

PERSONAL

CardionicaTM

Medical-grade portable single-lead EKG.

Ideal for heart rhythm check, for the detection of atrial fibrillation, tachycardia, bradycardia and for stroke prevention



MAIN features



1 MINUTE TEST

Track your heart rhythm in one minute, everywhere you are and with the accuracy of a clinical setting.



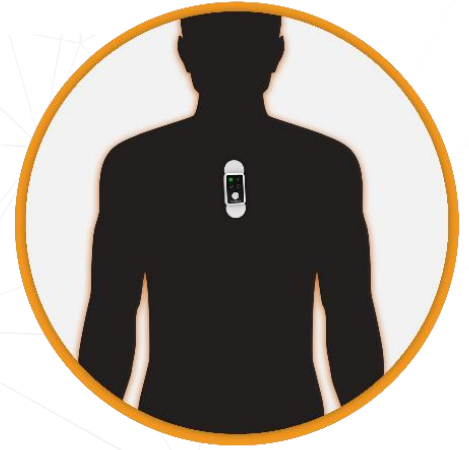
REAL-TIME EKG

Immediate detection of possible arrhythmias: atrial fibrillation, bradycardia, tachycardia.



REUSABLE ELECTRODE

The native sensor for EKG. 4X always included. Replacement can be purchased separately.



DISTINCTIVE features



FIRST OF ITS KIND

Use it in Stand-Alone or Connected with your Smartphone.



2020 ESC Guidelines for AF

EKG analysis in line with 2020 AF guidelines (ECG, P-wave, RR irregularity).



CERTIFIED ACCURACY

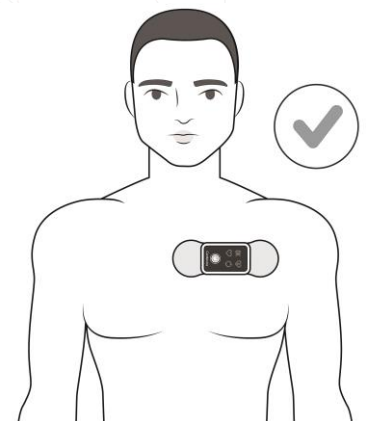
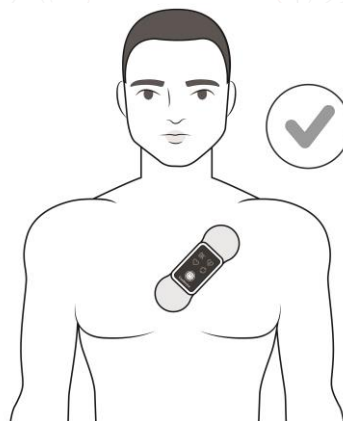
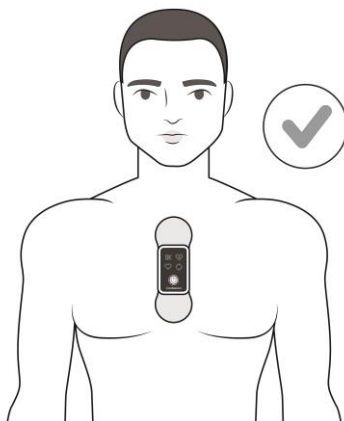
Accurate in compliance with international Standard IEC 60601-2-47.



QUALITY & INNOVATION

Noise reduction and motion artefact detection.

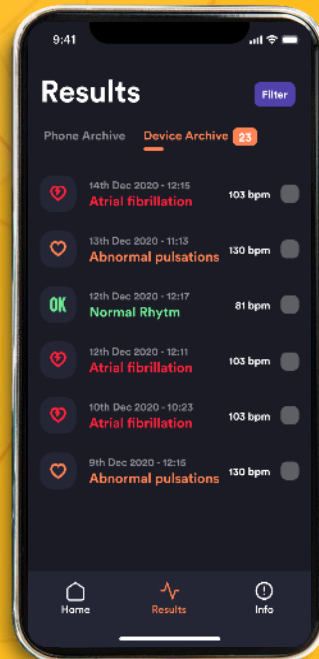
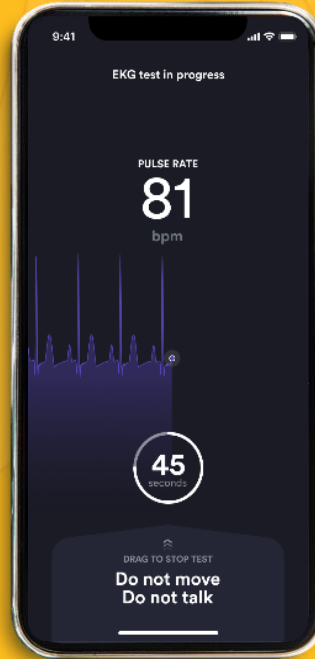
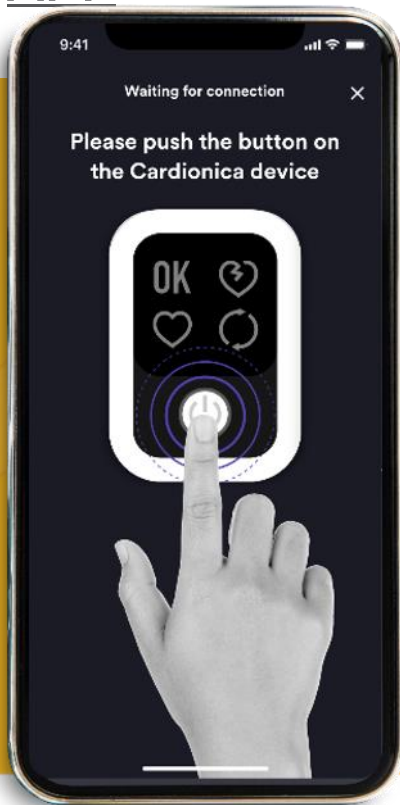
SMALL & LIGHTWEIGHT
Dimensions:
5.7 x 3.7 x 1.5 cm



