

Real Time Continuous Vital Signs Monitoring



User Manual

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Information in this document is subject to change without notice. The latest version of this manual can be found at www.sensogram.com

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SensoSCAN (hardware) version: 4.5

SensoSCAN iOS App (software) version: 1.40 (148) SensoSCAN Android App (software) version: 0.69

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1. Introduction

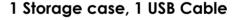
Thank you for choosing SensoSCAN. SensoSCAN is a non-invasive wireless wearable mobile device that allows real-time, continuous, remote monitoring and analysis of vital signs. SensoSCAN measures the heart rate, blood pressure, oxygen saturation, and respiration rate. The device works in conjunction with iOS and Android smartphones and tablets to monitor, share and analyze the data. It is packed in an esthetic and convenient design especially made for comfort and ease of use.

Sensogram Technologies recommends reading this user manual thoroughly to understand the full capabilities of the SensoSCAN device as well as the necessary care and precautions to take.

If you have any other questions, please visit our website under the support section at: http://www.sensogram.com

2. Package Contents

1 SensoSCAN







3. Requirements

To use SensoSCAN and monitor the parameters, you must have:

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• An iOS (iPad, iPhone, iPod touch) or Android mobile device:

For iOS: the versions 7.0 and higher

For Android: the version 4.3 and higher

Bluetooth version 4.0 and higher

 The SensoSCAN Application is installed on the iOS or Android mobile device

To calibrate SensoSCAN, you must have:

• A blood pressure meter also called a sphygmomanometer

4. Product Overview

4.1. The Principle

SensoSCAN captures vital signs through optical biosensors. The captured and calculated values are transmitted via Bluethooth in real-time to a smartphone or tablet, which displays the parameters. The SensoSCAN Application also allows the user to send the data to a dedicated secured cloud system that is accessible via the SensoSCAN web portal by a health professional practitioner or any person authorized by you. All parameters are saved and accessible via the SensoSCAN web portal.

4.2. Intended Use

Practitioners or any individual can use SensoSCAN, whether it is in a professional setting or at home. Authorized professionals or family members can receive remote access to monitor the real-time parameters of the SensoSCAN user.

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4.3. Parts Description



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4.4. Status Screen

The Status Screen provides a number of indicators which, when lit, indicate certain connections are advailable. The table below explains the different possible states.

Symbol	SensoSCAN Status
Square	Device ON , Device setting up, calculating values or the finger is not inserted
Bluetooth	Device ON , Bluetooth connected
Battery	Device ON, battery level
USB	Device ON, USB cable connected; charging
No Light	Device OFF

4.5. SensoSCAN Application

Every SensoSCAN can operate independently or can connect to an application that runs on an iPhone or an Andorid mobile. The User Guide associated with those applications are handled in separate documents.

4.6. First Time Battery Charging

Before using SensoSCAN the first time, completely charge the battery, using the micro-USB cable provided.

4.7. Connect SensoSCAN to the App

All available (unconnected) SensoSCANs are visible in the SensoSCAN Application Preferences page and can be selected to set the connection. Only one SensoSCAN can be connected at a time. The connection method is captured in the SensoSCAN Application User Guide.

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5. SensoSCAN Use

5.1. Measuring Process

SensoSCAN can be used on any finger of the two hands. Before using it, ensure that your hands are clean and that no ring(s) or other objects will interfere.

If the nail of the finger you use for the measurement is cut short and clean from any artificial products such as fingernail polish, painting, or false nail, insert finger and position it under the LED.

If the nail is painted or false, you must insert the finger in the position to pass through the back opening.

- 1. Press the Power On Button once. That will start SensoSCAN.
- 2. Insert finger and the Status Screen will present a bulb signalling proper operation.
- 3. Short presses on the Power button will scroll trough a number of screens:
 - a. Heart Rate (HR) and Oxigenation (SP)
 - b. Heart Rate (HR) and Respiration Rate (RR)
 - c. Blood Pressure (BP), in the order presenting the Systolic and Diastolic Values
 - d. Back to the Setup Screen

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- 4. Check the battery level. If the battery level indicator is low, charge the battery.
- The blood pressure needs up to 20 seconds to be displayed (the time to perform an automatic calibration).
- When you are finished, remove your finger and switch SensoSCAN OFF by holding down the power button for three seconds.

5.2. Battery Charging

To charge the battery use the charging cable provided (USB 2.0 cable micro-B to type A).

- Insert the Micro-USB connector side in the SensoSCAN plug.
- 2. Insert the USB connector side in a free powered USB plug.
- 3. A full charge takes up to 45 minutes.
- 4. The battery is fully charged when the Battery Symbol displays all the 5 bars in the Status Screen.



5.3. Blood Pressure Measurement Protocol

The blood pressure measurement protocol is linked to the calibration section in the SensoSCAN Application User Guide. It is only a recommendation and a general guideline to help the user improve the calibration precision. If you take the measurement yourself, you need a third party blood pressure meter. Otherwise, ask a health professional practitioner to do it. Tell him/her that you need to know your systolic and diastolic results.

