

TECHNICAL datasheet

PRODUCT - Cardionica

REF - 91200000

Indication for use

Cardionica is a medical device that detects atrial fibrillation episodes through a single-lead electrocardiogram (EKG) 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)

Cardionica Patch



Reusable patch (code 91200405)

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® 5 ready

Internally powered

Type BF Apparatus

Type of electrical protection

Safety level for shock hazard

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

Applied norms

Humidity: MIN 15% RH,
MAX 90%RH
Altitude < 3000 m

IEC 60601-1:2005 + A1:2012 +
A2:2020
IEC 60601-1-2:2014 + A1:2020
IEC 60601-1-6:2010 + A1:2013 +
A2:2020
IEC 60601-1-9:2007 + A1:2013 +
A2:2020
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)

EKG

EKG lead

Input differential range

Frequency response

Common mode rejection ratio

DC offset correction

Input impedance

Sampling rate

Resolution

Memory capacity

Measured parameters

single lead
±6.25 mV
0.167 Hz to 30 Hz
100 dB @50Hz

±300 mV

> 10 MOhm

250 S/s

18 bit; 0.048 μ V

100 ECG, 1 minute each

Atrial fibrillation, bradycardia or
tachycardia episodes

Heart rate (bpm) only with App
Cardionica

Available in pdf mode via App
Cardionica

Available as pdf file via App
Cardionica

Cardionica

EKG report

EKG data

Certificates & Registrations

CE 0476

CND code

GMDN code

Ministry of Health (Italy)

Class IIa (Reg. 2017/745/UE)

Z12050301 (Cardionica)

C020501 (Cardionica Patch)

62641 (Cardionica)

42489 (Cardionica Patch)

2494753/R (Cardionica)

2495459/R (Cardionica Patch)

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