



SensoSCAN S340®

Vital Sign Monitoring System &
SensoSCAN S340 User Manual

Part Number: UIN-023-100

This manual is intended to provide information for the proper operation of the SensoSCAN S340 vital signs monitoring system. 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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-Notes-



Do not operate the SensoSCAN S340 before reading the instructions

1 Introduction

Thank you for choosing the Sensogram Vital Signs Monitoring System (VSMS) to monitor and study your vital signs. These vital signs are your heart rate, breathing rate, amount of oxygen in your blood, and blood pressure. It works with most Apple and Android phones and tablets. Sensogram wants you to read this manual so you know what the Sensogram VSMS can do.

1.1 Intended Use

The Sensogram Vital Signs Monitoring System is a wireless remote monitoring system intended for use by healthcare professionals, patients with known or suspected chronic / acute conditions and health conscious individuals for discrete or continuous collection of physiological data in home and healthcare settings. This includes blood pressure, heart rate, respiratory rate, and oxygen saturation of arterial hemoglobin (SpO₂). Data is obtained from the Sensogram Sensor Module and is transmitted wirelessly to a central location where it is available real-time and securely stored for analysis. The Sensogram Vital Signs Monitoring System can be configured by to notify healthcare professionals or care providers when physiological data falls outside selected parameters.

The device is indicated for use on patients who are 18 years of age or older to provide remote monitoring of physiological information. The data from the Sensogram Vital Signs Monitoring System is intended for use by healthcare professionals (when prescribed or used under the care of a physician) as an aid to diagnosis and treatment. It is not intended for use on critical care patients or in an active monitoring environment.

The Sensogram Vital Signs Monitoring System is not intended to be used as the sole basis for making diagnosis or treatment decisions; it is intended to be used in conjunction with additional methods of assessing clinical signs and symptoms

2 Safety Considerations

The patient is the intended operator of the SensoSCAN S340 and it cannot be serviced by the patient. All functions are safe to use however, please read and obey all warnings, cautions, and notes that are listed throughout this manual. DO NOT operate SensoSCAN S340 before reading these instructions.



Warnings are about conditions that could result in injury to a person or cause serious problems with the SensoSCAN S340.



Cautions are about things that could result in problems with the SensoSCAN S340.

NOTE: *A note gives you additional information.*

2.1 Warnings



Warnings are about conditions that could result in injury to a person or cause serious problems if not adhered to.

- Do not use the SensoSCAN S340 if it is broken
- Do not use the SensoSCAN S340 when it is plugged in to a power source
- Do not use the SensoSCAN S340 when the battery is charging
- Excessive pressure might occur for prolonged periods so you will need to move the SensoSCAN S340 to another finger every 12 hours
- Do not use the SensoSCAN S340 in Magnetic Resonance Imaging (MRI)
- Do not use the SensoSCAN near pacemakers, insulin pumps, or heart assist devices (no closer than 30cm(12 inches)). These devices might cause degradation of SensoSCAN performance.

- Follow the American Heart Association guidelines for measuring your blood pressure or it may result in errors during calibration
- A new calibration is needed when the management of your blood pressure care changes
- The blood pressure measurement will require a separate blood pressure monitor for initial setup
- Do not use the SensoSCAN S340 in the presence of arrhythmias
- Remove dark fingernail polish before using the SensoSCAN S340
- Do not sterilize the SensoSCAN S340 with steam or high heat
- Do not use the SensoSCAN S340 on newborns or children (below 18 years old) because it is not used for these ages
- Do not adjust message sound levels signals so low that you cannot hear it because of normal noise
- Settings for you may not be right to use for someone else
- Make sure the message functions are turned ON where you will see them on the phone or tablet
- Do not attempt to use more than one SensoSCAN S340 on more than one phone or tablet that are close to each other
- Do not use the SensoSCAN S340 if the sensor or sensor area is damaged
- Do not use with flammable anesthetics
- Do not use the blood pressure cuff over your clothes
- Do not use SensoSCAN S340 over gloves or any other material between the sensor and direct contact with the skin
- Clean and disinfect the SensoSCAN S340 prior to reusing it on another patient

- The SensoSCAN S340 Pulse oximetry oxygen saturation (SpO2) does not distinguish carboxyhemoglobin (COHb), or methemoglobin (MEO2) from oxyhemoglobin (O2Hb). SensoSCAN S340 will only measure (O2Hb). False reading might occur in the presence of Dyshemoglobin
- Do not use in wet locations
- If storage temperature is out of range (high or low), operating temperature specifications allow 15 minutes for the SensoSCAN S340 to come to the same temperature as the environment of use

2.2 Cautions



Cautions are about things that could result in problems with the SensoSCAN S340.

- Moving the SensoSCAN S340 away from a phone or tablet that is running the Sensogram App will lose the vital signs data
- An internet or cell phone connection is required to establish vital sign reporting
- Electromagnetic interference may affect the SensoSCAN S340. If interference is seen, move away from the cause of the interference
- Threats through the internet can compromise security. Keep your phone or tablet updated with the newest version
- If you suspect your SensoSCAN S340 or phone App has been affected, contact Sensogram customer support for assistance
- The SensoSCAN S340 is intended to be used on adult fingers from a minimum of 16.5mm to 22.2mm (U.S. Ring size of 6 to 13). Vital signs may vary on fingers outside these parameters
- Use only the appropriate size blood pressure cuff when taking readings
- Do not attempt to pair multiple SensoSCAN S340s to one phone or tablet running the Sensogram Application
- Only use approved accessories to operate SensoSCAN S340

2.3 Definition of Terms

Throughout this manual you will see words in SMALL CAPS. Any time you see a word like this, refer to this section to identify the definition for this context

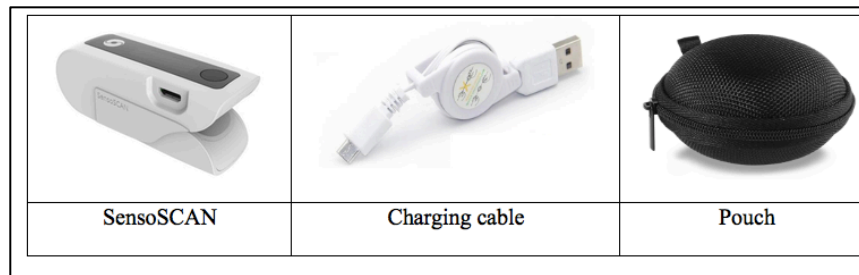
- Care Provider: A person who is authorized to practice medicine or by the State in which the doctor practices; or any other person determined by the Secretary to be capable of providing health care services
- User: The person using the Sensogram Vital Sign Monitoring System
- Session: The time when a SensoSCAN S340 starts to take your vital signs until the time it stops. A session can end when the connection between the phone or tablet and the SensoSCAN S340 is lost, taking the SensoSCAN S340 off your finger, or turning the SensoSCAN S340 off. You can have multiple sessions in a day
- Bluetooth (BLE): a standard for the short-range wireless interconnection of mobile phones, computers, and other electronic devices
- Stream: Transmitting data to the SensoPORTAL that allows a remote care provider to see real-time data that is being transmitted
- PPG: An optically obtained wave that can be used to detect blood volume changes
- End User: The person using or wearing the SensoSCAN S340
- App: An application downloaded by a user to a mobile phone or tablet
- Firmware: Permanent software loaded to run the functions of the SensoSCAN S340