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- Take the measurement in the morning or in the evening before going to bed, and in either case, before doing any physical activity, eating, drinking, smoking, or taking medicine.
- 2. Notice that those factors, in addition to stress, excitement, and certain psychological states can influence the blood pressure results.
- 3. Place the blood pressure meter on a table.
- 4. Site down comfortably on a chair, feet on the floor, without crossing your legs.
- 5. Keep relaxed for about 5 minutes before taking the measurement.
- 6. Put the armband on your arm as explained in the user manual of your digital blood pressure meter.
- 7. Place your arm on the table at heart level.
- 8. Start the measuring process.
- 9. Don't move and keep relaxed during the entire process.
- 10. Repeat the entire process (1 to 8) on the same arm three times to validate the results.
- 11. If the three results are close to each other, take the average. If not, restart the process later or on another day.

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6. Specifications

General Information Product Name: SensoSCAN

Parameters Heart Rate (BPM)

Blood Pressure (mmHg)

SPO₂ (%)

Respiration Rate (BRPM)

Skin Temperature¹

Fall Detection¹

Pain Level¹

Location & Altitude²

Communication Wireless: Bluetooth LE 4.0

Battery Type: Rechargeable lithium polymer

Life time: $6h \sim 8h$ (on a full charge)

Charging time: Up to 45 minutes

Charging temperature: 0 °C ~ 45 °C (32 °F

~ 113 °F)

Environmental operating

conditions

Temperature: -17° C $\sim 60^{\circ}$ C (1.4°F $\sim 40^{\circ}$ F)

Humidity: ≤ 90% RH

Environmental transport

and storage conditions

Temperature for less than 3 months: -

20°C ~ 45°C (-4°F ~ 113°F)

Temperature for more than 3 months: 0°C

~ 30°C (32°F ~ 86°F)

Humidity: ≤ 90% RH

Finger size Diameter: 7 mm ~ 11 mm

Length: ≥ 27 mm

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¹ Not available in this version

² Displayed on the web portal

Weight and dimensions Total weight: 19 grams

Size: 51 x 20 x 30 mm (L/W/H)

Accessories 1 Storage case

1 Micro-USB charging cable

7. General Safety and Precautions

- READ the information in this user manual thoroughly before using SensoSCAN.
- **DO NOT** use SensoSCAN in a moving environment as this may produce inaccurate measurements.
- **DO NOT** attempt to open, or disassemble SensoSCAN, or to remove the battery.
- DO NOT use a microwave or other heating device to dry SensoSCAN.
- DO NOT drop SensoSCAN onto a hard surface to avoid causing damage to the device.
- DO NOT use SensoSCAN if it is damaged or cracked.
- **DO NOT** use SensoSCAN in areas where electronic equipment is prohibited.
- DO NOT wear SensoSCAN while doing X-ray radiography, Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or diathermy treatment. X-ray, strong magnetic fields and extreme heat could damage the device.
- **DO NOT** use conventional high temperature sterilization process.
- DO NOT use SensoSCAN where there is a risk of water immersion, in the rain, in the shower, or any other similar environment. The device is not waterproof.
- DO NOT dispose of SensoSCAN with the household waste. It
 contains substances that may be damaging to the environment.
 Instead take it to a recycling collection point to ensure it is
 properly eliminated.

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8. Care and Maintenance

8.1. Usage Conditions

Use SensoSCAN in a clean, dry and safe place protected from extreme heat and where there is no risk of water immersion or splashes, and within the environmental conditions described in the specification chapter. SensoSCAN can operate under any light conditions without affecting the parameters.

8.2. Storage Conditions

Always store SensoSCAN in a safe, clean, and dry location protected from dust, direct sunlight and extreme temperatures (see the specifications chapter).

8.3. Cleaning

Use a lint-free soft cloth moistened with antibacterial solution to clean SensoSCAN. Clean gently with care all surfaces of SensoSCAN and allow to dry before the next use or storage. Sterilization with dry UV light is allowed.

9. Disclaimer

Sensogram Technologies is not liable, or responsible for incidental, or consequential damages, personal injury, property damage, or other damages arising from the use of this document or the software and hardware described in this document. It is the responsibility of the user to ensure that SensoSCAN is used in proper environmental conditions, and in a location and manner that is applicable for its intended use.

10. Compliance Information

For United States and Canada

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FCC ID : 2AF5O-\$300 IC ID : 20709-\$300

This device complies with part 15 of the FCC Rules and with RSS-247 of Industry Canada. Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Ce dispositif est conforme à la norme CNR-247 d'Industrie Canada applicable aux appareils radio exempts de licence. Son fonctionnement est sujet aux deux conditions suivantes: (1) le dispositif ne doit pas produire de brouillage préjudiciable, et (2) ce dispositif doit accepter tout brouillage reçu, y compris un brouillage susceptible de provoquer un fonctionnement indésirable.

Warning: Any changes or modifications not expressly approved by the party responsible for compliance may void the authority granted to the user to operate this equipment under the FCC and IC regulations.

Avertissement: Les changements ou modifications non expressément approuvés par la partie responsable de la conformité peut annuler l'autorisation accordée à l'utilisateur de faire fonctionner cet équipement en vertu des règlements de la FCC et IC.

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 FCC Rules and ICES-003 of Industry Canada. 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:

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- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and the receiver.
- Connect the equipment into an outlet different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

For Europe

Hereby, Sensogram Technologies, Inc. declares that this SensoSCAN product is in compliance with the essential requirements and other relevant provisions of the Medical Devices Directive 93/42/EEC as well as the R&TTE Directive 1999/5/EC on radio and telecommunications equipment. The full text of the Declaration of Conformity can be obtained by Sensogram Technologies, Inc.

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