

General description

The Device is intended to supervise the right functioning of the heart – at home and on the way. The device provides information on the average heart rate, the blood oxygen level and on the potential deviation from normal ECG. For the precise assessment and detailed illustration of the recorded data, the device uses the smartphone's screen via Bluetooth connection. The recorded results can be forwarded to your doctor and any person indicated via e-mail. The built-in accumulator can be charged with a micro USB plug.

- The Device needs approximately 60 seconds to complete the measuring necessary to prepare the cardiogram.
- Based on the measured data, the Device carries out an automatic analysis and provides the results.
- With one full battery charge, 135 or so measuring can be carried out. The Device can store up to 50 measurement data on the device itself. After that measurement data are overwritten.
- The Device is capable of:
 - downloading ECG-data.
 - storing measurement results in a chronological order.
 - displaying ECG waveforms as reference information to a healthcare professional.
 - preparing the ECG in a format that allows doctors to evaluate crucial information.



Picture 1

Scope

Intended purpose:

- Risk analysis for supraventricularis (eg. atrial fibrillation), Ventricular tachycardia and sudden cardiac death.

Patients to be treated:

- Anyone can use the device, so athletes, healthy people and people with heart disease can just as well get information on certain aspects of their heart. The most beneficial may be for groups at risk (eg. cardiovascular patients) without any prognostication or for patients with already developed cardiovascular disease, showing any appearing arrhythmia.

Disease, condition requiring treatment (indication):

- Supraventricularis (eg. atrial fibrillation) Ventricular tachycardia and sudden cardiac death.

Functional description

Operating principle:

The Device gains measurement data from bipolar ECG lead deriving from a single lead of the traditional 12-lead ECG test (the so-called Einthoven I lead due to the operating principle of the device). The analysis of the measured data is carried out by a software developed by the manufacturer, based on the analysis of the co-called Poincaré plots. The Device can record the main features of the heart's electrical activity in a portable format.

The measuring device forwards the data to a smartphone via Bluetooth connection (Android and iOS operation system), where a dedicated application performs data-processing and the displays the results.

Technical description:

The Device is small-sized, portable and has a plastic cover. The ECG sensors are made of conductive material and were coated.

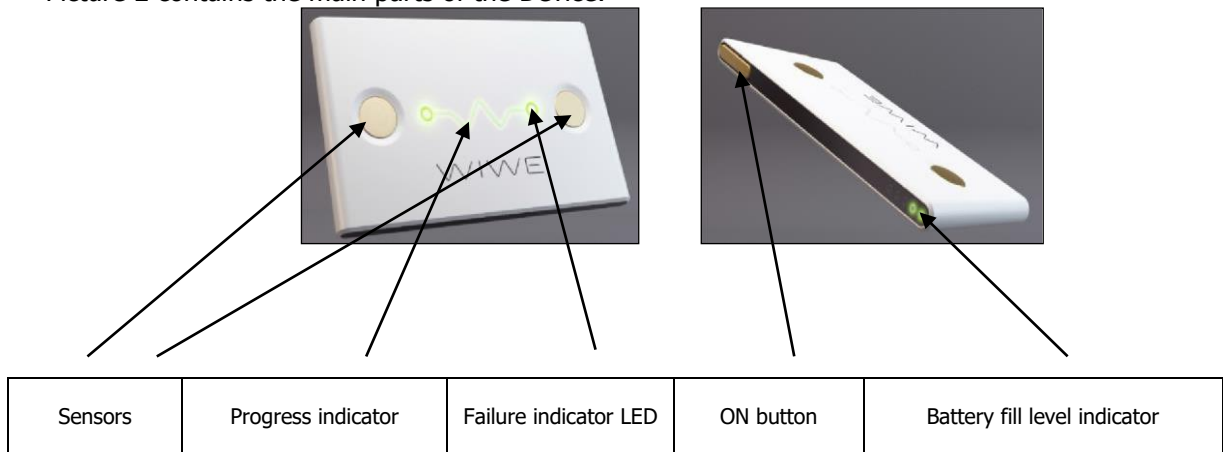
The Device is supplied with an ON button, 2 sensors, a LED line indicating the measuring progress, battery fill level indicators (4 LEDs) and an accumulator charging indicator LED (red).

Power supply is ensured by a non-replaceable lithium-ion accumulator. Thus, the lifespan of the device is determined by the lifespan of the accumulator.

Main components of the Device:

- plastic cover,
- sensors,
- indicator LEDs,
- ON button,
- printed circuit board with built-in components and connectors,
- accumulator,
- USB cable for charging.

Picture 2 contains the main parts of the Device.



Picture 2

Main technical data:

IP class: IP22

Type of touchable parts: BF

Touchable parts: the entire cover

Operating mode: non-continuous

Life expectancy of cover and electrical parts: 6 years

Accumulator type: lithium-ion

Weight: 32 g

Size (cover, width x height x depth): 87,50 x 54 x 5,5 mm