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INSTRUCTIONS FOR USE – PRECORDIOR AF APP

General

The Precordior AF App product ("Precordior AF App") consists of the mobile application ("mobile app") and the cloud service. The mobile app can be installed on Android or iOS mobile devices, both having separate software versions ("Android" and "iOS") with similar functionality. Android mobile devices must use the Android 4.3 operating system or later version and iOS mobile devices the iOS 10.3 operating system or later version. The mobile app is applicable to all smartphones using the aforementioned operating systems that include a gyroscope and accelerometer. The list of tested smartphone models is available at www.precordior.com. In addition, a working internet connection and valid e-mail address are required for correct operation.

Intended use

The intended use is to detect atrial fibrillation in adult population. The target group is adult population. Indication for use is medical professional's or layman's suspicion of atrial fibrillation or intention to exclude or detect the existence of possible atrial fibrillation.

In the case of a medical emergency or other symptomatic or suspected medical condition the use of Precordior AF App does not replace the investigation made by a medical professional. If you are not feeling well or experience any other distressing symptoms, please seek medical attention without a delay.

Restrictions of use

There are no absolute contraindications for the use of Precordior AF App.

The measurement must not be taken in the case of:
- You have damaged skin on your chest in the measurement area.
- You have the phone plugged in to a charger.
- Your phone has a casing on it. Please remove smartphone casing for the duration of the measurement.

For persons with a cardiac pacemaker, the smartphone on the chest should be kept 15-20 cm away from the pacemaker while recording.

Measurement

Please remove any thick clothing from your chest. Lie down on your back. Take a comfortable position, as the measurement takes about one minute. Start the measurement by pressing the Start button, which is followed by a 10 second countdown. During the countdown, place the device on your chest. During the measurement, beeps indicate the progress of the measurement event. You will know that the measurement is complete when you hear an audible alarm. You can then remove the phone from your chest. Interpretation of measurement data starts immediately upon completion of the measurement. Depending on the speed of your network connection, the result will be displayed within approximately 15 seconds after the end of the measurement event.

Results

The measurement result indicates your heart rate and whether or not signs of atrial fibrillation were detected. The displayed heart rate is an average number obtained in the measurement and may vary between 30-180 beats per minute. If there is a problem during the measurement, such as from motion artifact, coughing or talking, it may be interrupted prematurely. In this case, you will be requested to take

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a new measurement. In the case of a result indicating signs of atrial fibrillation, you will be asked to take a repeated measurement. In this case two consecutive measurements with the same result is considered the official result. Results will not be automatically conveyed to third parties. Therefore, it is utterly important that the user takes responsibility for possible follow-up actions with healthcare professionals. In the case that Precordior AF App indicates suspected atrial fibrillation we instruct you to seek medical attention without delay.

Measurement history

All measurement results are automatically stored in the measurement history. If necessary, individual results can be removed from the measurement history view.

Safe use

Safe use of this product is guaranteed only if these instructions are followed.

Product lifecycle

The lifecycle of this product is defined as the period of time until a new version is released.

Termination of use

The use of Precordior AF App may be terminated by uninstalling the mobile app from your smartphone.

Further information on our service

Do you have any questions about our service? Our customer service is available at info@precordior.com.

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This is a standalone medical device software in risk class IIa according to rule 10 of the valid EU Directive 2007/47/EC.

CE 0537 **Notified Body: Eurofins Expert Services Oy, Finland.**