second time.

In Automatic mode, when you press this button, the study starts respecting its configuration. The study stops only at the end of the study.

In Rhythm mode, pressing this button starts saving the electrocardiographic signal depending on the configured mode. This Mode stops automatically when the study is finished printing.

4.1.8 File

By pressing this button you enter the menu of studies saved in the internal memory of the equipment. From here they can be edited, printed, viewed on the screen and transmitted to the PC through the communication port.

4.1.9 Navigation Keys

Menu settings include less used equipment options and are used to customize the EKG machine for the user. The use of the Menu options is described in the manual under Keys and Menus, Menu part.

To manage these Menus, the equipment includes two different ways. By means of the touch screen or the use of the navigation keys, these are made up of a group of 5 buttons Up, Down, Right, Left and Accept.

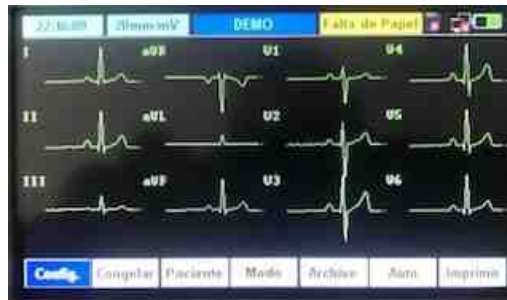
4.2 Menús

In the work screen we have three defined sectors.

An upper bar where system messages such as time, sensitivity, system messages, study status, equipment connection and the Battery status bar are placed.

A middle sector with the electrocardiographic signs and warnings for use.

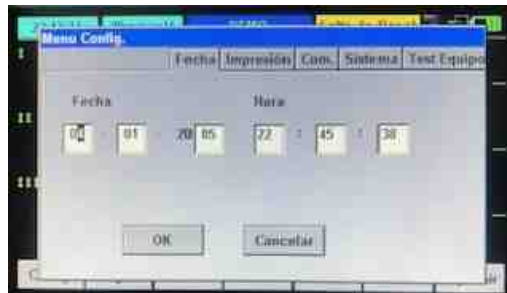
A lower bar with the Menu for the configuration of the equipment.



4.2.1 Setting

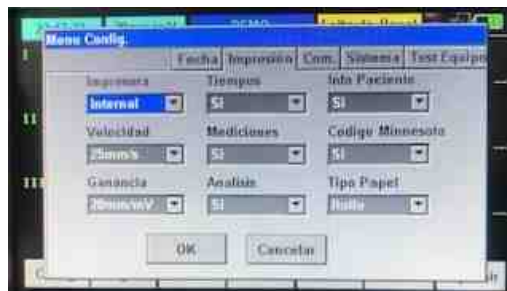
4.2.1.1 Date and Time

The screen displays the date and time for the use of the system. This will be important when reporting it in the printed studies and is part of the ID of the studies stored in the internal memory. It can be changed with the touch screen, with a numeric keyboard that is activated by touching on the parameter to be changed or with the Navigation Keys.



4.2.1.2 Print

The configuration of the report that will be printed is made on the screen. The options are as follows:



Printer: Yes / No. By accepting Yes, the study carried out is printed on paper by pressing Paper advance. With NO, the study is saved in the internal memory (this option must be enabled) and the study is not printed on paper.

Speed: Print speed is selected. The options are 5mm / s, 10mm / s, 12.5mm / s, 25mm / s and 50mm / s

Gain: The amplitude of the signal to be printed is selected. Options are 2.5mm / mV, 5mm / mV, 10mm / mV, 20mm / mV, and Automatic

Times: Yes / No. By accepting Yes, a time template is printed with the information of each lead and the measurement points.

Measurements: Yes / No. By accepting Yes, the time and amplitude values of the electrocardiographic signal are printed.

Analysis:

Patient Info: Yes / No. By accepting Yes, a template with the patient's data is printed at the end of the study.

Minnesota Code: Yes / No. By accepting Yes, the corresponding codes are printed at the end of the study.

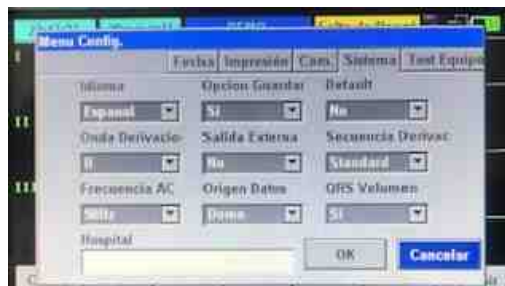
Paper Type: The type of paper to be used is selected, Roll or Ream

4.2.1.3 Communication

The communication ports are configured on the screen. The use of this Menu is reserved for technical personnel.

4.2.1.4 System

On the screen the configuration of the system of use is made. The options are as follows:



Language: Spanish / English

Lead Wave: The lead that will be used as the Rhythm channel is selected. All 12 leads are available.

AC frequency: 50/60 Hz

Save Option: Yes / No. By accepting Yes, the studies carried out are saved in the internal memory.

External output: Yes / No.

Data Source: ECG / Demo / External.

