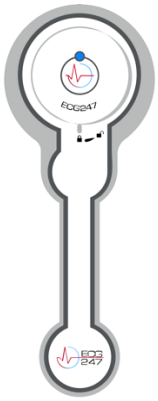
# ECG247 Smart Heart Sensor

# User guide

Model number 353 010



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# ECG247 Smart Heart Sensor

## Components

- ECG247 electrode patch (single use)
- ECG247 sensor (reusable)
- ECG247 mobile application
- ECG247 web portal: www.ecg247.com

## Certification

ECG247 Smart Heart Sensor is CE-approved in accordance with MDR (EU) 2017/754, certificate HZ2312866-1 (CE0197).

# Intention for use

ECG247 Smart Heart Sensor is used for ambulatory, long-term, continuous heart rhythm recording (ECG) to diagnose heart rhythm disturbances (arrhythmias). ECG247 Smart Heart Sensor can be used for self-testing and/or in collaboration with healthcare personnel. The ECG247 Smart Heart Sensor can be used both to screen for heart rhythm disorders and to investigate symptoms.

The ECG247 Smart Heart Sensor is a medical diagnostic tool for detecting the following heart rhythm disturbances: atrial fibrillation/flutter, ventricular tachycardia, supraventricular tachycardia, bradycardia and pauses.

Heart rhythm disturbances is a common term for all deviations from normal heart rhythm (sinus rhythm). Heart rhythm disorders can cause a fast, slow, or irregular heart rhythm and symptoms such as an irregular heartbeat, palpitations, dizziness, or fainting.

Heart signals have different characteristics for everyone. ECG247 cannot guarantee that the ECG247 Smart Heart Sensor will detect all possible types of heart rhythm disturbances in everyone, nor that heart rhythm disturbances have not occurred, even if the test shows normal findings. The automatic rhythm analysis can misinterpret heart rhythm signals, leading the system to incorrectly warn of a possible heart rhythm disorder. In the event of a warning of a possible heart rhythm disorder, the test must always be evaluated by a physician.

ECG247 Smart Heart Sensor should not be used for:

- Real-time heart rhythm monitoring in hospitals
- Diagnosing myocardial infarction
- In patients during MRI
- Children <10 kg
- Pregnant women

ECG247 Smart Heart Sensor must be kept out of the reach of children.

Always contact a physician for heart symptoms.

# Perform ECG247 test

## 1. Download the ECG247 app

The ECG247 app is available for download from the App Store or Google Play and must be installed on a mobile phone. The mobile phone must have internet access (WIFI or mobile data) throughout the test period. The ECG247 app requires a minimum of 500 MB of available storage capacity on the mobile phone.






ECG247 app requires updated iOS and Android versions - see www.ecg247.com

## 2. Create user

A user can be created by healthcare personnel in the ECG247 web portal (invited test) or by a consumer in the ECG247 app (consumer test).

### Invited test

- Use the link from SMS or scan the QR code in the app to open the ECG247 app in invited mode. Note: The ECG247 app must be downloaded first.
- Enter Personal ID

### Consumer test

- Accept terms and conditions
- Enter phone number
- Enter the one-time code from SMS
- Allow access to location data. This is necessary for communication with the ECG247 sensor.
- Enter personal information

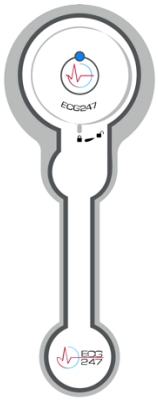
## 3. Start test

Follow the instructions in the app. Updated software is automatically downloaded to the ECG247 sensor.

### Mount and activate the sensor

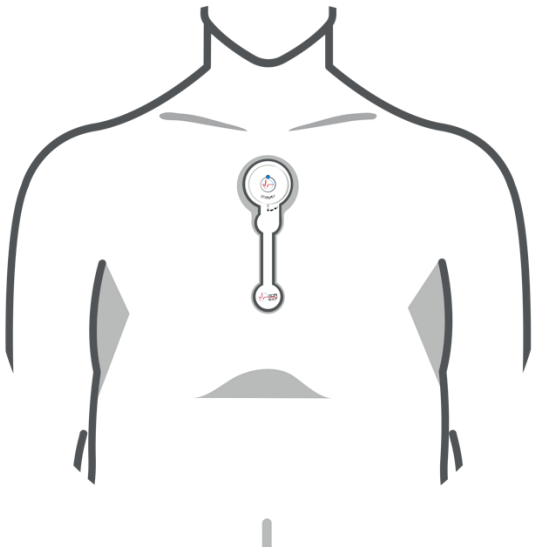
- Take the electrode patch out of the packaging. Avoid touching the green foil attached to the battery.

