ECG247 Smart Sensor System

Model number 353 010

Service Manual

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Appsens AS is the world leading producer of wireless ECG technology. The ECG247 Smart Sensor, combined with the ECG247 APP and a secured back-end service, can record data from the patient under a wide array of circumstances.

Please refer to our website www.appsens.no for further information and news about the technology.

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1 Scope of the service manual

This service manual is intended to be used by responsible technical or biomedical engineering personnel in hospitals/clinics for having necessary control of medical equipment in use and be able of carrying out necessary technical test and maintenance. For detailed information on how to use the ECG247 Smart Sensor System please find information in the User Guide.

2 Note on FCC Part 15 statement

Chapter 14 of this service manual includes a statement from the Federal Communications Commission (FCC). The referred note encapsules the limits for a Class B digital device, pursuant to Part 15 of the FCC rules.

3 ECG247 Smart Sensor System – overview

The ECG247 Smart Sensor, the ECG247 APP and the ECG247 Secured cloud services are designed and manufactured by Appsens AS in Lillesand, Norway and is marketed and sold by the licensed distributors.

The ECG247 Smart Sensor System is designed as a wearable arrhythmia detection solution to be easy and to feel safe to use by the patient. It is also an easy and user-friendly start-up procedure for starting a new ECG arrhythmia recording period, normally for 3-7 days.

An important part of the design has been to make mobility for the patient. The user shall as far as possible be able to do the same daily activities as he/she has been used to, and also do physical training exercises still being monitored for arrhythmia events.

This documentation is the reference guide for the ECG247 Smart Sensor the ECG247 APP, and the ECG247 secured back-end services provided by Appsens.

4 System Components and Product Model Number

The ECG247 Smart Sensor System is defined by Product Model Number 353 010.
ECG247 Smart Sensor System components consist of:

ECG247 Smart Sensor	Active Device for diagnosis intended to allow direct diagnosis or monitoring of vital physiological processes. Intended for short term use less than 30 days (re-usable)	**GMDN 44423**
ECG247 Electrode	Disposable plaster patch with battery to be used with ECG247 Smart Sensor (disposable)	**GMDN 62597**
ECG247 APP software	Smartphone APP to be used with ECG247 Smart Sensor in connection with a secured back-end storage and WEB service - Single-patient physiologic monitoring system application software in connection with a secured back-end storage service (downloadable from AppStore and Google Play)	**GMDN 59378**
ECG247 Web software	Secured Back-end storage and analyser with WEB-service. Electrocardiographic long-term ambulatory recording analyser application software, (Cloud service with WEB-logon)	**GMDN 41651**

4.1 Required Accessory

The user will need to wear a Smartphone (Android version 8.0 or higher or iOS version 11 or higher) with Bluetooth communication and mobile data/Internet access.

The user will need to have the mobile in a proximity of 10 meters during the arrhythmia investigation in order to receive detected arrhythmia episodes and for transfer of data to the secured could-based storage.

To access the ECG247 WEB, a browser for PC/MAC is required (Chrome, Safari, Firefox or Edge).

5 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! 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 (e.g. MR, X-ray, 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! 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.

6 Declaration of conformity

6.1 Conformity to standards

This product is developed in conformity with the following standards:

Medical Device Directive (MDD 93/42/EEC)

IEC 60601-1:2005; AMD 1:2012

IEC 60601-1-2:2014

IEC 60601-6:2010; AMD1:2013

IEC 60601-1-11:2015

IEC 60601-2-47:2012

IEC 60601-4-2:2016

IEC 60529:1989

IEC 62304:2006

IEC 62366:2015
ISO 10993-1:2009, 5:2009, 10:2010
ISO 22077-1 and ISO 22077 - 3

6.2 Classification as medical device

The ECG 247 Smart sensor system is classified as: **Class II a,** according to Medical Device Directive (93/42/EEC), Annex II, Chapter III, Rule 10.:

- Intended for short term use <30 days
- Active Device for diagnosis
- Intended to allow direct diagnosis or monitoring of vital physiological processes

6.3 Certification

The ECG247 Smart Sensor System is certified for CE-conformance, certificate No.: 10000366191-PA-NA-NOR, valid until 27 May 2024.
Biocompatibility: According to ISO 10993.
Water protection: IP44 (protected against showering)

6.4 Intended use

ECG247 Smart Sensor System is developed as a wearable device for diagnosis of cardiac arrhythmias (atrial fibrillation, ventricular tachycardia, supraventricular tachycardia and pause) based on a one-lead ECG-signal registration for 3-7 days use during normal daily activities including physical activity and training sessions, and automatic analysis for possible arrhythmia situations.

The system gives possibilities for immediate visualization of actual arrhythmia findings in near-real-time follow-up.

Heart signals are unique for each individual – having different shapes and sizes for different people. We cannot guarantee that the ECG247 test will detect every possible type of heart rhythm disorder for everyone. For the same reason, the automatic rhythm analysis can misinterpret the heart rhythm signals so that the system incorrectly warns of possible heart rhythm disturbance.

If the test results show that you have a possible heart rhythm disorders, we recommend that you have the test results/registration assessed by a physician.

ECG247 Smart Sensor is a re-usable medical device to be mounted on a disposable ECG247 Smart Sensor Patch to be sticked to the user's chest, and will be wirelessly connected to a Smartphone ECG247 APP with a dedicated software and secured back-end storage service, to act as a wearable active device for indication of possible arrhythmia situations.

ECG247 Smart Sensor System can be used as an automatic analysis for possible arrhythmia situations according to a color-coded condition of clinical severity as a long-term ECG monitoring procedure.

The user will in the APP receive detailed instructions on how to start an arrhythmia investigation and correctly place the sensor on the chest and will at any time get notifications of possible arrhythmia events detected.

ECG247 Smart Sensor is developed as a medical diagnostic tool for self-test of cardiac arrhythmias carried out by citizens without any need of a doctor's prescription, or to be carried out by health care personnel.

The user can from the APP or the WEB-service have an overview of the test and find information of detected arrhythmia episodes and recorded ECG-signals, and can choose to share access to this information with named persons or health care organisations, as for instance his/her local doctor for evaluation.

Upon the user's request, it is possible to purchase a cardiologist's evaluation of the findings.

Any detected arrhythmia episodes should be evaluated by a medical doctor and for decisions of preventive actions or medication.

ECG247 Smart Sensor cannot be used for infants weighing less than 10 Kg.

ECG247 Smart Sensor is not tested in children, and we would therefore not recommend that children take the test.

ECG247 Smart Sensor cannot be used during defibrillation and should in such cases be removed.

ECG247 Smart Sensor cannot be used for persons using pacemaker of internal defibrillator.

ECG247 Smart Sensor is not tested on pregnant women, and we would therefore not recommend that pregnant women take the test.

ECG247 Smart Sensor is not tested on persons with extreme obesity, and we would therefore not recommend the use for persons with BMI >40 (Obesity Class III).

The user will need to have a Smartphone with the ECG247APP installed and be in a proximity of 10 meters to the phone in order to reliably detect and store actual arrhythmia episodes.

When using the patch some skin irritation may naturally occur. Major ailments are unlikely, however if it should happen it is recommended to terminate the test and remove the patch from the skin. Damages to the skin such as skin rash will normally heal itself within few days. If the ailments persist it is recommended to contact a physician.