ECG enters data from patient

Demo is a temporary operating mode to simulate the operation of the equipment

External input signal from external source

Default: Yes / No. By accepting Yes, the base configuration is restored when the equipment is turned on again.

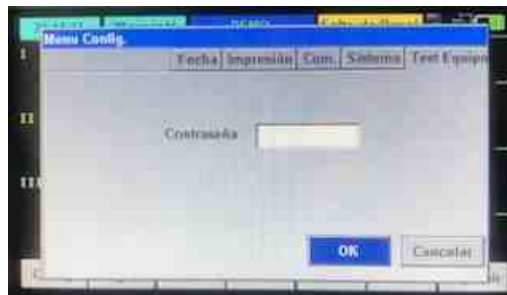
Derivation sequence: Standard / Cabrera

QRS Volume: Off / Yes. It emits a Beep with each detected QRS.

Hospital: In this window it is possible to enter the name of the institution conducting the studies. An alphanumeric keyboard will be present on the screen for entering it once the option has been selected.

4.2.1.5 Test Equipment

In this screen, tests of the equipment and future updates of the system are carried out. The use of this Menu is reserved for technical personnel.



4.2.2 Freeze

When activating this command, the input of the electrocardiographic signal to the screen is stopped, keeping the last ones available.

4.2.3 Patient

The screen is loaded with patient data to be printed in the study. This load is optional and in case of not loading data, a template is printed (if configured with the Yes option) to use as a guide in the manual filling of data.



The available fields are the following:

Name / Age / Weight / Gender / Medical / Height / Pressure / Pacemaker / Observations

The study ID is automatically generated in the format one digit of the month / two digits for the day / hour and minutes (taken when the equipment is turned on) / three digits of order

These data will be part of the study saved in the internal memory (if it is configured Save Study Yes).

At the end of the study, the data is automatically deleted.

4.2.4 Working mode

On the screen the configuration of the way in which the study will be printed is made. The options are as follows:



Working mode: Auto / Manual / Rhythm

Type: Select the type of report to print.

RG603		
Manual	Automatic	Rhythm
1 Channel 3 Channels	1x12 1x12 + Rhythm 2x6 2x6 + Rhythm 3x4	Rhythm 1 Rhythm 3

RG606		
Manual	Automatic	Rhythm
1 Channel 3 Channels 6 Channels	1x12 1x12 + Rhythm 2x6 2x6 + Rhythm 3x4 3x4 + Rhythm 6x2 6 + 3x2	Rhythm 1 Rhythm 3

Sampling Mode: Pre-Sampling / Real

Preview: Yes / No.

Low Pass Filter:

EMG Filater: Yes / No. By accepting Yes, the base configuration is restored.

DFT filter:

AC Filater: On / Off

Speed: Print speed is selected. The options are 5mm / sec, 10mm / sec, 12.5mm / sec, 25mm / sec. And 50mm / sec.

Gain: The amplitude of the signal to be printed is selected. Options are 2.5mm / mV, 5mm / mV, 10mm / mV, 20mm / mV, and Automatic

Take Time: Select the take time of each group of leads in a study performed in Automatic mode. The options are 2 sec, 3 sec, 4 sec, 5 sec, and 10 sec.

4.2.5 Memory File

In the Memory File screen we have three defined sectors.

An upper bar where the description of each column is placed, Order number / Name / ID / Date. The study ID is automatically generated with the format day / two digits of the month / hour and minutes (taken when the equipment is turned on) / three digits of order.

A middle sector with the file listing in memory.

A lower bar with the Usage Menu for internal memory management. The initial screen is as follows:

	Nombre	ID	Fecha
1	CARLOS SERAFINI	731093600	2020.07.31 09:30:45
2	MIGUEL GOMEZ	731094500	2020.07.31 09:47:21
3	-----	731095600	2020.07.31 09:59:40

Editar Imprimir Trans A SD Borrar Siguiente Regresar

Edit: It is possible to edit part of the patient's data

Print: Prints the selected study on paper under the current configuration of the equipment. To stop printing press again.

Trans: Transmits the selected study to the PC through the communication port. This operation has an acceptance screen.

To SD: Reserved

Delete: Delete the selected file, this operation has a confirmation screen.

Next: This goes to the next screen

Return: Returns to the main work screen.

The second screen contains the following commands:

	Nombre	ID	Fecha
1	CARLOS SERAFINI	731093600	2020.07.31 09:30:45
2	MIGUEL GOMEZ	731094500	2020.07.31 09:47:21
3	-----	731095600	2020.07.31 09:59:40

Antes Trans Todo Todo a SD Borrar Todo Pantalla Regresar

Before: Returns to the previous screen.

Trans All: Transmits all the studies to the PC through the communication port. This operation has an acceptance screen.

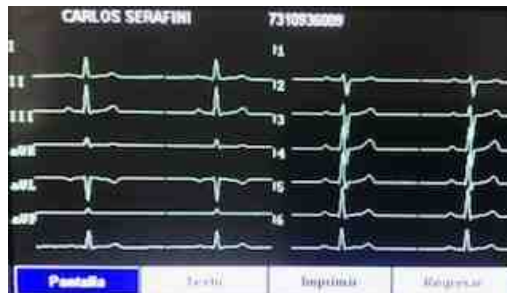
All to SD: Reserved

Delete All: Delete all files, this operation has a confirmation screen

Screen: Entering this screen we can see the study selected in the list of files.