- Remove the label on the back of the sensor.
- Place the sensor on the upper part of the electrode patch. The cursor must point to the open lock symbol
- Rotate clockwise until the cursor points to the closed lock symbol
- Press and hold at the centre of the sensor until the blue light comes on
- Accept Bluetooth connection



## Attach the sensor to the chest

- Clean the skin over the sternum with water and soap. Do not use alcoholic detergents. Any hair must be removed. Do not use moisturiser. The skin must be clean and free of soap residue before the sensor is attached.
- Remove the protective plastic from the adhesive surface of the electrode patch and attach the sensor to the upper part of the sternum, a little below the jugular pit, with the sensor up.
- Press the electrode patch firmly to the skin.



## 4. Registration and analysis of the heart rhythm

- The heart sensor identifies the heart rhythm signals at the start of the test. Avoid touching the sensor during the start-up period.
- The ECG247 app will notify you if the heart rhythm signals are not satisfactory. See "Troubleshooting".
- You can then use the phone as usual, but the ECG247 app must be open in the background.
- A manually saved ECG recording can be started by pressing the "Symptoms?" button in the app (describe symptoms) or by pressing firmly on the centre of the sensor.

## 5. Stop test

- End the test in the ECG247 app. We recommend a test duration of 3-7 days or longer if feasible.
- Remove the ECG247 sensor and electrode patch from the chest.

# ECG247 app

## Test

The test duration, heart rate, ECG (optional), and results from the automatic test analysis (optional) are displayed during an ongoing test.

- A manual ECG recording is started (1-minute recording) by clicking "Symptoms?". Please describe any symptoms. The description will be available to the doctor in the ECG247 portal.
- More information about the results is displayed when you click the test analysis. This function is optional for invited tests. Any findings of heart rhythm disturbances must always be confirmed by a physician.
- A more detailed ECG window showing heart rate and real-time ECG opens when you click the test analysis. This function is optional for invited tests.

## Results

Previous tests are displayed in the Results screen. Clicking a test displays more detailed information about it. This function is optional for invited tests.

## Share test (consumer tests)

ECG247 tests can be shared with a physician. Press the share button to retrieve a sharing code. The physician must enter the sharing code in the ECG247 web portal to access the test. Please note that each sharing code is only valid for few minutes. The physician will have access to the test as long as the user does not withdraw access in the ECG247 app.

## Cardiologist review (consumer tests)

ECG247 tests can be assessed by a cardiologist associated with ECG247 (Appsens AS). This is a paid service. The report will be available in the app when executed. Our cardiologists can only assess the ECG247 test. All medical questions, examinations, and treatments must be carried out by the local physician.

## Profile (consumer tests)

The Profile screen gives the opportunity to change the personal information, delete the user profile, read more about the ECG247 Smart Heart Sensor and order new ECG247 electrode patches.

# ECG247 Web Portal

All test results and ECG recordings are available in the ECG247 web portal (www.ecg247.com). This service is open to everyone but is primarily intended for healthcare professionals with expertise in ECG interpretation. ECG247 web portal should be used on a PC (not a phone or tablet).

Consumers can see their own test using their mobile number and code from SMS.

For healthcare professionals, registration with personal details, e-mail and mobile number is required, as well as secure login with two-factor authentication.

Healthcare professionals can register their own patients and start/stop tests from the ECG247 web portal.

ECG247 web portal for healthcare professionals provides access to all invited and shared tests (via code from the patient's ECG247 app). It is also possible to share access to a test with other registered healthcare personnel via an access code.

Users with their own organization in the ECG247 system can manage users themselves in the "Users" menu.