Compatible SOFTWARE

CARDIONICA APP

Mobile App for Personal use
REAL-TIME EKG test on your Smartphone!



For iOS and Android
Main Features:

- ✓ Automatic pairing via Bluetooth®
- ✓ Real-Time Electrocardiogram and immediate detection of possible arrhythmias
- ✓ Save your Electrocardiogram in PDF; Share PDF report via email, whatsapp, cloud server, and other Apps



MIR
MEDICAL INTERNATIONAL RESEARCH

TECHNICAL datasheet

PRODUCT - Cardionica

REF - 91200000

Indication for use

Cardionica is a medical device that detects atrial fibrillation episodes through a single-lead electrocardiogram (ECG) with the adhesive electrode placed on the chest. Its use is intended for healthcare operators or adults who want to check the presence of atrial fibrillation episodes.



Storage/shipping conditions

Temperature:	MIN -25 °C, MAX + 70 °C
Humidity:	MIN 10% RH; MAX 90%RH

Operating conditions

Temperature:	MIN + 5 °C, MAX + 40 °C
Humidity:	MIN 15% RH, MAX 90%RH

Applied norms

IEC 60601-1:2005 + A1:2012
EN 60601-1-2:2015
EN 60601-1-6:2010
EN 60601-1-9:2013
EN 60601-1-11:2015
EN 60601-2-47:2012
ISO 10993-1:2018

Shelf life

Cardionica	5 years
Patch	2 years

How to use

Stand alone
Connection with App Cardionica (iOS, Android)

ECG

ECG lead	single lead
Input differential range	±6.25 mV
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
Memory capacity	100 ECG, 1 minute each
Measured parameters	Atrial fibrillation, bradycardia or tachycardia episodes Heart rate (bpm) only with App Cardionica
ECG report	Available in pdf mode via App Cardionica
ECG data	Available as edf file via App Cardionica

Certificates & Registrations

CE 0476	Class IIa MED 9826 (MDD 93/42/CE)
CND code	Z12050301 (Cardionica) C020501 (CardioDot)
GMDN code	62641 (Cardionica) 42489 (CardioDot)
Ministry of Health (Italy)	2205399

Technical specification

Main body

Width	15 mm
Length	57 mm
Thickness	37 mm
Weight	20 g (battery included)

Patch CardioDot



Reusable patch (code 912002)

Accelerometer Power supply Current capacity Consumption Autonomy Connectivity Display Keyboard Leds

Tri-axial accelerometer
Lithium 3V (CR2032)
210 mAh
max ~8 mA (during archive sharing)
300 uses or 2 years
Bluetooth® 4.0
none
none
Green
Orange
Red

Type of electrical protection Safety level for shock hazard

Internally powered
Type BF Apparatus

Conditions of use

Apparatus for continuous use

ITALY

MIR Head Office
Via del Maggiolino, 125
00155 Roma
Tel. +39 06 22 754 777
Fax +39 06 22 754 785
Mir.spirometry.com

USA

MIR USA, Inc.
5462 S. Westridge Drive
New Berlin, WI 53151
Phone +1 (262) 565-6797
Fax +1 (262) 364-2030

FRANCE

MIR Local Office
Jardin des Entreprises,
290, Chemin de Saint Dionisy
30980 LANGLADE (France)
Phone +33 (0)4 66 37 20 68
Fax +33 (0)4 84 25 14 32