3 Product Overview

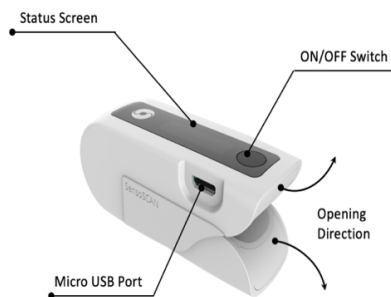
3.1 Package Contents

The package comes with the following:

- SensoSCAN S340
- Charging Cable (Micro-USB)
- Storage Pouch
- Quick Start Guide



3.2 SensoSCAN S340 Features








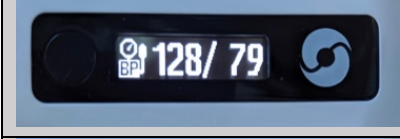



SensoSCAN S340 measures your vital signs. The values are shown on the screen and can be transmitted to the Sensogram App on your phone or tablet. The data can be seen and read remotely or shown as history by a CARE PROVIDER with your permission.

Vital Sign Screens:

	Heart Rate
	Breath Rate

	SP0 ₂ (oxygenation)
	Blood Pressure

3.3 Display Screens

	Initial screen when turned on NOTE: If your finger is removed or not sensed, then this screen will appear
	The last 6 numbers of the SensoSCAN S340 ID will be shown here.
	Pulse Rate NOTE: BPM stands for Beats Per Minute.
	Breath Rate NOTE: B/M stands for Breaths Per Minute.
	Oxygen Measurement NOTE: % stands for percentage of Oxygen in the blood.
	Blood Pressure NOTE: It is read from left to right as being Systolic / Diastolic.
	BP sync screen NOTE: This screen lets you know the Blood Pressure is currently being calculated. If this screen persists then please follow calibration instructions of this manual.
	The SensoSCAN S340 is connected via Bluetooth to a phone or tablet
	The SensoSCAN S340 is currently charging as indicated by the lightning bolt over the battery

3.4 Charging the Battery



Review the warnings and cautions located in section 2 of this manual before proceeding

SensoSCAN S340 uses a Lithium-Ion rechargeable battery. With the Micro USB cable, you can charge your battery from a power source. A full charge will take up to 45 minutes and when full, the battery should last about ~6hrs to 8hrs.

NOTE: The battery is not a serviceable part.

1. Insert the small side of the charging cable into the SensoSCAN S340 port
2. Insert the large side into a USB plug. This could be a plug on a computer, a USB power adapter plugged into a wall, or a USB power station

NOTE: The USB power adapter should be placed in an easy to access location

NOTE: Only the Triplite U280-001-W2-HG is approved to be used as a power adapter during SensoSCAN operation

3. The battery will take up to 45 minutes to fully charge



3.5 Overnight Holder Accessory

The optional overnight holder is an additional accessory that can be purchased at www.sensogram.com. This accessory allows a user to wear the SensoSCAN S340 during sleep without the worry of the SensoSCAN S340 falling off so easily.



To place the overnight holder on the SENSOSCAN S340, do the following:

1. Line up the overnight holder with the SensoSCAN S340 as shown



2. Insert the top end of the holder into the USB port of the SensoSCAN S340



3. Place your finger inside the SensoSCAN S340 and power on. You are now ready to sleep with it on your finger



4 Mobile Application

The SensoSCAN S340 utilizes an App with your phone or tablet. You can also view your account data from a web browser(SensoPORTAL).



Review the warnings and cautions located in section 2 of this manual before proceeding

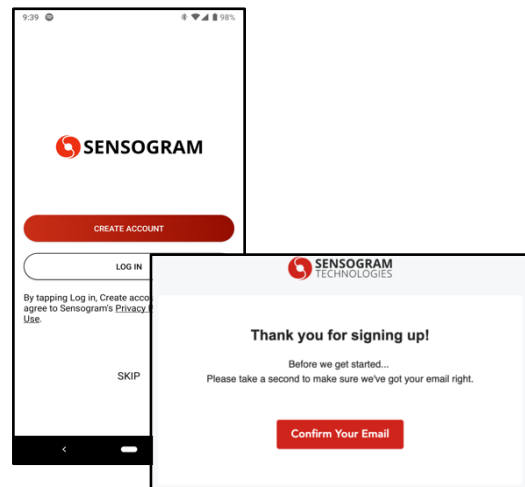
4.1 How to install the Sensogram App

Search for "Sensogram" on the App Store or the Google Play store and install the Sensogram App on your phone or tablet.

4.2 Create your account

When you open the App, you will be asked to allow the App to use your location. It will also ask you to turn on your Bluetooth, if it currently is not on. Consult the manufacturer of your phone or tablet on how to change this setting ⚙️.

1. Tap on Create Account
2. Follow the next several screens to set your email, password, username, and profile information
NOTE: Your password should never be shared with other USERS and Sensogram Technologies Inc will not ask for your password
3. Once finished you will be shown a message to check your email and confirm. You are now ready to use the Sensogram App



4.3 Connect the SensoSCAN S340 to your phone or tablet

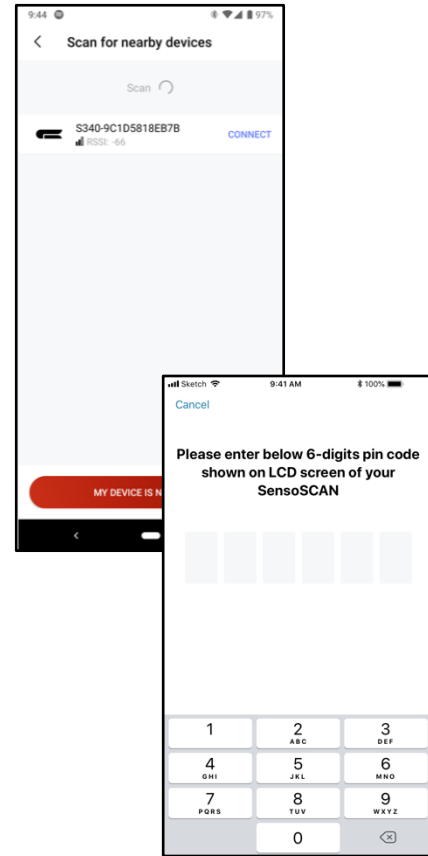


Review the warnings and cautions located in section 2 of this manual before proceeding