Return: Returns to the main work screen.

In the screen option we can see the following:



Screen: It shows us the electrocardiographic signals of the selected study.

Text: It presents all the patient information and signal measurements of the selected study.

Print: Prints the selected study on paper under the current configuration of the equipment. To stop printing press again.

Return: Returns to the main work screen.

4.2.6 Manual / Automatic / Rhythm

Change the way of use between Manual / Automatic / Rhythm respecting the settings of each mode.

4.2.7 To print

In Manual Mode, pressing this button starts printing the configured leads, the paper advance is stopped by pressing 'a second time.

In Automatic mode, pressing this button starts the study respecting its settings. The study stops only at the end of the study.

In Rhythm mode, pressing this button starts saving the electrocardiographic signal depending on the configured mode. This Mode stops automatically when the study is finished printing.

5 User Mode

The machine has two different types of ECG setup modes, one through the use of shortcut keys and the second through the On-Screen Menu.

The shortcut keys are Mode, Span, and Memory Access. These are changed at any time during the study using them as expressed in the Key Functions point of this manual.

Menu settings include less used equipment options and are used to customize the EKG machine for the user. The use of the Menu options is described in the manual under Keys and Menus, Menu part.

5.1 Loading paper

Loading paper is a simple maneuver on the RG6XX Electrocardiographs. To load the roll you must:

- Open the printer compartment by pulling up on the side handles of the cover until it is unlocked.



- Remove the roll core from the printer compartment.
- Remove the core spindle from the old roll tube and place it on a new roll.
- Place the new roll with the roll core into the printer compartment keeping the print side down at the end of the paper roll.
- Lock the ends of the roll core in the internal notches of the compartment.
- Take the end of the paper roll with your fingers and remove about 5cm of paper.



- Close the cover by grasping the end of the paper with your fingers and pressing until it locks onto the printer compartment.
- Check that the paper is not misplaced (twisted, folded, wrinkled, etc.).

5.2 Patient Connection

The patient circuit is configured for the use of patient cables with up to 10 electrodes, with protection against defibrillation, with Connection Code No. 1 (usually European), as established in the IEC-60601-2-51 Ed1 standard.

To make the connection, you must:

- Conveniently position the patient in a comfortable position, lying down or sitting.
- Ensure that the patient is electrically isolated from ground. Check that there is no contact between the patient and any conductive surface that may be connected to ground or to some voltage level.
- Prepare the patient's skin to connect the electrodes, avoiding cross contamination. These areas must be clean, disinfected and free of impurities that may hinder driving (hair, grease, talcum, cloth, plastic, etc).

Connection diagram	Colour	Code 1	Electrode	Location
<p>Extremity Connection</p> <p>Detail of connections in the</p>	Red	R	Limb	Right arm
	Yellow	L	Limb	Left arm

Connection diagram	Colour	Code 1	Electrode	Location
Thorax	Green	F	Limb	Left leg
	Black	N	Limb	Right leg
	Red	C1	Suction	4th Intercostal space to the right edge of the sternum.
	Yellow	C2	Suction	4th Intercostal space to the left edge of the sternum.
	Green	C3	Suction	5th rib between C2 and C4
	Brown	C4	Suction	5th left intercostal space, left clavicle midline level.
	Black	C5	Suction	Left anterior axillary line at the horizontal level of C4.
	Violet	C6	Suction	Left mid-axillary line at the horizontal level of C4.

Respecting the diagram in the table, and using disposable gloves, place the forceps with the limb electrodes and the precordial electrodes in the corresponding positions on the patient.

Connect, respecting the diagram, the long tips of the patient cable in the corresponding electrode holder forceps (four), checking that the clamping screw is properly adjusted, and the short tips in the corresponding precordial electrodes (maximum six), sliding the pin on the pear and verifying that it is well adjusted.

The false contacts between the tips and the electrodes generate noise and instability in the ECG signals.

After connecting the tips of the patient cable over the precordial electrodes and the electrode holder forceps, discard the gloves.

Subsequently, connect the DB15 tab of the patient cable on the device's patient circuit connector, and tighten the fixing screws.

WARNING: Before connecting the electrols to the patient, make sure that the DB-25 tab of the patient cable is firmly screwed to the equipment, to prevent it from coming loose and carrying leakage currents to the patient.

WARNING: Only the patient cable models recommended by Cardiotécnica SRL, listed in the accessories chapter, should be used. The use of inappropriate patient cables can compromise patient safety.

WARNING: The connectors and accessible conductive parts of the equipment must not be improperly connected.

WARNING: Do not connect the patient, directly or indirectly, to the protective earth input of the equipment.

5.3 Conducting the Study

With the Patient connected and the Electrocardiograph configured according to the need, check that the patient's electrocardiographic signals are displayed on the equipment screen. The RG6XX Electrocardiograph system permanently controls the connection of the tips of the patient cable. When an electrode is disconnected, a visual and audible warning is issued, indicating the electrode to be repositioned.