## Summary

The summary provides a tabular overview of the test results

## ECG

The ECG tab shows all ECG recordings sorted and hierarchically categorised:

| Arrhythmia | Red | Orange | Yellow | Green | Black |
|---|---|---|---|---|---|
| Ventricular tachycardia | ≥30 s | | > 4 beats | | |
| Pause (4-30 s) | x | | | | |
| Bradycardia (< 30 beats/min) | ≥30 s | | | | |
| Supraventricular tachycardia | ≥30 s | | 15-30 s | | |
| Atrial fibrillation | | ≥30 s | | | |
| Atrial flutter | | ≥30 s | | | |
| Heart rate >180 beats/min | | | ≥5 min | 15 s – 5 min | |
| Ventricular ectopic beat | | | | x | |
| Supraventricular ectopic beat | | | | x | |

| | | | | | |
|---|---|---|---|---|---|
| Periodic recording | | | | x | |
| Manual recording | | | | | x |

ECG recordings can be selected for the PDF report.
Measurement tools to measure distance/duration are available by clicking in the ECG.
ECG amplitude and paper speed can be adjusted, and R waves can be marked automatically.
You can choose between Lead A and Lead B for each ECG recording. If needed, a baseline filter can be applied to enhance signal quality.

## Heart rate

Heart rate displays the heart rate during the test period.
To assess the ECG at specific times during the test period, use this page. The dots above the heart rate graph indicate ECG recordings. By pressing a dot, the desired ECG is displayed below the heart rate graph.

## Create PDF report

To perform a manual assessment, begin by reviewing the ECG data and make any necessary adjustments to the automatic arrhythmia analysis by clicking the pencil icon. Once your assessment is complete, generate a PDF report by selecting the "Create report" button located at the bottom of the screen. Your most recent changes are saved automatically. You can then download the PDF report and save it in the patient's health record for future reference.

## Download PDF report

The tab shows an overview of all PDF reports.

# Notifications and alarms

## Sensor is disconnected

The app notifies with a warning message if the sensor disconnects from the phone. The most common cause is a distance between the sensor and the phone that is too long. Communication is automatically restored when the phone is again near the sensor. The heart rhythm signals are stored in the sensor until communication is restored (max approx. 1 hour).

## No heart rhythm signals

Ensure the electrode patch is securely adhered to the skin and verify that the sensor is firmly connected to the patch. If the patch is loose or the sensor is not fully attached, reapply to ensure better contact, or replace it with a new electrode patch as needed.

## Low signal quality

Check whether the electrode patch has loosened from the skin. Try attaching it better or switch to a new electrode patch.

## Bluetooth is turned off

Turn on the mobile phone's Bluetooth communication.

## Terminated test

The app notifies if the test is stopped from the ECG247 web portal.

## Low battery level

End test or change electrode patch.

# Tips for a successful test

- Follow the instructions in the ECG247 app carefully when starting the test.
- Do not remove the green foil attached to the battery at the electrode patch.
- Body hair must be removed, and the skin over the sternum must be clean and dry before the electrode patch is attached.
- The electrode patch should be applied on the upper part of the sternum.
- The mobile phone should remain in the vicinity of the sensor throughout the test period.
- Turn off battery-saving modes and charge your mobile phone every day.
- Handle the sensor with care.
- Check the ECG247 app at least twice a day. If the test has stopped, you can start a new test without removing the sensor and patch.
- You can exercise and shower, but not bathe/swim with the sensor.
- The recommended test duration is a minimum of 3 days.

## Precautions

- Always contact a physician for heart symptoms.
- Contact a physician if significant skin irritation occurs when using the electrode patch.
- The ECG247 electrode patch can only be used once. Do not attempt to replace the battery.
- The battery cannot be charged.
- If the electrode patch becomes loose, it must be replaced with a new electrode patch. ECG247 cannot guarantee the adhesion time, which depends on skin conditions and external stresses
- Do not place the ECG247 electrode patch on an area with skin damage or wounds.
- Do not immerse the sensor in water. The sensor withstands normal showering.
- The ECG247 Smart Heart Sensor contains a radio transmitter (Bluetooth) and must not be used in areas where such equipment is prohibited.
- The ECG247 Smart Heart Sensor should not be used for children weighing <10 kg or pregnant women.
- ECG247 does not detect pacemaker signals and may therefore misinterpret the heart rhythm in individuals with a pacemaker or defibrillator.