Do not put the SensoSCAN S340 on your finger during this section

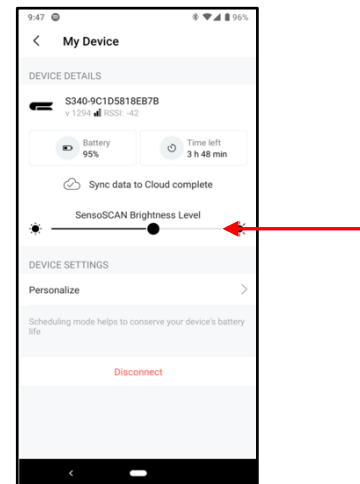
1. Make sure Bluetooth is ON in your phone or tablet
NOTE: The App will inform you if it is not turned on
2. Log into the Sensogram App
NOTE: New USERS will have the option to start a 7-day trial or sign up for Premium access
3. The Sensogram App will begin scanning for a nearby SensoSCAN S340 to connect to
4. Turn SensoSCAN S340 on by pressing the ON/OFF switch so it can be seen
5. When you see your SensoSCAN S340, tap "Connect" You can identify the SensoSCAN S340 by going to "ID: XXXXXX" listed on the SensoSCAN S340 screen. The 6-digit ID shown will match the last 6 digits the App screen
6. The first-time connecting the SensoSCAN S340, will require you to type in a 6-digit number code. Enter the code shown on the SensoSCAN S340 in the Sensogram App
NOTE: This ensures a secure connection with SensoSCAN S340.



4.4 Adjusting the brightness of the display

The brightness of the Status Screen can be increased for outside light or decreased for dark areas. Use these steps to change the brightness:

1. Login to the App and connect the SensoSCAN S340
2. Tap on the SensoSCAN S340 picture in the upper right-hand corner
3. Use the slide dot to adjust the brightness
NOTE: Be careful as the display can be set so low that it looks like it is off.

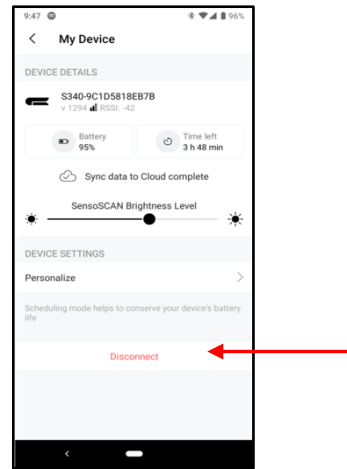


4.5 Disconnect SensoSCAN S340

To disconnect a SensoSCAN S340 from a phone or tablet, use these steps:

1. Tap the SensoSCAN S340 picture in the upper right-hand corner
2. Tap the “Disconnect” button at the bottom of the page

NOTE: This will stop the SensoSCAN S340 connection. You will have to follow steps in section 4.3 to connect again



5 Operation

5.1 Initial setup

- Before you begin, follow the steps in section 4 of this manual to do the following:
 - Install the App (4.1)
 - Create an Account (4.2)
 - Connect the SensoSCAN S340 (4.3)

5.2 First use of SensoSCAN S340

Before placing the SensoSCAN S340 on your finger, follow the American Heart Association guideline for home blood pressure monitor use outlined below:

NOTE: Reference www.heart.org for more information

- **BE STILL:** Don't smoke, drink caffeinated beverages, or exercise within 30 minutes before measuring your blood pressure. Empty your bladder and ensure at least 5 minutes of quiet rest before measurements.
- **SIT CORRECTLY:** Sit with your back straight and supported (on a dining chair, rather than a sofa). Your feet should be flat on the floor and your legs should not be crossed. Your arm should be supported on a flat surface (such as a table) with your finger using the SensoSCAN S340 placed near heart level.
- **Don't take the measurement while talking or moving**

The SensoSCAN S340 can be used on ANY finger with the display on the top of the finger. **NOTE:** See below. Make sure hands are clean and the finger you are using does not have rings, gloves, or dark nail polish. Insert your finger completely into the SensoSCAN S340. **NOTE:** If not done properly, you may not show correct vital signs.



Placed correctly on the finger

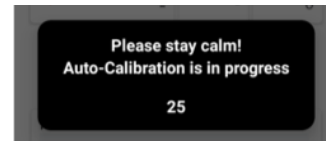


Sensor detects a finger

At this time, place the SensoSCAN S340 on your finger, and then connect it to the Sensogram App. A profile identification process will occur, this is important for Blood Pressure(BP) calibration.

Do the following:

1. Remain as still as possible when you see the message to the right
2. Be calm and do not talk during the SESSION
3. Do not move
4. This process will take up to 1 minute to complete



5.3 Blood Pressure Calibration Process

NOTE: A Calibration is how the SensoSCAN S340 knows your blood pressure. This is a way to make sure the blood pressure you see is correct.



Review the warnings and cautions located in section 2 of this manual before proceeding

What you need to know about calibration:

- A new USER is required to complete an initial calibration before using the SensoSCAN S340
- This requires a SensoSCAN S340 and a blood pressure monitor for a reference reading. You must follow the AHA guide for taking blood pressure.
- Measured on your upper arm with a cuff-based BP monitor
- The steps to do this are guided by the mobile App
- You have to complete section 4 of this manual

American Heart Association process for taking blood pressure:

NOTE: Reference www.heart.org

- Do not smoke, exercise, have any caffeine or alcohol for 30 minutes
- Relax in a chair for 5 minutes or more with your left arm resting on a flat surface and your upper arm is at the same level as your heart
- Be calm and do not talk
- Use a blood pressure monitor that is calibrated and confirmed
- Make sure the cuff fits your upper arm
- Place the bottom of the cuff on the upper arm above the elbow

Begin Calibration:

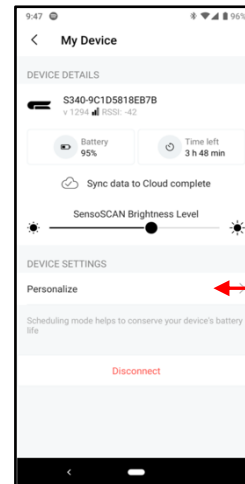
1. Warm your hands prior to placing the SensoSCAN S340 on your finger
2. Login to the Sensogram App