In the event that the preamplifier is saturated due to some external condition, the equipment indicates INOPERABLE in the upper margin of the screen.

This condition is automatically corrected when the amplifier leaves saturation.

There are three modes of use Manual, Automatic and Rhythm. Each of these modes have the possibility of being configured according to the professional's need.

WARNING

In the event of external electromagnetic interference, it may happen that the display restarts, but the equipment will continue to operate without user intervention, or the display turns off so the operator must restart the equipment. When the equipment is restarted there is no risk to the patient or the user.

IMPORTANT

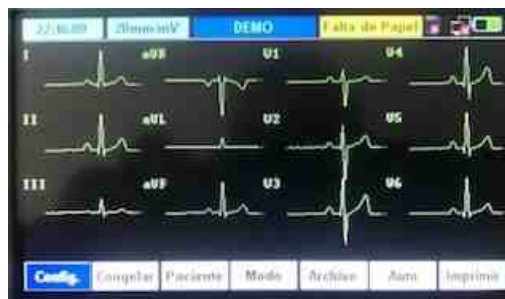
The information presented on the equipment screen is for guidance only. All measurements and analyzes must be performed on paper printing.

5.3.1 Turning on the Equipment

With the equipment off, pressing the On / Off Key turns the equipment on. After the splash screen, you automatically go to the work screen.

The equipment saves the last present configuration of the Amplitude, Speed, Filters and other work configurations. The EKG machine always turns on in Automatic Mode.

Work Screen



5.3.2 Manual Mode

The equipment turns on in the calibration bypass, with the patient connected to verify the presence of a signal on the screen. Check the Sensitivity, Speed and Filters settings.

Make a change of derivation or group of derivations with the Right Arrow Key, on the screen verify the change of derivation or group of derivations according to the number of channels to be printed.

Press the Run Key (paper advance) to print the same and with a second press stop the paper advance.

Repeat the operation for all the leads to be recorded in the study.

In this mode you can configure the number of channels to print

RG603: 1 and 3 channels

RG606: 1, 3 and 6 channels

Manual Mode Screen



The patient cable shows the connection status of the electrodes on the body.

When the cable is shown in Green, it means that it has good contact with the patient. In Red it appears when the electrode is Disconnected.



This sector of the screen shows us the value of Beats per Minute (BPM) at the moment, the heart indicates each detected beat.

5.3.3 Automatic mode

This mode performs a full survey by simply pressing the Run button. It is carried out with the number of channels configured in the equipment, respecting the selected taking time and at the end of the same it prints, in the case of being configured the Patient Data, the time templates and their values.

The different ways of printing are as follows:

RG603	RG606
1x12	1x12

1x12 + Rhythm 2x6 2x6 + Rhythm 3x4	1x12 + Rhythm 2x6 2x6 + Rhythm 3x4 3x4 + Rhythm 6x2 6 + 3x2
---	---

The equipment turns on in the calibration bypass, with the patient connected to verify the presence of a signal on the screen. Check the Sensitivity, Speed, Print Type, Shooting Times and Filters settings. Set the type of report to print with the different options.

Press the Run Key (paper advance) to start the study, after a few seconds of the process, the equipment will begin to print the leads, then the Time templates (if configured) and at the end the data form of the patient along with signal times (if configured). At the end of the study the paper advance stops and remains in the calibration bypass waiting for a new study.

If you need to stop the paper advance, press the Run key.

Auto Mode Screen



5.3.4 Rhythm Mode

The Rhythm Mode has two modes Rhythm 1 and Rhythm 3

Rhythm 1

When we press the Paper Advance button, it stores 60 seconds of lead II in memory, a countdown counter shows us the time. When the counter reaches 0, it automatically starts printing the 60 seconds stored in three lines.

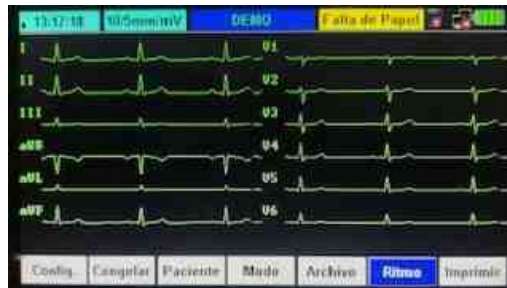
The upper one from 0 to 20 seconds. the average of 20 to 40 seconds. and the lower one from 40 to 60 seconds.

Rhythm 3

When we press the Paper Advance button, it stores 20 seconds of leads II, V1 and V5 in memory, a countdown counter shows us the time. When the counter reaches 0, it automatically starts printing the 20 seconds stored in three lines.

The upper 0 to 20 seconds of lead II, the middle of lead V1, and the lower one of lead V5.

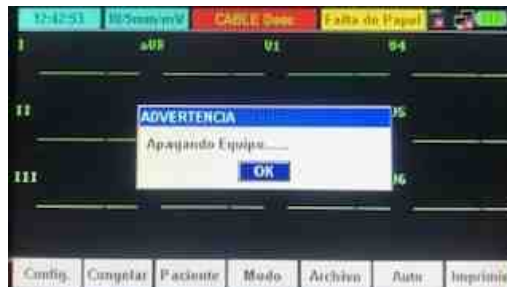
Rhythm Mode Screen



5.3.5 Equipment Shutdown

If the equipment is on when pressing the On / Off key, it starts a shutdown routine. The equipment can be switched off at any time.