7 Long-term ECG Monitoring, Arrhythmia Detection and Classification

Long-term ECG monitoring procedures can be recommended for persons with clinical conditions as:

- Increased risk of stroke due to AF
  - Age >65 years
  - Hypertension
  - Diabetes
  - Chronic/prior cardiovascular disease
  - Prior TIA/stroke
- Symptoms suspicious of arrhythmias
  - Palpitations
  - Tachycardia
  - Bradycardia
  - Syncope
- Cardiovascular diseases with increased risk of arrhythmias
- Evaluation of treatment of cardiac arrhythmias

The ECG247 Smart Sensor System shall detect arrhythmias classified according to the actual clinical severity of the arrhythmia condition where the duration of the actual condition give different severities, defined as a color-coded Severity Index:

Table 1 Overview of arrhythmias detected by the ECG247 Smart Sensor System

Arrhythmia Type	RED conditions	Orange conditions	Yellow conditions	Green conditions
Ventricular Tachycardia	≥30 sec		< 30 sec and > 4 beats	
Pause	≥5 sec			
Heart Rate < 30 bpm (Bradycardia)	≥30 sec			< 30 and ≥ 15 sec
Supraventricular tachycardia	≥30 sec		< 30 and ≥ 15 sec	< 15 sec and > 5 sec
Atrial Fibrillation		≥30 sec	< 30 and ≥ 15 sec	< 15 sec and > 5 sec
Atrial Flutter		≥30 sec	< 30 and ≥ 15 sec	< 15 sec and > 5 sec
Heart Rate > 180 bpm (Tachycardia)			≥ 5 min	<5 min and ≥ 15 sec
Irregular Beat				X
Ventricular Extrasystole				X
Supraventricular Extrasystole				X

RED = Detected arrhythmia that should be evaluated by a cardiologist

ORANGE = Atrial Fibrillation arrhythmia that should be evaluated by a cardiologist

YELLOW = Detected minor arrhythmia episodes that should be evaluated by a cardiologist

GREEN = Normal occurrence of arrhythmia episodes

Episodes of detected single Ventricular or Supraventricular beats as well as other Irregular beats are detected as Green conditions.

Detected arrhythmia episodes are indicated in the ECG247 APP according to the actual color-coded conditions and will give the user a description related to the actual detections.

- A medical doctor needs to assess test results and verifies findings before any treatment.

8 ECG247 Smart Sensor identification and software versions

When starting up a new arrhythmia investigation on a patient, the ECG247 Smart Sensor will connect to the smartphone APP. In the APP under the menu Profile, you will find information of the connected sensor with a unique Sensor-ID. In addition, you will find information of the implemented sensor Firmware version number, and version number for the ECG247 APP.

When downloading the ECG247 APP, it will automatically be installed with permissions for automatic update. When starting a new investigation, the ECG247 APP will connect to the ECG247 Smart Sensor and check the installed software version number. If a newer version of the Firmware is available, the APP will instruct the user to accept downloading and installing the newer Firmware. This is recommended in order to have the latest functions and bug-fixes to be installed.

9 Equipment acceptance control

When a hospital/clinic needs to carry out a system test for acceptance control, the following procedure can be used:

1. Visual check of ECG247 Smart Sensor and ECG247 Electrode
    a. Take a visual check of both the ECG247 Smart Sensor and the ECG247 Electrode.
    b. Both components are marked with a batch number, production date and for the ECG247 Electrode also the expiry date. When tearing of the protective cover underneath the ECG247 Smart Sensor, this information will be removed, and it will not be possible to track this information.
2. Mount the ECG247 Smart Sensor to the ECG247 Electrode and download the ECG247 APP on a smartphone.
    a. Start up a new investigation.
    b. In the APP menu Profile, look up the actual Sensor ID (a unique number) and the Sensor Firmware version number.
    c. The ECG247 Smart Sensor unique Sensor-ID may be recorded in the database of medical devices/ inventory register of equipment.
    d. In the ECG247 WEB service it can be possible for persons with administrative/ technical admissions to track the frequency of use for actual Sensor-ID's connected to the hospital/clinic's ECG247 Cloud-service database.
3. Test and verify ECG recordings
    a. In order to avoid connecting the ECG247 Electrode to a patient or test-person, it can be possible to connect a suitable ECG signal phantom to the two signal pick-up electrodes of the ECG247 Electrode (see figure below).
    b. The ECG signal phantom may be configured for different types of arrhythmias, and it is thus possible to conduct a test of detected arrhythmias according to table 1.
    c. In the ECG247 APP if can be possible to have a visual inspection of the ECG recordings in real-time. The display will optimise the signal amplification in order to have best fit in the window, so it may not be possible to measure the exact signal curve deflection compared to mV/div.
    d. Log in to the ECG247 WEB services with appropriate user and access for selecting the actual Investigation-ID in order to observe the actual arrhythmias detected and the corresponding ECG curves. The signal amplification can be selected (10, 20 or 50 mm/mV), and the x-axes can show different resolutions (25 or 50 mm/s). The actual beat types are annotated. If any arrhythmias are detected, it is shown as the actual finding, and the annotated event is shown in the ECG curve with corresponding colour.
4. Verify the sensor identification
    a. Log in to the ECG247 WEB service with appropriate user and access for administrative or technical persons, to have access to the dashboard where you can select an overview of the actual Sensor-ID's belonging to the hospital/clinic.
5. If the ECG247 Smart Sensor System has implemented any integrations to the hospital's Electronic Health Record (EHR) system, it is recommended to test functionalities in the actual

