

Cardionica

USER MANUAL



Thank you for choosing
a **MIR - Medical International Research** - product

Keep the original packaging!

If your product has a problem, use the original packaging to ship it back to your local distributor or the manufacturer.

Follow the rules below to return the product for repair:

- ship the product in its original packaging;
- shipping costs are borne by the sender.

Manufacturer's address:

MIR– Medical International Research S.p.A.:
Viale Luigi Schiavonetti 270
00173 ROMA (ITALY)

Tel ++ 39 0622754777

Fax ++ 39 0622754785

Website: www.spirometry.com

Email: mir@spirometry.com

MIR pursues an improvement policy to continuously evolve the technology of its products. That's why MIR reserves to update these user instructions if needed. Please email any suggestions to: mir@spirometry.com.

MIR cannot be held responsible for any damage caused by users failing to follow these instructions and/or the warnings contained in this manual.

Please note that, due to printing limitations, the images contained in this manual may differ from the actual device. It is prohibited to copy this manual in whole or in part.

TERMINOLOGY USED IN THIS MANUAL

WARNING: Indicates a potentially hazardous situation that could result in severe injury if not prevented.

CAUTION: Indicates a potentially hazardous situation that could result in minor or moderate injury if not prevented.

ATTENTION: Indicates caution when using and servicing the device to prevent failures.



SUMMARY

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1. CONTENT DESCRIPTION

1 device, 1 CR2032 battery, 2 reusable electrodes, 1 user manual.

<p>Description of product Cardionica is a device for detecting atrial fibrillation from a single-lead electrocardiogram (ECG). Cardionica uses a CR2032 battery</p>	
<p>Cardionica is placed on the chest through an adhesive electrode.</p>	
<ul style="list-style-type: none"> A. Device B. Reusable electrode for personal use C. Green light indicator: presence of sinus rhythm (normal) D. Orange heart indicator: presence of bradycardia or tachycardia E. Red light indicator: presence of atrial fibrillation F. Orange light indicator (repeat): impossible to make a diagnosis. Repeat the measurement G. Power switch H. Battery hatch 	

Cardionica records a **1-minute single-lead electrocardiogram**. At the end of the recording, it provides the results through the **light indicators**.

OK

When the green indicator lights up, it means that Cardionica has not detected atrial fibrillation.



When the red broken **heart** indicator lights up, it means that Cardionica has detected atrial fibrillation



When the orange indicator (repeat) lights up, it means that the electrocardiogram cannot be done. **Repeat the measurement**



The **orange heart** indicator lights up when the device has not detected atrial fibrillation but the heart rate is below 50 beats per minute or above 100 beats per minute.

Cardionica can be used by adults as a screening method for atrial fibrillation, people with an atrial fibrillation history, or people with symptoms like palpitations and tachycardia to periodically check the presence of atrial fibrillation.

**WARNING:**

Cardionica detects only atrial fibrillation. It does not detect other life-threatening arrhythmias. The atrial fibrillation detector checks the presence of fibrillation only during the recording. It does not monitor the heart activity continuously. Therefore, it cannot warn you if you experienced atrial fibrillation in the past or will do in the future.

2. INDICATIONS FOR USE

Cardionica records, stores and transfers a single-channel electrocardiographic (ECG) trace. Cardionica also displays the result of ECG analysis, detecting the presence of normal sinus rhythm, atrial

fibrillation, bradycardia, tachycardia and more. Cardionica can also display the ECG when used in conjunction with a smartphone/tablet. Cardionica is intended for use by healthcare professionals, patients with known or suspected heart disease and health-conscious individuals. The device has not been tested and is not intended for paediatric use (older than 18 years).

MIR066 can be used in hospital setting, physician's office, pharmacy, and home.

3. COUNTERINDICATIONS

Cardionica **must not be used** in the following cases:

- children and pregnant women.
- patients with implanted pacemakers or defibrillators.

The electrode **must not be used** in the following cases:

- patients with known allergies to adhesive materials or hydrogels.
- In the presence of wounds, injury, or irritated skin on the application area.

4. SAFETY PRECAUTIONS



WARNING:

- This device must not be used near water or in a humid environment
- Do not use this device in places where temperature and humidity do not fall within the range indicated in the product's label.
- Do not sterilise the device.
- Audio, video, and similar electronic equipment can interfere with Cardionica's operation. Stay away from this equipment during the recording.
- Do not record in places where the device is exposed to intense electromagnetic fields, e.g., near arc welders, high-power radio transmitters, etc.
- Do not make sudden movements or record from moving vehicles.
- Do not expose the device to strong impact or vibrations.
- Do not dismantle, repair, or modify the device.
- Do not record if the electrodes are dirty or have lost adhesion.
- Do not use the device for purposes other than those indicated in this manual.
- The recordings may fail if the electrode is applied to an area with a large amount of fat, hair, or dry skin.
- Use the device only on intact skin.

