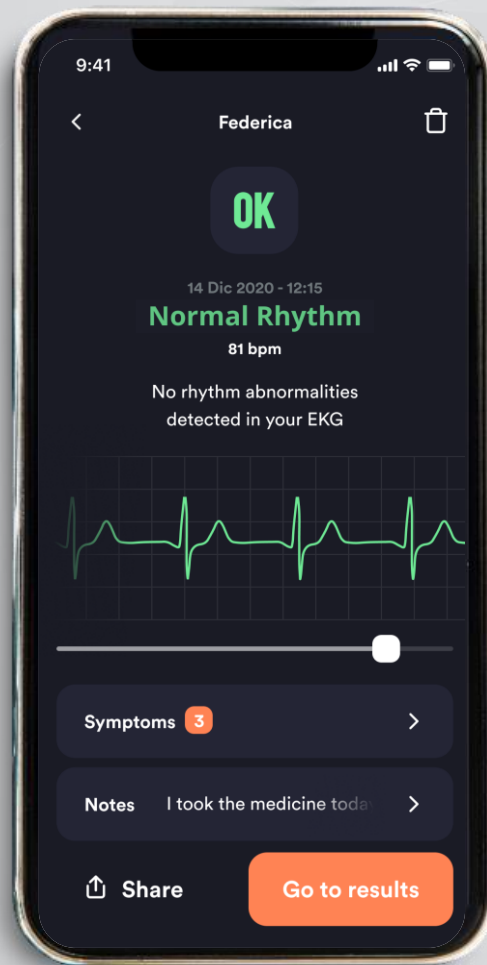


PERSONAL

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.



SMALL & LIGHTWEIGHT
Dimensions:
5.7 x 3.7 x 1.5 cm

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).



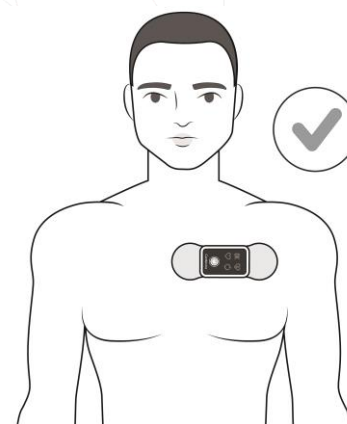
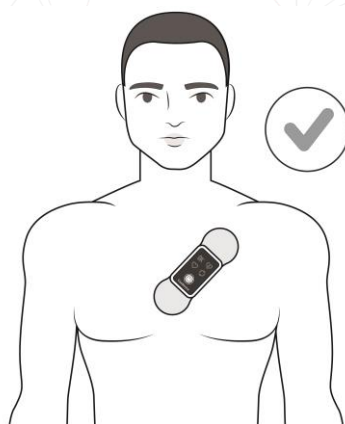
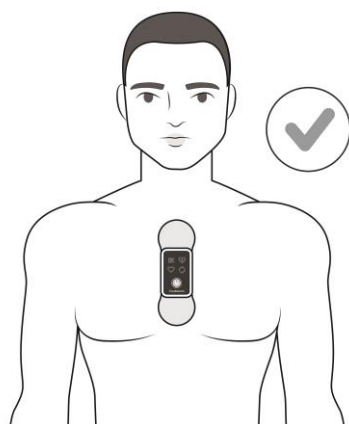
CERTIFIED ACCURACY

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



QUALITY & INNOVATION

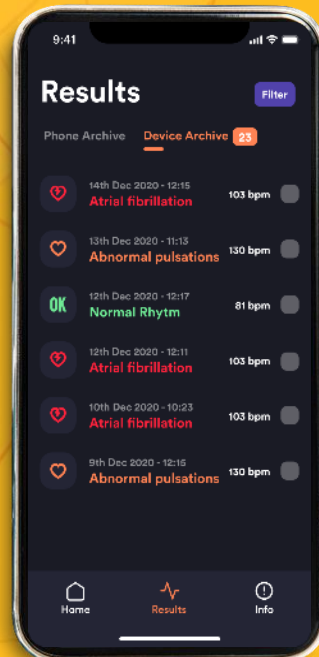
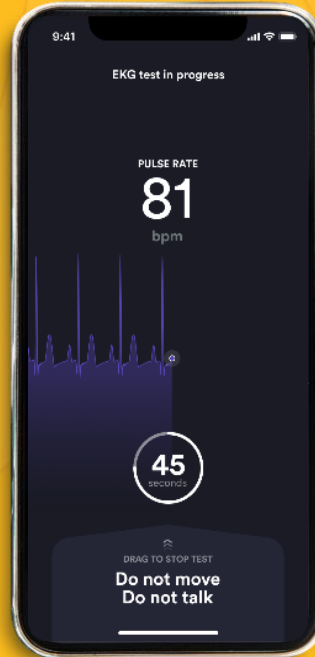
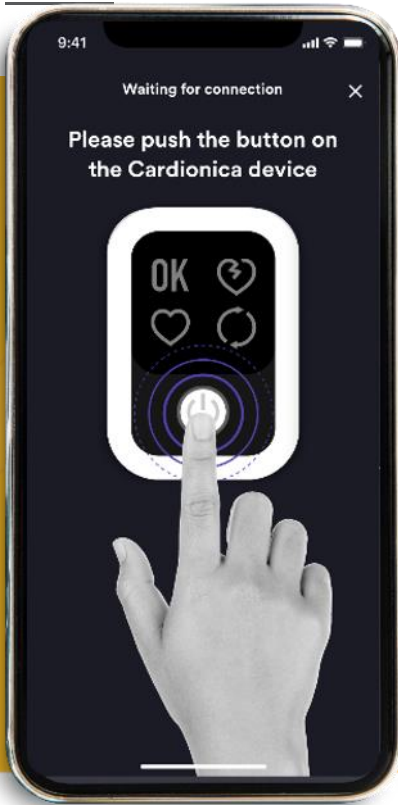
Noise reduction and motion artefact detection.



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.



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 ~8 mA (during archive sharing)
Autonomy	300 uses 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

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

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