ECG247 Smart Heart Sensor
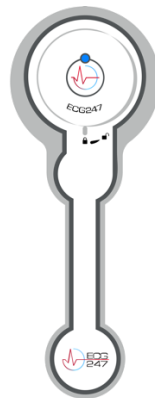
User guide

Model number 353 010

Rev. 3.5
27.08.2024

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Content

ECG247 Smart Heart Sensor

Components

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

Classification

- ECG247 sensor (reusable)
  - GMDN 38729 Telemetric electrocardiographic ambulatory recorder
  - GTIN: 7090052220023
  - Model number: 353010
- ECG247 electrode patch (single use)
  - GMDN 62597 Ambulatory recorder conductive patch
  - GTIN: 7090052220016
  - Model number: 353010
- ECG247 APP mobil application
  - GMDN 62169 Wireless patient monitor/sensor reporting software, layperson-use
- ECG247 WEB portal
  - GMDN 41651 Electrocardiographic long-term ambulatory recording analyser application software

Registration

- EUDAMED registration: B-NOMF000013438ECG247P9, ECG247 Smart Heart Sensor System

Certification

ECG247 Smart Heart Sensor is CE-approved (CE2460) in accordance with regulations of medical devices (MDD 93/42/EEC).

Indication for use

ECG247 Smart Heart Sensor is used for ambulatory long-term continuous heart rhythm recording (ECG) for diagnostics of 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 for screening for heart rhythm disorders and for investigating 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 can cause symptoms such as irregular heartbeat, palpitations, dizziness or fainting.

Heart signals have different characters for each individual. ECG247 cannot guarantee that the ECG247 Smart Heart Sensor will detect all possible types of heart rhythm disturbances in everyone and cannot guarantee that heart rhythm disturbances have not occurred even if the test shows normal findings. The automatic rhythm analysis can misinterpret the heart rhythm signals and the system can incorrectly warn of a possible heart rhythm disorder. In case of warning of a possible heart rhythm disorder, the test must always be assessed by a physician.

ECG247 Smart Heart Sensor should not be used for:
• Real-time heart rhythm monitoring in hospitals
• Children <10 kg

ECG247 Smart Heart Sensor is not recommended for use in
• Pregnant women
• People with severe obesity (BMI>40)
• People with a pacemaker or implanted defibrillator (ICD)

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

ECG247 Smart Heart Sensor cannot be used for investigation of myocardial infarction/coronary artery disease.

Always contact a physician for heart symptoms.

Perform test

1. Download the ECG247 app

The ECG247 app is downloaded from AppStore 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.

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

2. Create user

User can be created by healthcare personnel in ECG247 web portal (invited test) or by consumer in ECG247 app (consumer test).

Invited test
- Use link from SMS, scan QR code or enter invitation code in 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 the communication with the ECG247 sensor.
- Enter personal information

3. Start test

Press "Start new test" and 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. Cursor must point to 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
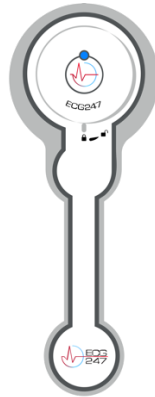
Attach the sensor to the chest

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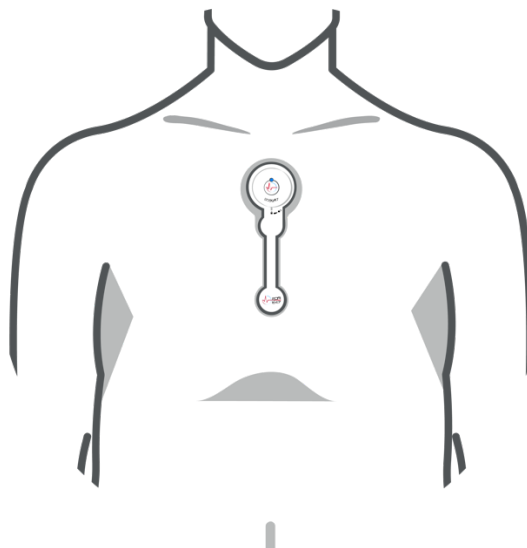
4. Registration and analysis of the heart rhythm

- 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 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 center of the sensor.

5. Stop test

- Press Stop test in the ECG247 app. We recommend a minimum 3-days test period.
- Remove the ECG247 sensor and electrode patch from the chest.

ECG247 app

Test

A new test is started from the Test screen. The test duration, the heart rate, the ECG (optional) and the results from the automatic test analysis (optional) are displayed during an ongoing test.