## Warnings

- The ECG247 Heart Monitor contains small parts and must be kept out of children's reach.
- The ECG247 Heart Monitor must not be swallowed.
- The ECG247 Heart Monitor (sensor) must not be opened or dismantled.
- The ECG247 Heart Monitor should not be used in areas where mobile phones are not permitted.
- The ECG247 Heart Monitor should not be used during magnetic resonance (MR) examinations.
- The ECG247 Heart Monitor should not be used near strong electromagnetic fields.
- The ECG247 Heart Monitor must not be covered with metal or conductive materials.
- The ECG247 Heart Monitor emits low levels of electromagnetic radiation.
- The ECG247 Heart Monitor may cause skin irritation – contact a doctor if necessary.
- The ECG247 Heart Monitor may not detect all heart rhythm disturbances in everyone.
- Any rhythm disturbances must always be confirmed by a doctor.
- The ECG247 Heart Monitor may issue false alarms about heart rhythm disturbances.
- The ECG247 Heart Monitor cannot detect signs of heart attack/ischaemic heart disease – always contact a doctor if you experience heart symptoms.

## Use during flights

ECG247 Smart Heart Sensor uses Bluetooth Low Energy (BLE) to communicate with the mobile phone. During flights, the mobile phone must be set to "Flight mode". When "Flight mode" is switched off, normal functionality resumes.

## Data security

ECG247 complies with the requirements for processing sensitive health data and personal data under the GDPR. See www.ecg247.com for more information.

## Reuse of the ECG247 sensor

The sensor is removed from the electrode patch by turning it counterclockwise until the pointer aligns with an open lock symbol. Clean the sensor with a disinfecting cloth. The sensor must not be immersed in water or other liquids.

## Maintenance of the ECG247 sensor

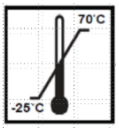
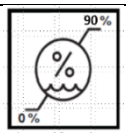
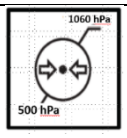
The ECG247 Smart Heart Sensor is disassembled from the electrode after use and can be reused with a new ECG247 electrode patch. The sensor shall be cleaned after use and requires no further maintenance.

## Waste management

The battery is removed from the electrode patch and recycled as "batteries". The remainder of the electrode patch is treated as residual waste. The sensor can be reused. Defective sensors are recycled as "electronic waste"

# Safety signs and label markings

| Symbols used in the packaging material | Meaning of the symbol |
|---|---|
| CE | CE-conformance of equipment with the number reference to the actual Notified Body |
| Model number | 353 010 |
| | Legal manufacturer<br>Appsens AS, Senterveien 30, Lillesand, Norway. www.ecg247.com |
| 2019-10-23 | Manufacturing date |
| 2022-10-23 | Expiry date |
| LOT | Lot number from manufacturing |
| REF | Packages reference number |
| www.ecg247.com | Refer to electronic instructions for use |
| | Do not reuse (ECG247 Electrode patch) |
| **(IP44)** | The finally mounted product consisting of ECG247 Sensor and ECG247 Electrode patch is certified according to IP44 rating that the product is protected against solid objects that are over 1mm (e.g. tools and small wires) and also protected against water splashing from any angle. |
| | BF classified equipment |
| | Bluetooth logo* |
| | Non-ionizing electromagnetic radiation<br>To indicate the medical device, include RF transmitters. |

| | |
|---|---|
|   | Not for use near strong magnetic fields |
|   | Storage temperature |
|   | Storage humidity |
|   | Storage pressure |
|  | Fragile, please handle with care |
|  | During transportation, keep package dry and protected from rain |
|  | Caution<br>Additional instructions that explain use of the device is found in the ECG247 manual documentation |
|  | General Warning Sign<br>The user guide included warnings that should be read by the user prior to use |
|  | Universal recycling symbol<br>This symbol is a general symbol indicating that an object is capable of being recycled but not that it will necessarily be accepted in all recycling collection systems or that it has been recycled. |
|  | Electronic waste (ECG247 Sensor) |

ECG247 US Patent No.: US 8311603 B2, PT 20230201 (349900) og WO 2021/150122 A1Apple is a trademark of Apple, Inc., registered in the U.S. and other countries. App Store is a service mark of Apple, Inc. Android is a trademark, and Google Inc. Google Play is a trademark of Google Inc. The Bluetooth® mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Appsens AS is under license. Other trademarks and trade names are those of their respective owners.

# Disclaimers and warnings

**Disclaimer:** Appsens AS or its partners cannot be held responsible for incorrect use of this equipment or for use outside the equipment's operating norms. All use of the equipment not described in this documentation is considered incorrect use.