5. CLEANING, STORING, AND SERVICING THE DEVICE

Cardionica doesn't need to be disinfected. Clean Cardionica when needed using a damp cloth and soap.



WARNING: do not use the same electrodes on different persons to prevent cross-infection and disease transmission between users

Store Cardionica and its accessories in its case, avoiding:

- Places exposed to direct sunlight
- Places subject to high temperature or humidity
- Next to fire or naked flame
- Places exposed to strong vibrations
- Places exposed to intense electromagnetic fields.

WARNING

This system doesn't need maintenance. However:

Before every use, check the condition of the electrodes. Replace the electrode if dirty or has lost adherence.

Do not use the same electrodes on different persons to prevent cross infection and disease transmission between users.

5.1 REPLACING THE BATTERY

Replace the battery when you hear the low battery signal upon activation:

1. Remove the battery hatch by rotating it anticlockwise while pressing it firmly



2. Remove the battery and replace it with a new cr2032 3v button battery.



3. Face the positive terminal upwards so you can read the code. Remove the protective adhesive (if present)



4. Close the hatch. Remember that the battery hatch can be inserted only from one side and must be rotated.



6. WARNINGS

- Cardionica does not provide a complete diagnosis of cardiac conditions. It must never be used as a base for starting or modifying the therapy without consulting the physician.
- This device does not analyse all heart rate and cardiac waveform aspects, especially if related to ischemic conditions.
- Do not make a diagnosis or prescribe or change a therapy based only on the analysis results. Self-diagnosis and self-treatment can compromise health.
- Users can always consult their physician if they notice health changes.
- Do not use the device in the presence of flammable anaesthetics, medicines, or pressurised oxygen (e.g., in a hyperbaric chamber, ultraviolet steriliser, or an oxygen tent).
- Do not use this device during MRI exams, medical or aesthetic treatments involving electromagnetic fields.
- Keep the device out of reach of children and persons unable to use it properly.
- This device has not been tested and it is not intended for pediatric use.
- Do not use defibrillators on patients wearing a sensor. The sensor is not protected from defib discharges. Defibrillators can cause sensor malfunction and injure the patient.
- Communication devices, such as mobile phones, WIFI systems, or portable radio transmitters can interfere with Cardionica's operation. These devices must stay at least 30 cm away from Cardionica when in use.

**WARNING:**

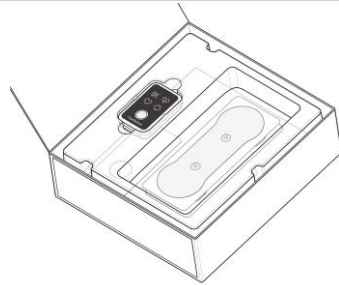
Cardionica cannot ensure that no arrhythmias or other health problems occur when an ECG is labelled as normal. Immediately inform the physician about your possible health changes.

**WARNING:**

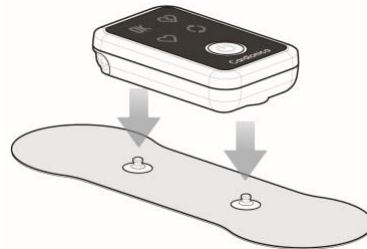
Report any serious accident involving the device to the manufacturer and the competent authority where the user/patient is established;

7. USING CARDIONICA

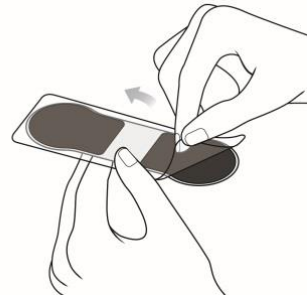
1. Open the box and check its content.
Contact MIR if the content differs from the list in section 1.



2. Apply one of the supplied electrodes to Cardionica without removing its protective film.



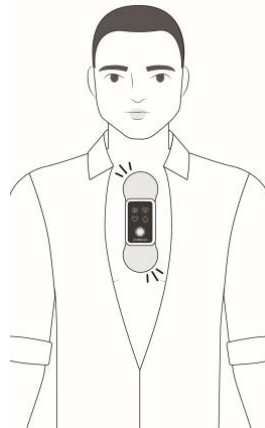
3. Remove the protective film only after having applied the electrode to Cardionica.