The display shows a Warning during shutdown.



6 Accessories

The RG6XX Electrocardiographs must be used exclusively with the accessories listed below, or with the replacements determined by CardioTécnica SRL.

Accessories	Codes	Mark
Patient Cable for 10-Terminal Electrocardiograph (3mm tips)	VE-CTCN-134	CardioTécnica
Adult Limb electrode set X 4 units (Includes limb electrodes)	VE-CTAN-002	CardioTécnica
Adult Precordial suction Electrodes X unit	VE-CTAN-009	CardioTécnica
Mains Power Cable (3-terminal grounded plug)	VE-CTAN-018	CardioTécnica or Similar
Ground wire (optional)	VE-CTAN-019	CardioTécnica
Thermosensitive Paper 50mmX30m	VE-CTAN-047	CardioTécnica or Similar
Thermosensitive Paper 80mmX30m	VE-CTAN-042	CardioTécnica or Similar
RG603 paper holder spindle (width 50mm)	VE-CTAN-080	CardioTécnica
RG606 paper holder spindle (width 80mm)	VE-CTAN-081	CardioTécnica
Bag	CT-ECG-008	CardioTécnica

The use of accessories other than those recommended compromises the safety and effectiveness of the RG6XX Electrocardiograph.

In case you need to expand the technical information on the accessories recommended for use with the RG6XX Electrocardiographs, the request must be made exclusively to CardioTécnica SRL.

6.1 Patient Cable

The configuration of the connection of the patient cables, for the RG6XX Electrocardiographs, is compatible with the use of up to 10 tips, with Connection Code No. 1 (usually European), as established in the IEC-60601-2-51 Ed1 standard .

The patient cable consists of a double insulated, shielded trunk cable of up to ten copper conductors, with an impedance of 10K Ω , with a DB15 male connector with two fixing screws at one end and a distribution box for ends at the other end. ; and a set of tips at the patient end, of different lengths, provided with 3mm diameter pins, with the following coding:

The screen displays information on the connection status of the electrodes with the patient, this corresponds to the following list:

- BD long RED cable right arm
- BI long YELLOW cable left arm

- PD long cable BLACK right leg
- PI long GREEN cable left leg
- V1 short wire RED precordial capture electrode 1
- V2 short YELLOW wire chest capture electrode 2
- V3 GREEN short cable chest capture electrode 3
- V4 short cable BROWN chest capture electrode 4
- V5 short cable BLACK chest capture electrode 5
- V6 short cable VIOLET chest capture electrode 6

WARNING: Only the patient cable models recommended by Cardiotécnica SRL should be used. The use of inappropriate patient cables can compromise patient safety.

6.2 Ground wire

It must be built with a minimum cable of 0.75mm section, be green / yellow according to the standard and at the ends a male banana connector and a terminal for clamping the discharge.

6.3 Mains Power Cable

It must be built with a 3-terminal plug with standard grounding, cable of 3 x 0.75mm, standard colors.

7 Maintenance

To guarantee the correct operation and safety of the RG6XX Electrocardiographs, the Responsible Organization must respect and enforce the Cleaning and Disinfection, Preventive Maintenance and Corrective Maintenance guidelines, developed in this chapter.

WARNING

Supplies and / or spare parts that were not provided by CardioTécnica S.R.L. should not be used. since these invalidate the equipment warranty, transfer responsibility to the owner and professional entity involved, also altering the safety and effectiveness of the equipment, putting the operator and, above all, the patient at risk.

IMPORTANT: No technician is authorized, unless expressly authorized in writing by this company, to intervene technically in the equipment.

CardioTécnica S.R.L. will not be responsible for direct or indirect damages if the equipment is modified without the explicit consent of the company.

Any responsibility arising from the use and / or storage of the equipment outside of the environmental conditions indicated in the user manual is declined, as well as the consequences of the incorrect power supply that includes the lack of ground connection, verified by personnel. registration or use of parts and accessories not provided by CardioTécnica SRL

7.1 General care

The RG6XX Electrocardiographs must be stored in their original boxes with protective buffers.

Handling of equipment should be gentle; They must not be hit, nor subjected to efforts to environmental conditions that exceed the indications of the Environmental Conditions title of this manual.

Do not spill liquids on the equipment, immerse it, get it wet, or expose it to abrasive atmospheres.

Equipment must not be sterilized.

The RG6XX Electrocardiographs must be used on flat surfaces, in a stable position and with the appropriate accessories.

The RG6XX electrocardiographs must be powered from adequate electrical installations, or, failing that, be used by battery.

7.2 Cleaning and disinfection

The RG6XX Electrocardiographs should be kept clean and disinfected. The periodicity of cleaning and disinfection must be established, validated and managed by the Responsible Organization, taking into account at least daily use, work environment, and designated users.

Cleaning and disinfection of the RG6XX electrocardiographs must be carried out with clean

cloth or paper cloths that do not release lint or other material residues, and that do not scratch the surface of the equipment.