3. Tap the SensoSCAN icon in the upper right-hand corner
4. Tap on "Personalize"
5. Follow the directions on screen
6. SensoSCAN S340 will begin to learn your BP

NOTE: If readings are not successful please warm your hands and go back to step 4

7. Type in the reference blood pressure numbers from the BP monitor
8. You will receive a success message when finished

NOTE: Please allow up to 5 minutes for your blood pressure to appear after calibration



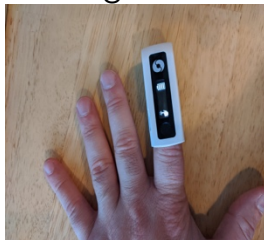
5.4 Taking vital measurements



Review the warnings and cautions located in section 2 of this manual before proceeding

The SensoSCAN S340 can be used on any finger. To start, make sure your hands are clean and no rings or other items are worn. Clean your fingernail so there is no dark nail polish or paint and remove artificial fingernails. Insert your finger so it is between the sensor windows.

1. Before you start, be sure the steps in section 4, 5.2, and 5.3 are done
2. Press the "Power On" button once to start the SensoSCAN S340
3. Insert your finger and the Status Screen will show a blinking Heart once your finger is detected



4. Once your heart rate is shown, by pressing the "Power On" button, these vital signs will show in the following order:
 - a. Breathing Rate (B/M)
 - b. Oxygen Saturation(%)
 - c. Blood Pressure (mmHg)

NOTE: Blood Pressure will be shown as Systolic/Diastolic values

NOTE: Blood Pressure measurement typically takes less than a minute but no longer than 5 minutes under optimal conditions

NOTE: Remain still for Blood Pressure measurement

NOTE: The first blood pressure number will not be right if you did not complete the calibration. Refer to section 5.3 for BP calibration

- d. ID number of the SensoSCAN S340. The Bluetooth icon will show if it is connected to the Sensogram App.
- e. Heart rate (BPM)

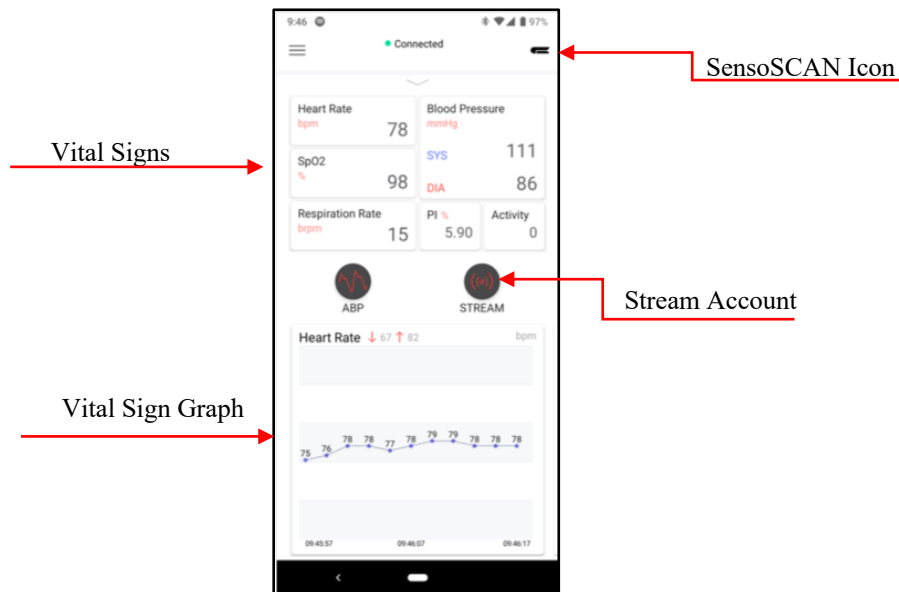
5.5 Using the Phone or Tablet App

When you log in and wear the SensoSCAN S340, the App will default to a HOME screen shown below. Each box contains a vital sign. Pulse Rate, SpO₂, Respiration Rate, Blood Pressure. You will also be able to access Current and Historical vital signs and also see the battery % of the SensoSCAN S340.

NOTE: Perfusion Index indicates how well your blood is flowing in your finger where $PI < .2$ = not enough blood flow

NOTE: Activity Index indicates the level of motion of the SensoSCAN S340 on a scale of 0-20:

0-2	Sitting Still on couch
2-4	Slow walking
4-6	Fast Walking
6+	Active motion, cardio workout



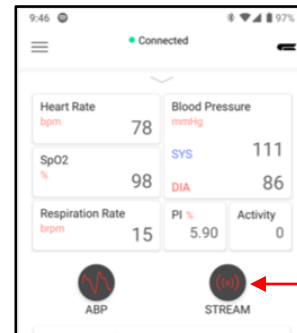
Tap a vital sign box and the corresponding graph below will be displayed

5.6 Streaming Vital Signs

The SensoSCAN S340 and the Sensogram App allows you to send (STREAM) vital signs and waveforms to your account so CARE PROVIDER can remotely see your vital signs.

To send the vital signs, use these steps:

1. Login to the Sensogram App
2. Connect your SensoSCAN S340
3. Place the SensoSCAN S340 on your finger
4. Tap the STREAM button
 - a. You can choose to send vital signs or vital signs and PPG waveform
 - b. Once you make your selection the STREAM icon will turn white



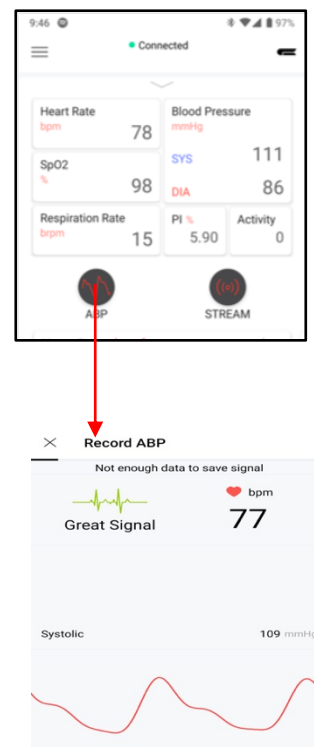
5.7 Saving the PPG Waveform

The Sensogram App can save your PPG waveform as a PDF file. Do the following:

1. Login to the Sensogram App
2. Connect your SensoSCAN S340
3. Place the SensoSCAN S340 on your finger
4. Tap the "ABP/PPG" icon

You will be brought to a screen which will now record your vital signs and wave form. After a short time, there will be enough data and you can save the info. Do the following:

1. "Share PPG" to your CARE PROVIDER via email
2. Tap done to close the window



6 Managing Your Network

Sensogram enables you to safely share information with one or more CARE PROVIDER(s). This feature will allow them to see your vital signs from a remote location. Doing so, enables your CARE PROVIDER(s) to manage the notification settings of your profile. Please consult your CARE PROVIDER about notification settings.