**Warning!** This product is not intended for life-preserving treatments.

**Warning!** This product must only be configured according to the User Guide.

**Warning!** To configure this product, the person must be able to read the content and give necessary input on the smartphone screen.

**Warning!** This product requires that the user can learn how to operate the device. If there are limitations in the user's learning capacity, such as young age, old age, mental instability, or mental or physical handicaps, the equipment must be used under the supervision of a responsible person who can assist.

**Warning!** This product must never be used with any accessories other than those specified in the accessory list in this document.

**Warning!** This equipment may not be used to record the activity of an implanted pacemaker device.

**Warning!** Do not modify this equipment without authorisation from the manufacturer.

**Warning!** Portable and mobile RF equipment, e.g. mobile phones, may interfere with medical equipment. Although no known EMC issues have been identified during testing, the performance of this equipment cannot be guaranteed when used with other RF equipment, such as a smartphone with the ECG247 APP installed.

**Warning!** This equipment should not be placed next to or stacked with other devices. If necessary, both this equipment and any adjacent or stacked medical devices must be carefully monitored to ensure they operate correctly in the intended configuration.

**Warning!** This equipment may not be used in strong electric or magnetic fields associated with Magnetic Resonance Imaging (MRI) and must be removed from the chest before MRI scans.

**Warning!** This equipment includes automated ECG analysis for arrhythmia detection, and all recordings should be validated by qualified medical personnel.

**Warning!** Do not place the ECG247 Electrode on skin sites with established erythema, lesions and injuries of any kind!

**Warning!** Do not use the ECG247 Electrode on users with shown irritating effects in direct electrode contact and report any incompatibility reactions observed to the distributor!

**Warning!** Do not use the ECG247 Electrode if the electrode hydrogel is dry!

**Warning!** Do not use the ECG247 Electrode for more than 14 days, and do not reapply a new ECG247 Electrode to the same area immediately after an examination has ended.

**Warning!** Do not use if the equipment is deformed or has other visible damage.

**Warning!** Detach the ECG247 Smart Sensor and remove the ECG247 electrode from the skin if the equipment is overheating or causing discomfort.

**Warning!** This product has a medical-grade plaster that can be applied directly to the skin. However, the user should always consider whether they have any allergies to medical plaster products before applying the product.

**Warning!** This product device emits electromagnetic radiation.

**Warning!** The Sensor may be used during showers. However, never immerse the sensor in any fluids.

**Warning!** This equipment is not intended for use on infants below 10 kg.

**Warning!** This equipment is not intended for use for ischemia detection.

**Warning!** The ECG247 Smart Sensor may be disturbed in its ability to record ECG signals by static electricity, caused by clothes rubbing against the sensor surface.

# Troubleshooting

- Failure to download the ECG247 app
  - Use of ECG247 requires the ECG247 app to be installed on your mobile phone. The app is downloaded from the App Store or Google Play. Not all mobile phones have access to the App Store or Google Play. An updated version of the operating system is necessary.
- The ECG247 sensor does not connect to the mobile phone
  - Try restarting the test. Follow all the steps in the user guide. Check that the sensor lights up blue when you press the sensor button. Make sure that the mobile's Bluetooth connection is switched on. Remove any previous connections to ECG247 sensors. If the problem persists, we recommend uninstalling the ECG247 app, switching off the mobile phone completely (rebooting) and restarting it before downloading the ECG247 app again.
- Automatic reconnection between sensor and telephone fails
  - Stop and start a new test without removing the sensor from the chest. Follow the instructions in the app.
- The test has stopped
  - Start a new test without removing the sensor from the chest. Follow the instructions in the app.
- The electrode patch has detached from the skin
  - Replace with a new electrode patch.

## Responsibility

The ECG247 Smart Heart Sensor must be used as described in the user guide. ECG247 Smart Heart Sensor cannot be connected to other equipment. ECG247 Smart Heart Sensor cannot be connected to any app other than the ECG247 app, nor to any similar equipment for signal or data transmission. ECG247 Smart Heart Sensor cannot be used for any form of medical treatment. Use of the ECG247 Smart Heart Sensor assumes that the user can understand and follow the user guide. Appsens AS is not responsible for use other than as described in this user guide.

## Serious incidents

Any serious incident related to use of the ECG247 Smart Heart Sensor should be reported to the manufacturer and to the relevant authority.

## Contact information

Appsens AS
Senterveien 30
4790 Lillesand
Norway
www.ecg247.com