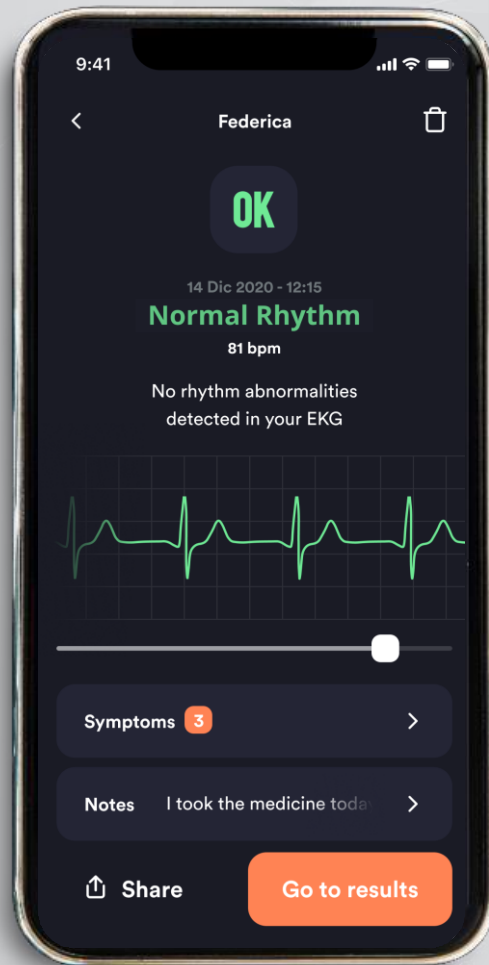


PERSONAL

# Cardionica<sup>TM</sup>

Medical-grade portable single-lead EKG.

Ideal for normal heart check prevention and management of atrial fibrillation, bradycardia, tachycardia.



# MAIN features



## 1 MINUTE TEST

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



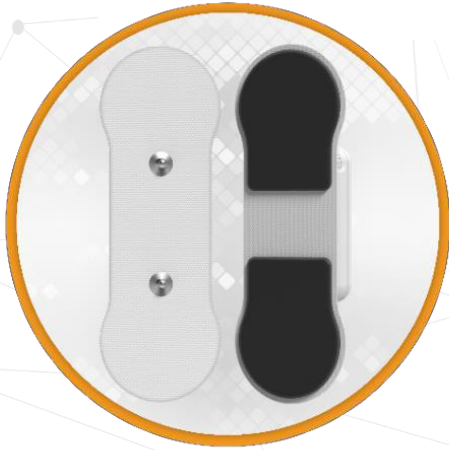
## REAL-TIME EKG

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

**SMALL & LIGHTWEIGHT**

Dimensions:  
5.7 x 3.7 x 1.5 cm



**FIRST OF ITS KIND**

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



**2020 AFIB GUIDELINES**

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



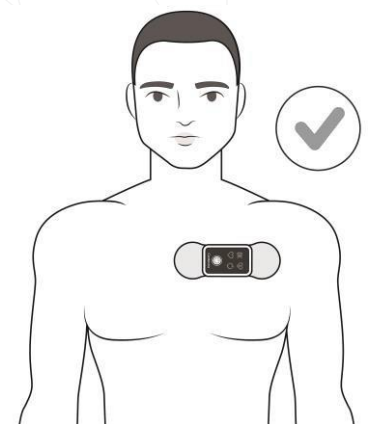
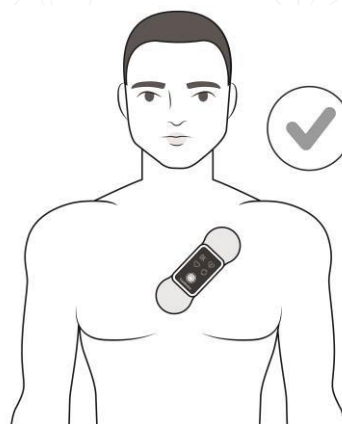
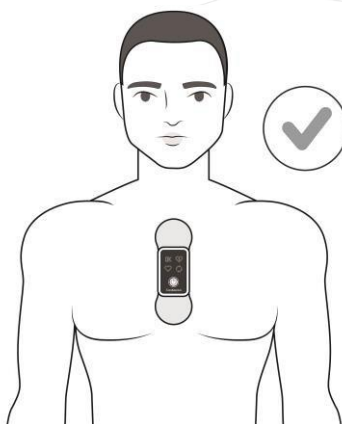
**CERTIFIED ACCURACY**

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



**QUALITY & INNOVATION**

Noise reduction algorithm and motion artefact detection.