- A manual ECG recording is started (1 minute) by clicking on "Symptoms?". Please describe any symptoms. The description will be available to the doctor in the ECG247 web portal.
- More information about the results is displayed by clicking on 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 by clicking on the test analysis. This function is optional for invited tests.

Results

Previous tests are displayed in the Results screen. Clicking on a test displays more detailed information about the test. 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 15 minutes. The physician will have access to the test as long as access is not withdrawn by the user in the ECG247 app.

Cardiologist review (consumer tests)

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

Profile (consumer tests)

The Profile screen gives the opportunity to change the personal information, 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 personnel with expertise in ECG interpretation. We recommend that the ECG247 web portal should be used with one of the following browsers: Chrome, Safari, Firefox, or Edge. 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 personnel, registration with personal details, e-mail and mobile number is required, as well as secure login with two-factor authentication.

Healthcare personnel 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).

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

Select ECG
Select ECG shows all ECG recordings sorted and categorized:

Arrhythmia	Red	Orange	Yellow	Green
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
Irregular beat				x
Ventricular ectopic beat				x
Supraventricular ectopic beat				x

Periodic recording				x
Manual recording				x

ECG recordings/ECG sequences can be selected for a 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.

Heart rate

Heart rate displays the heart rate during the test period.

To assess the ECG at specific times during the test period, use of this page is recommended. 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

Write a manual assessment and generate a PDF report by selecting the "Create report" button at the bottom of the screen. PDF reports can be downloaded and stored in the patient health record.

Previous reports

The Previous Reports 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 if the distance between the sensor and the phone is too long. Communication is automatically restored when the phone is near the sensor again. The heart rhythm signals are stored in the sensor until communication is restored (max approx. 1 hour).

No heart rhythm signals

Check whether the electrode patch is adhered to the skin. Try to attach it better or change to a new electrode patch.

Low signal quality

Check whether the electrode patch has loosened from the skin. Try to attach it better or change 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 sternum.
- The mobile phone should be in the vicinity of the sensor during the entire 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.
- Recommended test duration is minimum 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.
- When you start a test, make sure that no other ECG247 tests nearby are started at the same time, as this can lead to wrong sensor being connected to the mobile phone.
- 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, pregnant women, overweight (BMI>40) and people with pacemakers/defibrillators.

Warnings

- ECG247 Smart Heart Sensor contains small parts and must be kept away from children.
- ECG247 Smart Heart Sensor must not be swallowed.
- ECG247 Smart Heart Sensor (sensor) must not be opened/disassembled.
- ECG247 Smart Heart Sensor emits electromagnetic radiation.
- ECG247 Smart Heart Sensor can cause skin irritation - contact a physician.
- ECG247 Smart Heart Sensor will not be able to detect all heart rhythm disturbances in everyone. Any rhythm disturbances must always be confirmed by a physician.
- ECG247 Smart Heart Sensor can give false warnings about heart rhythm disturbances.
- ECG247 Smart Heart Sensor cannot look for signs of a myocardial infarction/ischemic heart disease - always contact a physician in case of symptoms from the heart.
- ECG247 Smart Heart Sensor and communication to the secured cloud storage may be affected by cyber-attacks on your mobile phone

Refer to Electromagnetic compatibility EMC and Disclaimer and warning section of this document for complete list of warnings.

Use during flights

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

Electromagnetic compatibility (EMC)

Electromagnetic compatibility (EMC) indicates the generation, propagation, and reception of electromagnetic energy. Electromagnetic disturbances can cause the ECG247 system to not function normally.

Warnings

- ECG247 Smart Heart Sensor must not be used in areas where mobile phones are not allowed.
- ECG247 Smart Heart Sensor must not be used closer than 30 cm from other medical equipment.
- ECG247 Smart Heart Sensor must not be used during defibrillation. In such situations, the sensor must be removed from the chest.
- ECG247 Smart Heart Sensor must not be used in the vicinity of other radio frequency (RF) transmission equipment such as microwave ovens, induction hobs etc.
- ECG247 Smart Heart Sensor must not be used during magnetic resonance (MR) examinations, PET examinations and/or Computer Tomography (CT) examinations.
- ECG247 Smart Heart Sensor must not be covered with metal or conductive materials.

Data security

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

Basic security

- ECG247 Smart Heart Sensor should be handled with care.
- DO NOT change the battery in the electrode patch - this is intended for single use.
- If the sensor and/or electrode patch is damaged, these must be replaced with new ones.
- Do not dismantle the sensor.