6.1 Sharing your account

Ensure the following are done prior to sharing:

- You must have an account with Sensogram
- You must have a SensoSCAN S340
- You must have a phone or tablet with the Sensogram App
- Your CARE PROVIDER must have an account with Sensogram
- Your CARE PROVIDER must be trusted by you to protect your information

NOTE: Make sure you remove previous CARE PROVIDER(s) who no longer need access to your account.

6.2 Allowing access using the App

Do the following to allow access:

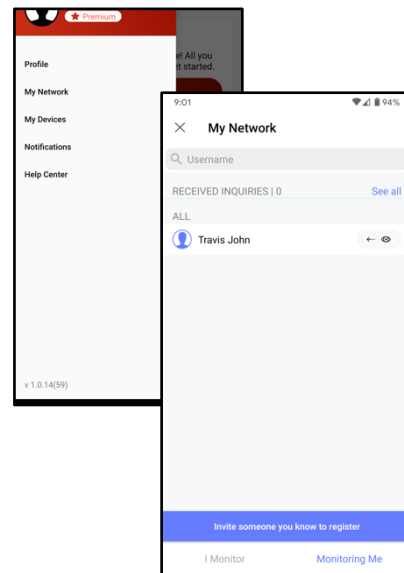
1. Login to the Sensogram App
2. Tap on the menu button in the upper left corner
3. Tap on "My Network"
4. Tap on "Monitoring Me" to view users and requests sent to you

NOTE: The CARE PROVIDER needs to request access from you to view your data.

NOTE: Please consult the Care Provider User Manual on how to request access

5. Tap the confirm icon next to the user you want to "Allow" access

NOTE: Do not allow unrecognized users access to your account



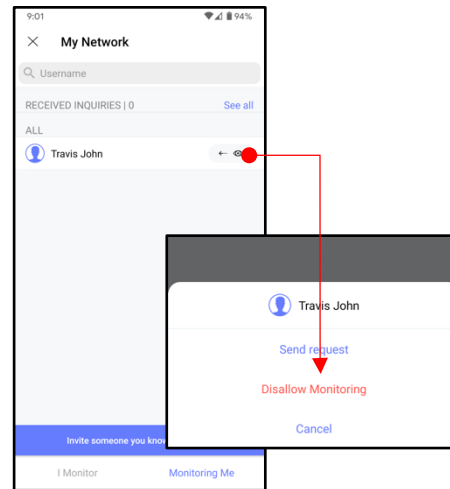
6.3 Removing access using the APP

The control of who sees your info is completely up to you. When required, you can remove any account that is currently monitoring you. If your CARE PROVIDER changes, make sure they are removed from your account in a timely manner.

Do the following:

1. Login to the Sensogram App
2. Tap on the menu button in the upper left corner
3. Tap on "My Network"
4. Tap on "Monitoring Me" to view users and requests sent to you
5. Tap the icon next to the user you want to remove
6. Tap "Disallow Monitoring" to remove access

NOTE: This will complete remove access from the user and they will have to request access again to be able to monitor your account



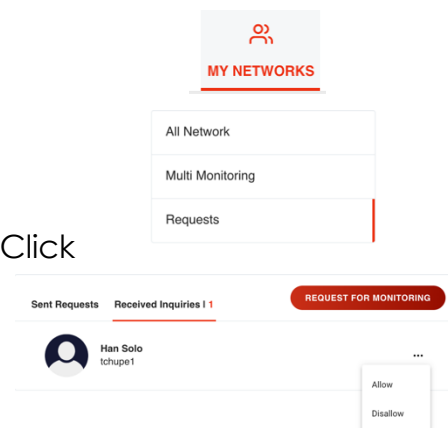
6.4 Managing access using the SensoPORTAL

The SensoPORTAL is a web-based application. Currently the supported web browsers are Google Chrome, Apple Safari, and Mozilla Firefox. SensoPORTAL allows you to view and manage your account using a web browser. SensoPORTAL can be accessed via cloud.sensogram.com.

To allow a CARE PROVIDER monitoring on your account, do the following:

1. Login to the SensoPORTAL
2. Click on "MY NETWORKS"
3. Click on "Requests"
4. Click on "Received Inquiries"
5. Select the icon next to the user and Click allow

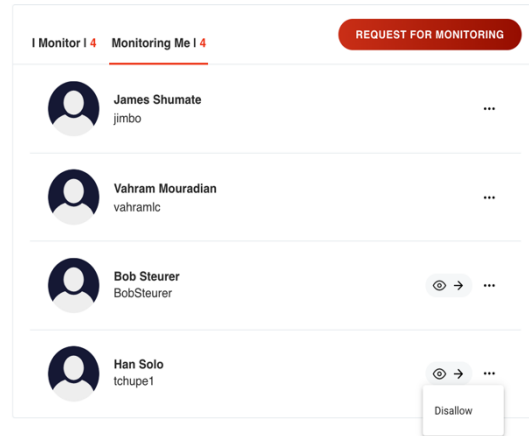
NOTE: Do not allow unrecognized users access to your account



To remove CARE PROVIDER access, do the following:

1. Login to the SensoPORTAL
2. Click on “MY NETWORKS”
3. Click on “Monitoring Me”
4. Click the 3 dot icon next to the user you want to remove
5. Click on “Disallow” to remove the user from monitoring your account

NOTE: This will complete remove access from the user and they will have to request access again to be able to monitor your account



7 System Notifications

The Sensogram Vital Sign Monitoring System uses the combination of Sensogram services and the SensoSCAN S340 to perform system notifications to END USERS and their CARE PROVIDER(S). The control of who gets your info is in your hands.

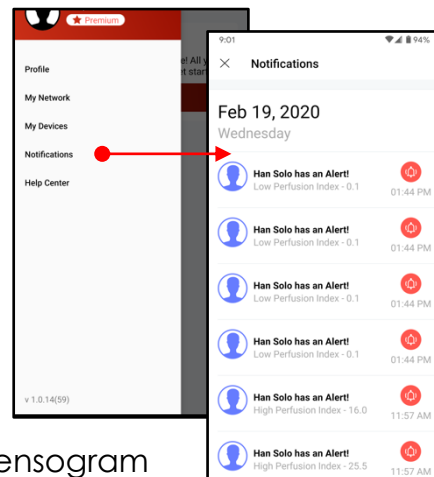
When vital signs are captured, they are measured against a minimum/maximum factory default value set by the manufacturer. If a vital sign is outside of the preset values, a notification will be sent to the END USER and any CARE PROVIDER(S) authorized to monitor their account.

