

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)
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® 5 ready
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

Altitude < 3000 m

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)

EKG

EKG 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

EKG report

Available in pdf mode via App Cardionica

EKG 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)

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