integration. Please refer to the actual implementation documents to see what needs to be tested and verified.

a. User authentication can be integrated in a single-sign-on function in order for the doctor/nurses to be linked directly to the ECG247 WEB service with automatic authentication and authorization.
b. Access to the actual patient can automatically be transferred from the EHR system, in order to display the correct patient in the ECG247 WEB service.
c. Clinical report as a PDF-file can be downloaded from the ECG247 WEB service, with automatic import to the EHR system and connected to the correct patient.
d. A FHIR-based Investigation Report may be exported from the ECG247 WEB service and with automatic import to the EHR system and connected to the correct patient.

10 Maintenance and periodic test

Maintenance of ECG247 Smart Sensor should only be done by trained service personnel by Appsens AS. In case of maintenance, the ECG247 Smart Sensor should be returned to Appsens AS, and the user will receive a new product as replacement.

It is recommended that competent technical/biomedical personnel run a random system test yearly according to the procedure described in chapter 9 Equipment acceptance control.

In cases of software updates in the integration between the ECG247 Smart Sensor System and the hospital/clinic's EHR system, the same test procedure should be followed to verify correct software updates.

10.1 Expected service life

The ECG247 Smart Sensor has an expected service life of 5 years after purchase.

Warning! Modifications or repairs are not allowed on the ECG 247 Smart Sensor or on the ECG 247 Electrode.

Warning! The battery in the ECG247 Electrode should never be replaced.

11 Cleaning instructions

ECG 247 Electrode is a disposable device and is not intended for reuse. The ECG247 Electrode may be cleaned during normal use with a disinfected towel, if needed.

ECG 247 Smart Sensor is re-usable and may be cleaned with a disinfection towel before reuse.

Warning! Never immerse any of the devices in the ECG 247 Smart Sensor System into water or any other fluids. Never try to clean the devices in water or immerse them into solvents or other fluids. Never immerse any parts of the ECG 247 Smart Sensor System into bathtubs, swimming pools or similar environments.

Warning! Never use solvents other than medical/disinfection alcohol to disinfect the equipment as they may damage the plastic enclosures.

12 Storage

Recommended storage conditions for ECG247 Smart Sensor and ECG247 Electrode:

Temperature: -25 -- +70 gr C
Humidity: 0-90%
Pressure: 500-1060 hPa

13 Referenced documents

No.	Title	Doc. no	Rev.	Author
1	ECG247 Smart Sensor System User Guide		2.24	Appsens
2	ECG247 Smart Sensor System Reference Guide		P2.22	Appsens
3				

14 FCC Part 15 statement

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the Federal Communications Commission (FCC) rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

• Reorient or relocate the receiving antenna.
• Increase the separation between the equipment and receiver.
• Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
• Consult the dealer or an experienced radio/TV technician for help.
Changes or modifications to this equipment not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Privacy of communications may not be ensured when using this device