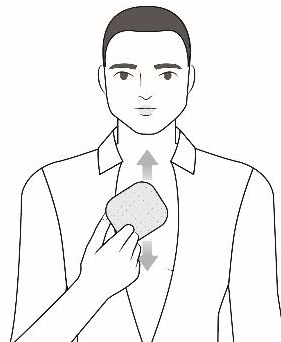
4. Sit down and apply Cardionica to the chest.



5. Make sure that the electrode adheres to the skin.



6. If necessary, clean the skin using a cloth dampened with ethyl alcohol.

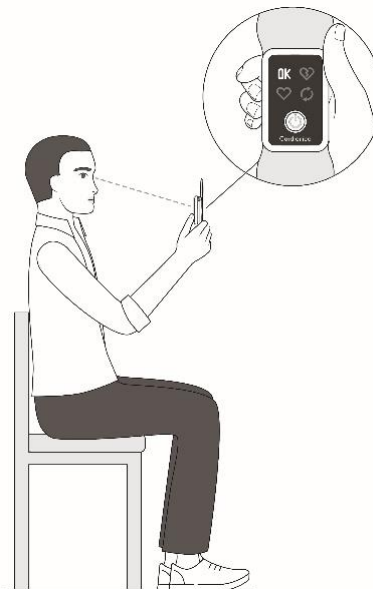


7. To ensure correct positioning, follow the instructions provided in section “Positioning Cardionica on the chest”.

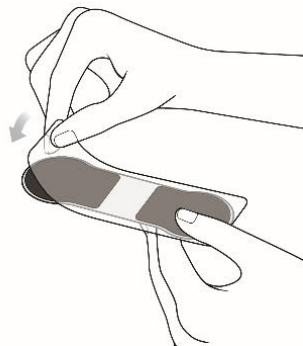
8. Press the button and wait for the exam to be complete.



9. Remove Cardionica from the chest when you hear the buzzer. Watch the light indicators .



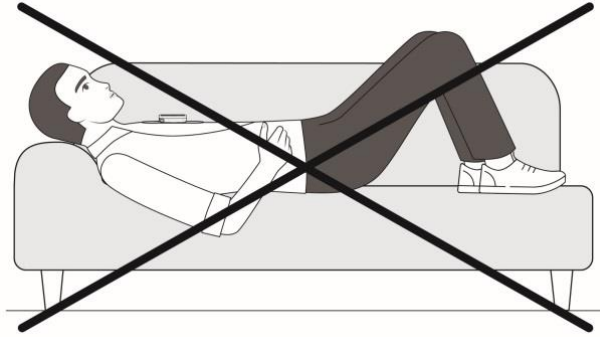
10. Apply the protective film on the electrode and place Cardionica back into its case. It is not necessary to remove the electrode from Cardionica



⚠ WARNING:

Use only the electrodes indicated in this manual (see section 14. Technical Specifications). Using electrodes other than those supplied or indicated in this manual can be a source of danger. Contact the manufacturer if in doubt.

ATTENTION: Always sit down when using Cardionica. Cardionica does not start the test if you are lying down.



ATTENTION: if you always apply the protective film to the electrodes and use them correctly, they can be used for 30 applications or stored for 6 months. Before every application, clean the skin with water and soap. Before and after each use, Apply some water (not much) to the electrode's adhesive part.

ATTENTION: replace the battery if you hear a sound that gradually fades when you press the button.



WARNING:

Do not use Cardionica in the presence of signs of damage. It can cause electrical discharges or reduce the quality of the acoustic signals.

8. USING CARDIONICA VIA APP

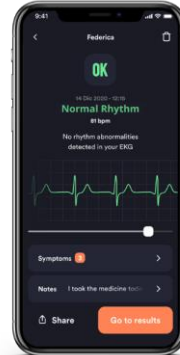
You can also use Cardionica on your smartphone or tablet.