7.1 Notifications in the Sensogram App

The Sensogram App will allow the end user to access any of the system notifications, past or present. Tapping on INBOX at the bottom menu bar will direct you to a list of notifications.

To access your historical notifications, do the following:

1. Login to the Sensogram App
2. Tap the menu in the upper left-hand corner
3. Tap on "Notifications"
4. A list of previous notifications will be there



Mobile phones or tablets are equipped to receive notifications from Apps currently loaded. Since Sensogram utilizes this feature, please ensure your notifications are turned on prior to using the Sensogram App. Consult the manufacturer of your phone or tablet on how to change this setting ⚙️

NOTE: Once you receive a notification, quickly navigate to the Sensogram App and read any notifications listed there.

8 Maintenance/Cleaning

8.1 Cleaning and Disinfecting

Follow these steps to clean the SensoSCAN S340 or the Overnight Holder accessory:

1. Turn the SensoSCAN S340 OFF
2. Use a lint free cloth that is damp with alcohol (70% isopropyl) and clean the outside of the SensoSCAN S340
3. Carefully clean the inside of the SensoSCAN S340, especially near the two sensor windows
4. Use a lint free cloth that is damp with alcohol (70% isopropyl) and clean the outside of the Overnight Holder

NOTE: It is recommended to clean the SensoSCAN S340 after each use

NOTE: To Sterilize use an Ozone gas sterilizer

8.2 Inspecting Equipment

Before use, inspect the SensoSCAN S340:

1. Look at the outside to see that it is clean, not broken, and pieces are not missing
2. Make sure there is no liquid on the outside
3. Look at the inside to see that it is clean and looks good. Do not use if you see damage
4. Inspect the USB cable for damage. If there are wires exposed, or any damage, do not use

8.3 Product Disposal



Review the warnings and cautions located in section 2 of this manual before proceeding

The SensoSCAN S340 should be taken to your nearest electronics recycling facility or other appropriate method as governed by local regulations. Do not dispose of as normal waste.

9 Update New Software

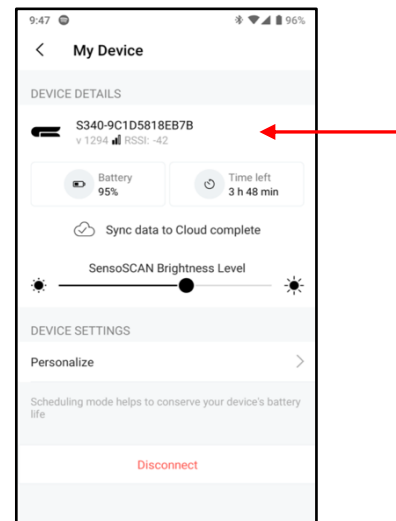
The SensoSYNC program sends data to your account and brings the SensoSCAN S340 up to date when it is needed. This program will be downloaded from www.sensogram.com using a Mac or PC computer.

9.1 How to check the SensoSCAN S340 Firmware version

The correct version is needed so you have accurate vital signs on your SensoSCAN S340. Follow the procedure below to check for the latest version.

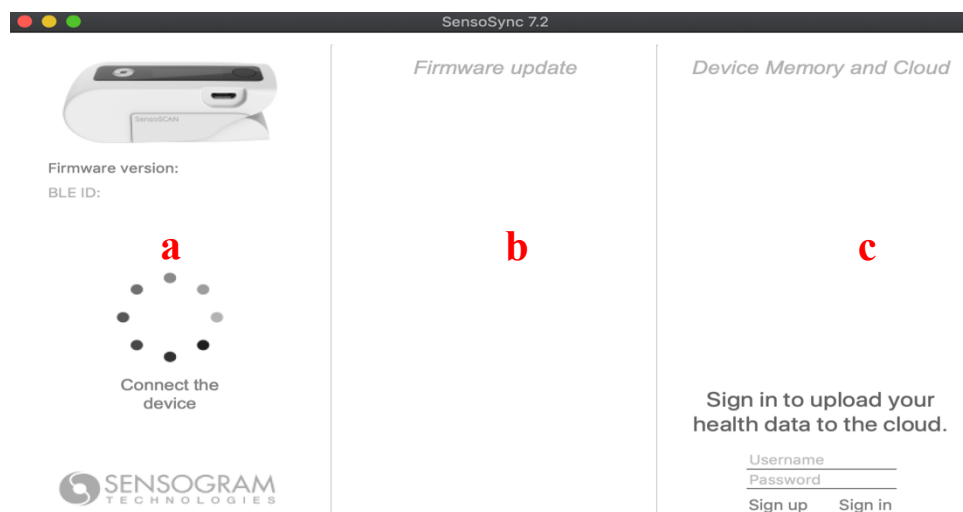
1. Login to the Sensogram App
2. Connect the SensoSCAN S340
3. Tap on the SensoSCAN S340 picture in the upper right-hand corner
4. The version # is located near "v"

NOTE: The SensoSCAN S340 will need to use the SensoSYNC program to update the firmware.



9.2 Using the SensoSYNC Utility

1. Go to www.sensogram.com to get the SensoSYNC program
2. Click on "Support" at the top
3. Click on "SensoSYNC Software"
4. Select the correct download link for your system
5. The program will begin downloading. Run the install package
6. When the program is done, start it
7. The following screen will be shown:

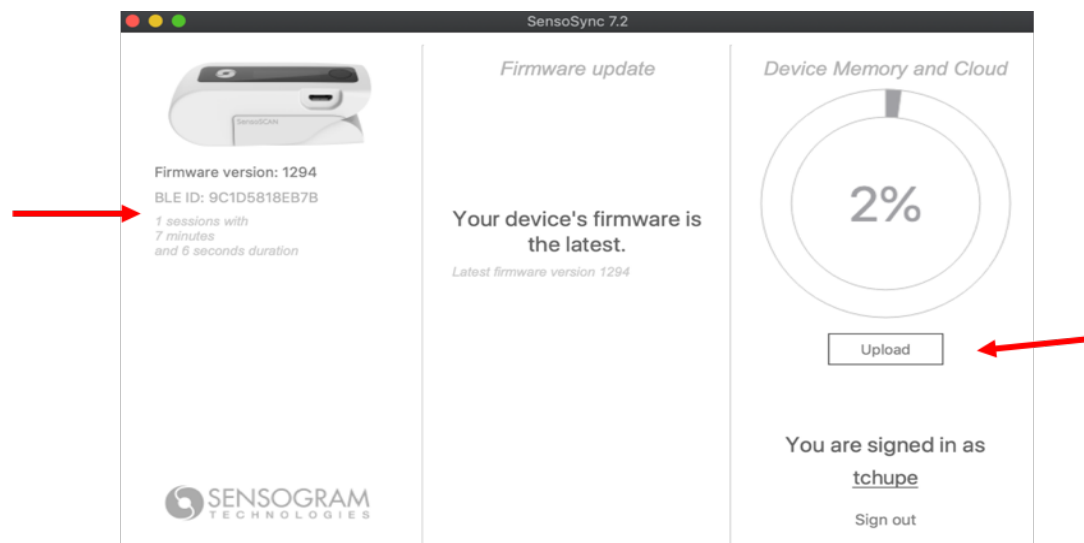


The 3 sections are:

- a. The left-hand section is searching for your SensoSCAN S340
 - i. Connect the USB cable to the SensoSCAN S340 and to the computer
 - ii. This will show your SensoSCAN S340 number (ID), the version, and any data that needs to be sent to your account
 - b. The middle section only shows when there is a new version available for your SensoSCAN S340

NOTE: Updating your firmware will erase ALL data on the SensoSCAN S340. Be sure any data is uploaded to your account prior to updating your firmware
 - c. The right-hand section is where you:
 - i. Login to your account
 - ii. Send data from the SensoSCAN S340 to your account
8. Once you are logged in and the SensoSCAN S340 is connected, the SensoSYNC screen will look like the image below

NOTE: This example shows a SensoSCAN S340 with 1 SESSION and 7 minutes of data on the SensoSCAN S340



9. When you select the "Upload" button in the right-hand section, the data from the SensoSCAN S340 will be sent to the current USER.
- NOTE:** Ensure data is being sent to the correct account before you select the Upload button

10 Troubleshooting

10.1 Customer Service

For SensoSCAN S340 warranty, service, or other questions please contact Sensogram Technologies Inc. directly at:


Phone +1 (833) 736-7647
 Email Support@sensogram.com
 Website www.sensogram.com

10.2 SensoSCAN S340

Problem	Possible Cause	Solution
Screen is blank	Brightness is turned down	Turn the brightness level up
	Battery is not charged	Plug in and charge the battery. If it does not charge, try another cable.
	SensoSCAN S340 is in power saver	Press the "ON/OFF" switch to turn ON
Low Perfusion	Fingers are Cold	Warm your fingers with a warm cloth or warm water
	Dirty sensor	Clean the window area as shown in section 8
Excessive Movement	You are moving too much	Keep still while it is on your finger
	You are moving too much to get a good signal	Stay still for 1 to 2 minutes
Blood Pressure stuck on BP-Sync	Calibration not complete	Follow the steps in section 5.3
	Movement detected	Follow steps for taking Blood Pressure in section 5.3. Do not move

SensoSCAN S340 will not charge	Cable not connected	Attach the cable and make sure it is firmly pushed in at both ends
	Charger is not completely plugged in	Make sure the USB charger is plugged into a power source
	Battery has died	Contact customer support
Vital Measurements are erratic	Skin is not clean and dry	Clean and dry the skin
	SensoSCAN S340 not secure on the finger	Try a different finger or use the Overnight Holder accessory (additional purchase required)
	Fingernail is artificial, has dark polish or paint, or is too long	Remove any dark polish, paint and/or cut the fingernail.
	Battery is extremely low	Charge the battery with a Micro-USB cable
	SensoSCAN S340 is not in the correct location	Change where the SensoSCAN S340 is on the finger or use a different finger

10.3 Sensogram App

Problem	Possible Cause	Solution
Cannot login	Username is incorrect	Check the username and try again.
	Password is incorrect	Check the password and try again. Use "Forgot Password" link to reset password
SensoSCAN S340 will not connect	Bluetooth is turned off	Make sure Bluetooth for the phone or tablet is turned on. Consult the manufacturer of your phone or tablet on how to change this setting 
	SensoSCAN S340 is not turned ON	Press the On/Off switch

	Bluetooth needs to be reset	Turn Bluetooth on the phone or tablet to OFF, then ON and connect
Will not display vital signs	App is out of date	Check the App Store or Google Play Store to update the Sensogram App
	SensoSCAN S340 not connected	Review section 4.3 to connect your SensoSCAN S340
	Sensor placement	Make sure the finger is placed all the way into the SensoSCAN S340
Blood Pressure will not show	Connection	Disconnect and reconnect the SensoSCAN S340 to the App
	Too much motion	Do not move while wearing SensoSCAN S340 so blood pressure will populate
	Calibration not performed	Follow Section 5.3 for calibration procedure
	Version is old	Check the version using the SensoSYNC App and get the latest one
Message says “The SensoSCAN S340 isn’t on the finger”	SensoSCAN S340 is not in the correct location	Place the SensoSCAN S340 fully on the finger
	Something is partially blocking the windows	Make sure nothing is blocking the windows and there is no ring on the finger
	Window is dirty	Clean the window area as shown in section 8.1
Message says “SensoSCAN S340 disconnected”	SensoSCAN S340 is turned off	Press the On/Off switch to turn the power ON
	The SensoSCAN S340 has moved too far away	Move back close to the phone or tablet running the Sensogram App

10.4 Sensogram Portal

Problem	Possible Cause	Solution
Cannot login	Username is incorrect	Check username and try again
	Password is incorrect	Check the password and try again. Use "Forgot Password" link to reset your password
Cannot view any live data	Turn on Streaming	Follow the steps in section 5.6 to STREAM data
	Connection is lost	Check your network connection and refresh the page
	Patient has taken the SensoSCAN S340 off	Contact the patient
Website does not show	Internet Browser is not updated	Update the internet browser and try again
	No internet connection	Check the internet connection and try again

11 Specifications and Safety Considerations

11.1 SensoSCAN S340 S340 Specifications

SensoSCAN S340 S340 Specification Sheet


Storage/Transport (packed/unpacked) Environment	<ul style="list-style-type: none"> • Temperature: -20 °C ~ +70°C • Humidity: at a relative humidity, up to 90 % • Atmospheric Pressure: 70 kPa ~ 106 KPa(70 kPa)
Operating Environment	<ul style="list-style-type: none"> • Operation Temperature: 5 °C ~ +45 °C (41 °F ~ 113 °F) • Atmospheric pressure: 70kPa ~ 106kPa • Operation Humidity: 15 % ~ 90 % , non-condensation • Ambient light: up to 20.000LUX
Power and Battery	<ul style="list-style-type: none"> • Type: Rechargeable Lithium-Ion Polymer, 240mAh • Lifetime: 8 hours on full charge in continuous working mode • Charging time: ~1.5 hours • Charging temperature: 0 °C ~ 45 °C (32 °F ~ 113 °F)
Product Lifecycle expectancy	<ul style="list-style-type: none"> • Commercial: 2 years under normal use (1 complete charge per day)
Dimension and Weight	<ul style="list-style-type: none"> • Dimension: 25.4(H)x24.7(W)x65.7(D)mm : ±1mm • Weight: ~27±1g • Finger size: 6 - 13 (US)
Display	<ul style="list-style-type: none"> • Type: 128x36 dot-matrix single-color OLED • The dimension of active area: 21.734 x 6.095 mm
Internal data Storage	<ul style="list-style-type: none"> • 41 SESSIONS can be stored • Each session can hold 24 hours of data