Before cleaning or disinfecting the RG6XX EKGs, you should:

- Power off the device from the front panel.
- Disconnect the detachable power cable from the fixed wall socket.
- Disconnect the detachable power cable from the base of the computer connector,
- Disconnect all accessories.
- Perform a visual inspection for bumps, scratches, and breaks on the cabinet, printer, screen, connectors.
- Gently rock and rotate the device looking for loose items inside.

To clean and disinfect the equipment and accessories you must:

- Clean the entire surface by rubbing with a cloth slightly dampened with a mild soap solution.
- Rinse off the remains of neutral soap with a cloth dampened with water.
- Dry the surface of the equipment with a dry cloth.
- Disinfect the surface of the equipment with a cloth dampened in isopropyl alcohol, or with a 70% ethyl alcohol solution, or with a quaternary ammonium disinfectant solution.
- Finally, let the disinfectant evaporate from the surface of the equipment.

7.3 Error Messages

Low battery	Indicates that the battery level has reached a point where it needs to be recharged	Connect the Equipment to the Mains. Check the Charge Indicator Led
Lack of Paper	The recorder does not detect paper.	Change the paper. Check the correct closing of the printer cover If the message is transitory, it is not necessary to change the paper
CABLE Desc.	Patient cable disconnected	Connect the patient cable to the equipment Check the Right Leg electrode contact
XX Desc.	Terminal XX of patient cable disconnected.	Check the contact of the electrode XX
Full Memory	The number of studies stored in the internal memory is greater than 100.	Delete the contents of Memory totally or partially
Password	Secure login screen	Enter Password

Password Error	The password entered is wrong	Enter Password
Please check cable connection and software	Unable to transfer files to PC	Check serial cable connection Verify software installed on PC
Warning	This always indicates paying attention	Verify the step to be carried out
DEMO	The equipment is working with internal signals for demonstration	Turn the equipment off and on again
CONNECTION STOPPED	It can be the consequence of a cut in the internal communication between devices.	Resets without operator intervention

7.4 Reviews to be performed by the operator

The check to be carried out by the operator is important before putting the equipment into operation. The operator must be adequately trained for this role. In the checkup you must:

- Check equipment for mechanical and functional damage.
- Check the mains power cable, check its insulation.
- Check the patient cable for signs of breakage.
- Check the limb electrodes, they should be clean and without apparent breakage.
- Check the chest electrodes, they must be clean and without apparent rupture.
- Check the mains voltage and that the connector is working correctly.
- Check the battery charge status.
- Check the functions of use.
- Check that the equipment works correctly as described in the instructions for use.

7.5 Periodic Safety Reviews

The safety check must be carried out at least every 12 months by qualified personnel, adequately trained with practical experience in revision tests and authorized by Cardiotécnica SRL. In the checkup, you must:

- Check equipment and accessories for mechanical and functional damage.
- Check your relevant security levels.
- Inspect the fuses and check for signs of degradation.
- Check the functions of use periodically.
- Check that the equipment works correctly as described in the instructions for use.
- Verify earth pole protection according to IEC 60601-1 standards.
- Carry out an earth protection resistance test according to IEC 60601-1 standards:

0.1Ω limit.

- Perform a current earth leakage test in accordance with IEC60601-1
- Carry out a patient leak test according to IEC60601-1: limit 10μA (CF)
- Carry out a patient leak test under a single fault condition with main voltage on the applied part according to IEC60601-1: limit 50μA (CF)
- The current leakage during the tests must not exceed the limits. The data must be measured correctly.
- If the equipment does not function properly or fails any of the above tests, it must be repaired.

7.6 Preventive Maintenance

The Responsible Organization must manage the preventive maintenance of the RG6XX Electrocardiographs in periods not exceeding 12 months.

The preventive maintenance of the RG6XX Electrocardiographs must be carried out exclusively by companies, or persons, authorized by CardioTécnica SRL.

7.7 Corrective maintenance

The Responsible Organization must prevent the use of the RG6XX Electrocardiographs and manage corrective maintenance, whenever:

- an inappropriate activity or response of the functions is detected,
- the battery charge lasts less than expected,
- the computer keyboard, printer, or display does not work,
- liquid is spilled on the equipment,
- the equipment falls from a height greater than 50cm, suffers blows or rough handling,
- The cabinet, keyboard, display, printer, connectors, or other components break,
- noises are heard from possible loose parts inside the equipment,
- the equipment is exposed to environmental conditions of use, transport or storage that exceed the indications of Section 1.3,
- the equipment is connected to an inadequate power supply,
- the USB port or patient circuit connector is improperly connected, or malfunction is suspected,

The corrective maintenance of the RG6XX Electrocardiographs must be carried out exclusively by companies, or persons, authorized by CardioTécnica SRL.