<p>Download the Cardionica app (developed by MIR) from Play Store (Android 5.0 onwards), or Apple Store (iOS 9.0 onwards). You cannot install the app on incompatible devices.</p>	
<p>Start the app, press Cardionica's power switch and make sure that it's connected to your smartphone.</p>	
<p>Use the ECG start tab on the app or Cardionica's power switch</p> <p>During the test, you can see the ECG tracing, heart rate, and the remaining seconds</p>	

The app also allows you to stop the test by scrolling upwards and clicking the “Stop Test” button



Once the ECG recording is complete, the app displays the result with the same indicators described in section 8. The test result is also displayed on the device. The app shows the heart rate in beats per minute (bpm). It also allows you to add symptoms (if any) and notes



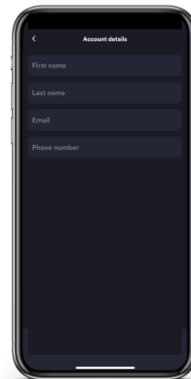
Furthermore, you can view the list of tests made by clicking the “Results” tab
By clicking a test, you can view the tracing



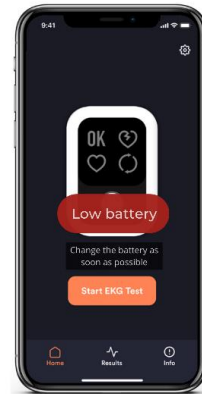
Another option is to associate a name to the tracings by clicking the settings icon ⚙️.

⚠️ WARNING

If the device is used on different persons, it's important to associate its name to the exam to prevent identification errors.

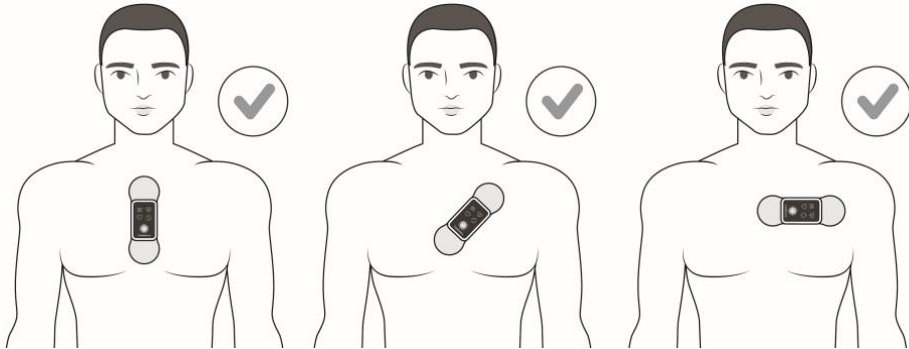


If the device has a low battery, the app displays the "low battery" message

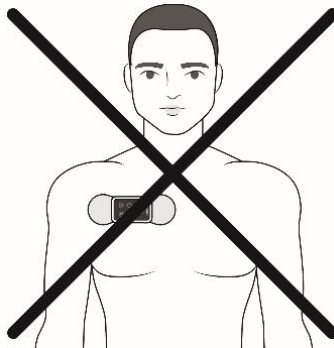


9. POSITIONING CARDIONICA ON THE CHEST

Correctly position Cardionica on the chest to have reliable measurements. Refer to the positions shown below:

**WARNING:**

Using Cardionica in different positions from those indicated can affect the test result.



10. INDICATORS (ATRIAL FIBRILLATION, NORMAL HEART RATE, NON-INTERPRETABLE RECORDING)

Cardionica provides an interpretation of the heart rate through a code and a buzzer, as described below:



The red heart indicator lights up if Cardionica detects atrial fibrillation in the ECG tracing (irregular heart rate and no P waves)



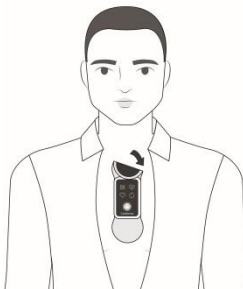
The orange heart indicator lights up when the Cardionica has not detected atrial fibrillation in the ECG tracing but has measured a heart rate lower than 50 bpm or higher than 100 bpm.



The orange indicator (repeat) lights up when Cardionica fails to interpret the ECG tracing.

This problem could be due to:

- Poor contact between the electrodes and skin.
The most common causes are:
 - Hair abundance.
 - Dirty electrode or no longer adherent.



- Incorrect position of Cardionica on the chest
- The person has moved while using Cardionica
- Presence of other arrhythmias.

TAKE APPROPRIATE ACTION AND REPEAT THE MEASUREMENT.

OK

When the green indicator lights up, it means that Cardionica has not detected atrial fibrillation.



WARNING:

Cardionica detects only the presence (or absence) of atrial fibrillation (AF). It does not detect other life-threatening arrhythmias. The green light indicator doesn't exclude the presence of other arrhythmias or ECG modification.

11. WHAT TO DO IF CARDIONICA DETECTS ATRIAL FIBRILLATION



WARNING:



If Cardionica detects atrial fibrillation (red heard indicator), we recommend repeating the measurement after a few minutes. If the result is confirmed, you're likely experiencing an atrial fibrillation episode.