Reuse of the ECG247 sensor

The sensor is removed from the electrode patch by turning the sensor counterclockwise until the pointer points to 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
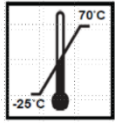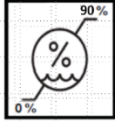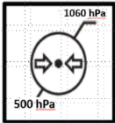
The ECG247 Smart Heart Sensor is disassembled from the electrode after use and can be reused with a new ECG247 electrode patch. The sensor shall be cleaned after use and do not require any other maintenance.

Waste management

The battery is removed from the electrode patch and recycled as "batteries". The remaining 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 2460	CE-conformance of equipment with the number reference to the actual Notified Body
Model number	353 010
(factory symbol)	Legal manufacturer Appsens AS, Senterveien 30, Lillesand, Norway. www.ecg247.com
(factory symbol) 2019-10-23	Manufacturing date
(hourglass symbol) 2022-10-23	Expiry date
LOT	Lot number from manufacturing
REF	Packages reference number
(instructions symbol) www.ecg247.com	Refer to electronic instructions for use
(do not reuse symbol)	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 figure symbol)	BF classified equipment
(Bluetooth logo)	Bluetooth logo*
(RF transmitter symbol)	Non-ionizing electromagnetic radiation 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 Additional instructions that explain use of the device is found in the ECG247 manual documentation
	General Warning Sign The user guide included warnings that should be read by the user prior to use
	Universal recycling symbol 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)

Disclaimers and warnings

Disclaimer: Appsens AS or its partners cannot be made responsible for incorrect use of this equipment or use outside the operating norms of the equipment. All usage of the equipment that is 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 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 like young age, old age, mental instabilities, mental or physical handicaps then the equipment must be used under supervision by a responsible person that can assist. That can be a parent, sibling or other family member or nurse that has learned how to operate the equipment.

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

Warning! This equipment may not be used to record the activity of an implanted pacemaker device. However, the equipment may be used by a patient with an implanted pacemaker device.

Warning! This equipment may not be used during defibrillation.

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

Warning! Portable and mobile RF equipment e.g. mobile phones may interfere with medical equipment. Though no known problems regarding EMC has been discovered during testing, the performance of this equipment cannot be guaranteed when operated together with other RF equipment than a smartphone with installed the ECG247 APP.

Warning! The ECG247 Smart Sensor should not be used in close proximity to another RF-transmission equipment like a microwave oven inductive cook-top or similar household equipment.

Warning! This equipment should not be used adjacent or stacked with other equipment, if so is necessary, both this and the stacked or adjacent medical equipment or system should be observed to verify normal operation in the configuration in which it will be used.

Warning! This equipment may not be used in strong electric or magnetic fields used for Magnetic Resonance Imaging (MRI), PET Scan, and/or Computer Tomography (CT) scans and needs to be removed from the chest before MRI, PET and/or CT scans and similar.

Warning! This equipment contains an automated analysis of ECG for arrhythmia detection, and any 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 new ECG247 Electrode to the same area immediately after an examination has been ended.

Warning! Do not use if the equipment is deformed or have other visible damages.

Warning! This product has medical approved plaster to be applied directly on the skin. However, the user should always consider whether he/she has any allergies to medical plaster products before the product is applied.

Warning! This product device emits electromagnetic radiation and emitted electromagnetic radiation may cause heating.

Warning! Never try to disconnect the ECG247 Smart Sensor from the disposable ECG247 Electrode during normal use.

Warning! Select Stop recording in the ECG247 APP before removing the sensor with the ECG247 Electrode from the surface of the skin.

Warning! The Sensor is a BF applied part and must not be brought into contact with any electrically conductive cables including electrical earth connections.

Warning! The Sensor may be used during showers. However never immerse the Sensor into any fluids.

Warning! This equipment is not intended used on infants below 10 kg.

Warning! This equipment is not intended used for ischemia detection.

Warning! Never use this equipment to diagnose unless you have the correct medical training.

Warning! The ECG247 Smart Sensor may be disturbed in recording ECG-signals by static electricity, due to cloths rubbing against the sensor surface. This can especially happen during physical exercise and when using t-shirts made of Acryl or Polycarbonate. However, the disturbances will normally be reduced by humidity caused by perspiration/sweat.

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. 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, switch off the mobile phone completely (reboot) and restart 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 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 has no responsibility for use other than that 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 relevant authority.

Contact information

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