7.8 Problem solving

7.8.1 Patient Cable Problems

There is no cardiac signal, it is saturated.	Check that all electrodes have good contact with the Patient, wait for the signals to reestablish and then start printing.
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There is no cardiac signal, it shows a straight line.	Verify that the electrode, metallic part, is in contact with the body correctly; otherwise, adjust the electrode position to the patient.
	Check if the limb electrodes and chest electrodes are rusty or discolored, clean them or replace them with new ones. Oxidation and aging cause conductive deterioration of the electrode foil, resulting in poor signal transmission.
	Clean the patient's skin with alcohol; Especially in winter, dry skin causes the resistance of the skin to enlarge, which will affect the signal taking.
	Clean the patient cable tips, chest electrodes, and limb electrodes, then reinstall. After prolonged use, the contacts become dirty or loose, which will lead to poor signal transmission.
	Check the appearance of the patient cable, if it has an obvious fracture replace it with a new patient cable. If the waveform is stable, the patient cable has problems and should be replaced.
	If you do not have a patient cable available, check if the terminal leads are conducting using a multimeter. If the lead wires have a problem, contact our service department to replace the patient cable.
	La otra razón de la falla puede ser interna. Primero, excluya las anteriores causas y luego comuníquese con nuestros técnicos de servicio si es necesario.

7.8.2 Printer Problems

Unclear print	When a printer failure occurs, such as poor or incorrect ECG printing, you can try cleaning the thermal printer head with a soft cotton swab moistened with medical alcohol.
	Check if the quality of the thermal paper is poor or if it is out of date. Replace the recording paper.
	If above is not applicable, guide the user to test the

	print head and check if the print head is broken. If so, contact the company's service department to replace the thermal print head.
The top half or the bottom half is blank.	Check whether the bearing at both ends of the paper compartment cover rubber shaft is worn and replace with a new bearing if it is.
The print on the paper or most of it is blank.	Make sure the thermal recording paper is not installed upside down.
	Check if the print head is heavily dirty (such as tape); this often happens when a new recording paper is replaced.

7.8.3 Problems with the keyboard

If a failure occurs in the Keypad, maintenance personnel can locate the failure.	Keyboard failure is likely due to a loose connection between the keyboard panel and the system control board due to shock or vibration during shipping. If necessary, a professional service engineer will disassemble the ECG machine and reconnect the inner cable.
	Check the keyboard, the keys may be bad from aging.

7.8.4 Alternating Current Interference

The apparent regular tremor of the ECG waveform in the AC interference print is shown below.



The causes of baseline deviation are varied, please check the following one by one:

- 1.-Make sure that the EKG machine is properly grounded according to the instructions.
- 2.-Make sure that the lead wires or electrodes are connected correctly.
- 3.-Make sure the electrodes and the patient's skin have been cleaned and covered with ECG gel.
- 4.-Make sure the examination bed is properly grounded.
- 5.-Make sure that the patient is not in contact with the wall or the metal part of the bed.

6.-Make sure the patient is not in contact with anyone else.

7.-Make sure there is no high-powered electrical equipment (such as an X-ray machine, an ultrasound scanner, etc.) operating nearby.

ATTENTION

Set the AC filter to YES, when AC interference still exists after completing the above checks.

7.8.5 EMG interference

Below is an irregular shaking of the ECG waveform due to EMG interference.



The causes of deviation from the baseline are varied; Perform the following checks one by one:

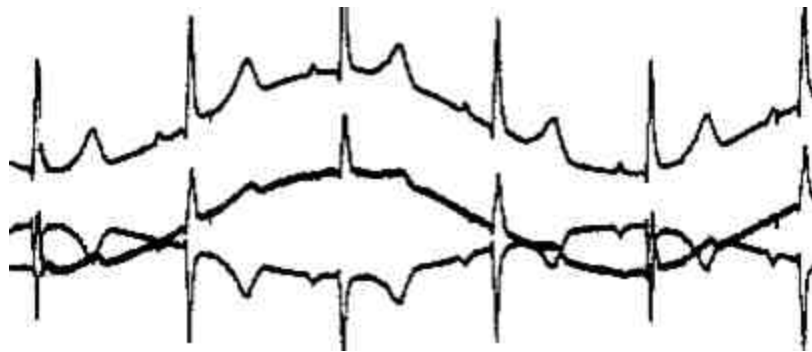
- 1.-Make sure the exam room is comfortable for the exam.
- 2.-Calm the patient from irritation or excitement.
- 3.-Make sure that the examination table is the correct size.
- 4.-Never talk to the patient during the ECG.
- 5.-Make sure that the electrode of the extremities is not too tight, this will make the patient feel uncomfortable.

CAUTION

Set the EMG filter to a lower value if the interference still exists after the above checks are completed, and note that the recorded ECG waveform, particularly the R wave, will attenuate a bit.

7.8.6 Baseline Deviation

The irregular movement of the ECG baseline due to baseline drift is shown below:



The causes of baseline deviation are varied, please check the following one by one:

- 1.-Make sure that the electrodes are in good contact with the skin.
- 2.-Make sure that the connection between the patient cable and the electrodes is normal.
- 3.-Make sure that the electrodes are clean and that the patient's skin in contact with the electrodes has been well treated beforehand.
- 4.-Make sure the electrodes and skin are covered with ECG gel.
- 5.-Keep the patient silent and immobile and prevent the patient from moving.