Refer to your physician or go to a healthcare facility. In most cases, atrial fibrillation doesn't require emergency treatment, nor is it life-threatening. However, it must be diagnosed and treated as soon as possible.

12. DATA SECURITY WARNINGS

The smartphone stores the user's personal data.

Potential threats such as the following:

- Malware installation
- Physical access to the smartphone
- Interception of communications
- Physical damage to the smartphone
- Theft of the smartphone could have an impact on the integrity or confidentiality of such data, such as:
 - Accessing of data in memory by unauthorized persons
 - Loss of data in memory
 - Inability to use smartphone for communications
 - The integrity check of the data is made automatically and in case of transmission error it will create a corruption of the data and the file will be illegible.

The following actions help reduce the risk of such events:

- Do not open or install files from suspicious sources
- Use antivirus software
- Back up your data periodically
- Do not leave your smartphone unattended
- Use a password to access the data
- Always check that the data used to send the results of the tests are correct

13. DISPOSAL

Never dispose of Cardionica as household waste. Its components must be disposed of correctly and recycled in compliance with the regulations in force.



Dispose of Cardionica in compliance with current WEEE (Waste Electrical and Electronic Equipment) regulations

14. TROUBLESHOOTING

Problem	Possible cause	Solution
A few seconds after the recording, the “repeat” indicator lights up	The contact between electrodes and skin is incorrect. The most common causes are: <ul style="list-style-type: none"> • damaged electrode (dirty or poorly adherent) • Hair abundance • Dry skin 	<ul style="list-style-type: none"> • Replace the electrode with a new one • Shave the area • Dampen the part with water
After pressing the power switch, all the indicators blink 10 times	<ul style="list-style-type: none"> • Hardware error 	Contact the manufacturer
After pressing the power switch, all the indicators blink 5 times	The last recording wasn't saved	You can keep using the device.

15. TECHNICAL SPECIFICATIONS

ECG lead:	Single lead
Input differential range	±6.25 mV
Memory storage	100 ECG
Frequency response	0.167 Hz to 30 Hz
Common mode rejection ratio	100 dB @50Hz
DC offset correction	±300 mV
Input impedance	> 10 MOhm
Sampling rate	250 S/s
Resolution	18 bit; 0.048 uV
Battery type:	CR2032
Battery life:	> 300 uses or 2 years
Dimensions:	5.7*3.7*1.5 cm
Weight:	20 g
Operating temperature:	+5°C ~ +40 °C
Operating humidity:	15%~90% (non-condensing)
Operational altitude:	< 3000 m
Storage temperature:	-25°C ~ +70 °C
Storage humidity:	15%~90% (non-condensing)
Operation type	Continuous
Electrodes	Reusable electrodes for personal use (REF 912004) Device class IIa (Regulation (EU) 2017/745 for medical devices)
Emission limits	CISPR 11 – Group 1 Class B
Electrostatic discharge protection	8kV contact, 15kV air
Magnetic field immunity	30 A/m
Radio Frequency Immunity	10 V/m @ 80-2700 MHz
Degree of electrical protection	BF














ATTENTION: If stored correctly, Cardionica can last 5 years.

16. APPLICABLE REGULATIONS

Cardionica meets the following regulations for the parts applicable to it:

- EN 60601-2-47:2012 -Medical electrical equipment - Edition 2.0 2012-02 Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems.
- EN 60601-1:2006/A1:2013 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- EN 60601-1-2:2015 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- EN 60601-1-6/A1:2015 Medical electrical equipment Part 1: General requirements for basic safety and essential performance - Collateral standard: Usability.
- EN 60601-1-11:2015 Medical electrical equipment Part 1: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
- EN 62304/A1:2015 - Medical device software - Software life-cycle processes.
- EN 62366-1:2015 Part 1: Application of usability engineering to medical devices.
- ISO 14971:2019 Medical devices – Application of risk management to medical devices.

17. SYMBOLS USED

	BF type part applied		Manufacturer's name and address
	Attention		Separate disposal. Comply with the local regulations in force for disposing of equipment subject to directive 2012/19/EU
	Follow the user instructions		Storage and transport temperature
	Medical device		CE symbol and Notified Body number 0476 This device complies with Regulation (EU) 2017/745 for medical devices
IPN1N2	IP rating (solids and liquids)		Product code
	Date of manufacture		UDI (Unique Device Identification)
	Keep away from sunlight		Keep away from rain/keep dry