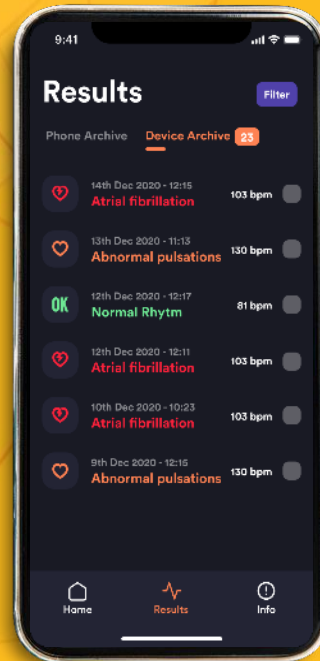
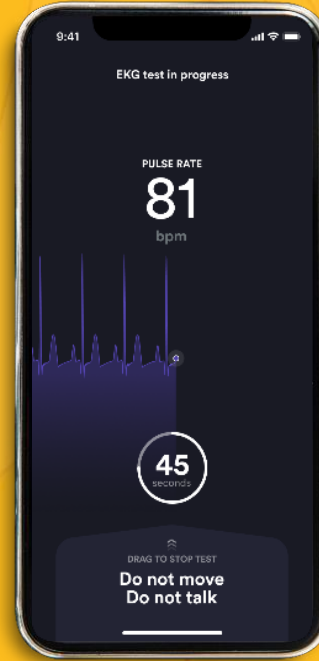
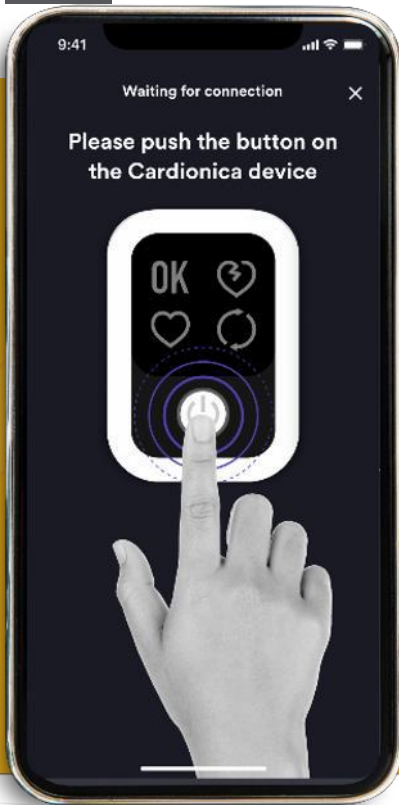


# Compatible SOFTWARE

## CARDIONICA APP

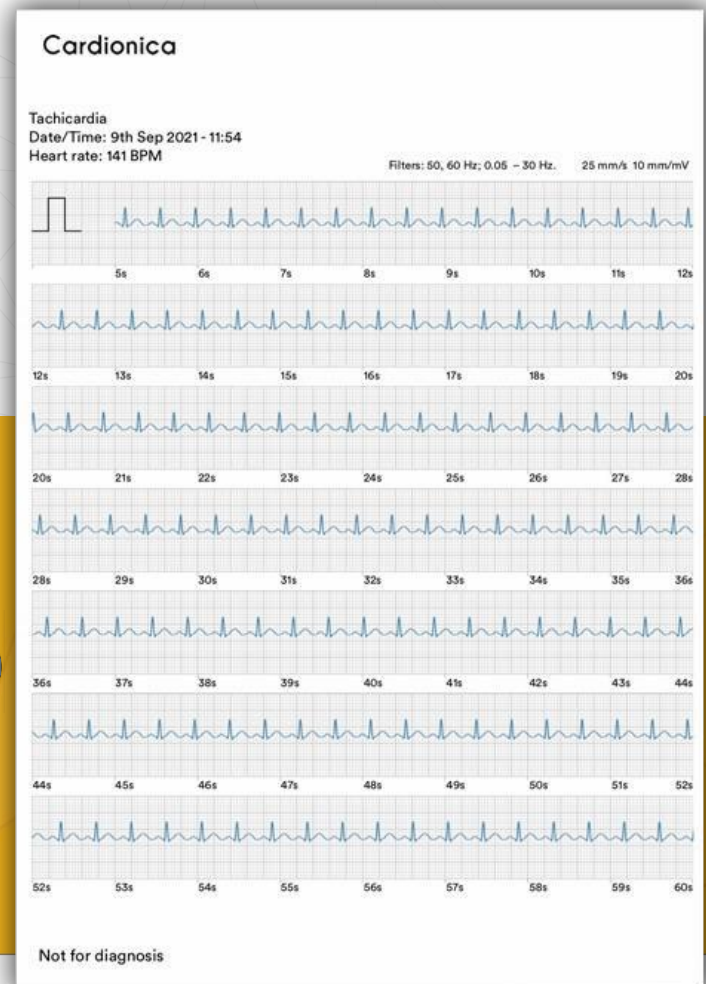
Mobile App for Personal use

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



Professional EKG tracing In PDF TO BE SHARED WITH ANYONE VIA EMAIL, WHATSAPP AND OTHER APPS

# 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

## How to use

Stand alone  
Connection with App Cardionica (iOS, Android)

## 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

Tri-axial accelerometer

### Power supply

Lithium 3V (CR2032)

### Current capacity

210 mAh

### Consumption

max ~7 mA (during archive sharing)

### Autonomy

300 user or 2 years

### Connectivity

Bluetooth® 4.0

### Display

none

### Keyboard

none

### Leds

Green  
Orange  
Red

### Type of electrical protection

Internally powered

### Safety level for shock hazard

Type BF Apparatus

### Conditions of use

Apparatus for continuous use

## 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 impedance

±300 mV **Input**  
> 10 MOhm

### Sampling rate

250 S/s

### Resolution

18 bit; 0.048 uV

### Memory capacity

100 ECG

### Measured parameters

bpm  
atrial fibrillation episodes

## Certificates & Registrations

### CE 0476

MED 9826 (MDD 93/42/CE)

### CND code

Z12050301 (Cardionica)

### GMDN code

C020501 (CardioDot)

### Ministry of Health

62641 (Cardionica)  
42489 (CardioDot)  
2205399

## ITALY

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