CAUTION

If the problem still cannot be solved, please turn up the baseline jitter filter, note that the recorded ECG waveforms, particularly the T wave and the ST segment, will be somewhat distorted.

7.8.7 Electrocardiograph Won't Turn On

AC power is not working properly or the battery is depleted.

- 1.-First check if the power outlet is properly connected.
- 2.-Verify that the local mains supply voltage is normal.
- 3.-If all the above is correct, check that the fuses are in good condition.
- 4.-If everything is normal after the previous examinations, send the equipment to the manufacturer for repair, as it may be damaged.

After turning on, the machine turns off automatically after a few minutes. While you are using the computer with an internal battery, but the battery power is insufficient, the computer will

turn off automatically.

- 1.-Connect the mains power to the equipment or charge the battery before working.
- 2.-If the user is using mains power and the equipment still turns off automatically, check the previous steps.

7.8.8 Incorrect Results

For the case of some special populations (such as pregnant women, vascular drug users, etc.) or mixed by obvious interference in the recording process, the result of the resting ECG analysis of this ECG machine may be inaccurate. The possible reason may be the following:

- 1.-Bad contact between the electrode and the patient's skin, caused by an inadequate treatment of the skin and an incorrect connection.
- 2.-The patient performs relatively large movements in the study process.
- 3.-Patient data was not completely entered.
- 4.-If there is too much interference from AC, EMG and respiration, the identification of the P and Q waves is sometimes not reliable enough.
- 5.-If there is slow fluctuation in the baseline, the identification of the ST segment and the T wave is sometimes not reliable enough.
- 6.-If the QRS complex has low voltage, it is possible that the R wave is lost and that the measurement of the electrical axis and the identification of the QRS division point may not be sufficiently reliable.
- 7.-If a frequent ventricular contraction occurs or various arrhythmias merge, the relevant detection parameters may not be reliable.
- 8.-The filter settings are incorrect.

Solution:

- 1.-Prepare the patient again and wait until the waveform is stable before retesting.
- 2.-Enter correctly all the patient's information.
- 3.-Reduce the interference according to the methods described in the point Alternating Current Interference, EMG Interference and Baseline Deviation before re-analyzing.
- 4.-Configure the filters appropriately.

8 Technical specifications

Safety standards met by the equipment	IEC60601-1, IEC 60601-1-4, IEC60601-2-25, EN 60601-2-51, EN ISO14971
	Class I with internal batteries.
	Type CF with Defibrillation Protection
AP Category.	NO
APG category	NO

Dimensions	270mm×205mm×65mm		
Weight	1.9kg aprox		
Display	4.3 "color TFT screen		
Atmosphere		Transportation and Storage	Use
	Temperature:	-10°C~70°C	5°C~40°C
	RH:	10%~95%	25%~95%

8.1 Performance Specifications

Printing machine	Registration method	Thermal printing of 8puntos/mm
	Paper:	Roll of 50mm x 30meters (RG603) Roll of 80mm x 20 meter (RG606)

	Effective width:	RG603 - 47mm RG606 - 72mm
	Paper speed:	5mm/s, 10mm/s, 12.5mm/s, 25mm/s, 50mm/s (±3%)

Detección BPM	Technique:	Peak Detection	
	BPM range:	30 BPM ~300 BPM	
	Precision:	±1BPM	
ECG	Derivations:	12 (I-II-III-aVR-aVL-aVF-V1-V2-V3-V4-V5-V6)	
	Acquisition mode:	12 Simultaneous Derivations	
	A / D resolution:	16 bits	
	Time constant:	≥3.2s	
	Sampling Rate	1000 samples/s per channel	
	Frequency response:	0.05Hz ~ 150Hz	
	Sensitivity:	2.5, 5, 10, 20 (mm/mV)	
	Input Impedance:	50M Ω (10Hz)	
	Input Circuit Current:	≤50nA	
	Input Voltage Range	<±5 mVpp	
	Calibration Voltage:	1mV±3%	
	Noise:	<15 μVp-p	
	Filters	AC Filter:	Si/No
		DFT Filter:	0.05/0.15/0.25/0.5
EMG Filter:		25Hz/35Hz/45Hz/Apagado	
Low Pass Filter:		150Hz/100Hz/75Hz	
CMRR		>100dB	
Patient leakage current:		<10,μA (220V~240V)	
Defibrillation protection			

Filters for transients, against electrostatic discharge, fast electrical transients and bursts, conducted disturbances and electrosurgical interference

Patient auxiliary current:	<0.1 μ A (DC)
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Dielectric strength:	4000V rms
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Communication Port	Serie RS232
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8.2 Maker

Maker: CARDIOTÉCNICA SRL
Av. Reservas Argentinos 443 - (C1408All) - CABA - Argentina.
Tel/Fax: 5411-4643-9436 / 5411-4643-9482
web: www.cardiotecnica.com.ar
E-mail: info@cardiotecnica.com.ar
Electrocardiograph: RG-603, RG-606, RG-601PC, RG-601PCergo.
AC Input: 110/220V~ 50/60Hz - Rechargeable battery 11,1V-2,2A - Power 35VA
Authorized by the **ANMAT - PM-1230-13**
Exclusive use for professionals and Health Institutions.

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