Vital Signs Specifications

Pulse Rate (PR)	
Measurement Range	30~200bpm
Accuracy	30-200bpm: ± 1 bpm, (PI at $\geq .2$)
Clinical Testing	SensoSCAN S340 passed the accuracy testing of Pulse Rate with an accuracy A_{RMS} of 1.9 ($A_{RMS} \leq 3$) within a wide range of oxygen saturation levels, 69-100%. The range evaluated during the study was 53-104 beats per minute.
Respiration Rate (RR)	
Measurement Range	6~35 BR
Accuracy	+3BR or 10% of reading whichever is higher
Clinical Testing	SensoSCAN S340 passed the accuracy testing of Respiration Rate with an accuracy A_{RMS} of 1.3 ($A_{RMS} \leq 3$) when the device was individually compared to the Reference End Tidal CO ₂ . The range evaluated during the study was 10-29 breaths per minute.
Pulse Oximetry SP0₂	
Measurement Range	70-100%
Accuracy	$\leq 2\%$
Clinical Testing	SensoSCAN S340 passed the accuracy testing of SPO₂ with an A_{RMS} value of 1.7 ($A_{RMS} \leq 3$) under steady-state/non-motion conditions over the SaO ₂ range of 70-100%
Blood Pressure (BP)	
Systolic Accuracy Range	60-240mmHg; ± 8 mmHg
Diastolic Accuracy Range	40-160mmHg; ± 8 mmHg
Clinical Testing	Compliance to ISO 80601-2-30:2018








11.2 Symbols

On your SensoSCAN S340 you will find the following symbols:

	Caution: Refer to accompanying document
IP22	Ingress Protection rating

	Follow waste and electrical and electronic equipment regulations
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On the SensoSCAN S340 packaging box, you will find the following symbols:

	Caution: Refer to accompanying document
IP22	Ingress Protection rating
	Follow waste and electrical and electronic equipment regulations
Li-ion	Lithium-ion battery
FCC	FCC ID
LOT	Manufacture Lot Number of the unit
	Date of manufacture
	Place of manufacture
	Temperature limit
	Atmospheric pressure limit
	Humidity Limit

11.3 EMC Compliance

The operator is the patient. There is not reciprocal interference posed by the device in normal use. Should interference occur, remove the device from the location of the interference. RF-Coexistence testing per FDA guidance was conducted with the SensoSCAN S340 in close proximity to both other medical devices, communication radios, metal detectors, and high-powered security systems. No degradation in any device was observed.

For United States

FCC ID: 2AF5O-S300

IC ID: 20709-S300

This SensoSCAN S340 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 SensoSCAN S340 may not cause interference, and
- (2) this SensoSCAN S340 must accept any interference, including interference that may cause undesired operation of the SensoSCAN S340.

11.4 Warranty and Life Cycle

Product Life Cycle is the progression of a product from introduction to disposal. The SensoSCAN S340 and its accessories life cycle is limited to 24 months from date of delivery.

Sensogram Technologies Inc. warrants to End User, for a period of one (1) year from the date of delivery, unless otherwise noted in specific documentation. Replacements will be issued for SensoSCAN S340 products under the warranty period and such replacements will be covered for a 90-day period. Products include Sensogram Technologies Inc. equipment only. Sensogram Technologies Inc. warrants that its disposables / Consumables products will be free from defects in workmanship and materials for a period of one (1) year from the date of purchase or the expiration date whichever occurs first.

Sensogram Technologies Inc. will not be liable under this warranty if its testing and/or examination discloses that the alleged defect in the Sensogram Technologies Inc. equipment does not exist or was caused by end user's or any unauthorized third person's misuse, neglect, improper installation or testing, attempts to repair, or any other cause beyond the scope of the intended use, or by accident, fire, lightning or other hazard or event of force majeure. The warranty for any hardware will become void if a hardware component is installed as an add-on and/or replacement part on the original hardware and such component part has not been approved for such inclusion by Sensogram Technologies Inc.

11.5 Cyber Security

Sensogram takes your security very seriously. For this reason, we have equipped our system to only accept trusted SensoSCAN S340s. We have also enabled authentications for our USERS and encrypt all data being transferred from the SensoSCAN S340 to your cloud account. In addition, our servers are equipped with breach detection software to identify breaches in a timely manner. We also have in place a backup and recovery protocol in order to roll back to a specific time and date. If for any reason you feel there is an issue, please don't hesitate to contact our support.

11.6 Patient Security

- The SensoSCAN S340 uses industry standard wireless protocols. Follow your institutional protocols for wireless security. It is highly recommended to use a minimum of WPA2 wireless encryption on a secure network
- No patient identifiable information is stored by the SensoSCAN S340. Patient information is stored only on the data record retained by the Sensogram system.

11.7 Patient Privacy and Data Protection

Sensogram Technologies Inc. HIPAA Policy

HIPAA represents the Health Insurance Portability and Accountability Act in the U.S., which was approved by Congress in 1996, and provides patients with uniform access to their medical records and more control over how their personal health information is used and disclosed. It also requires CARE PROVIDER(s) to safeguard the security and confidentiality of medical records for all patients. Sensogram Technologies Inc. takes all required steps to be in compliance with HIPAA regulations. Our employees are trained and have adopted a privacy plan. Our management is responsible for ensuring that the procedures are implemented and up to date with current regulations. Feel free to ask any questions about how Personal Health Information, PHI will be protected.

Information we may collect and maintain

We collect non-public personal information about:

- Real-time patient vital signs such as Heart Rate, Respiration Rate, blood oxygen level, Blood Pressure and related current real-time health information including height, age, and weigh

How we protect your information

Our staff is trained to adhere to the following privacy measures with regards to Protected Health Information (PHI). Each member of Sensogram Technologies Inc. staff must read and sign an Employee Confidentiality and Invention Assignment Agreement which outlines Sensogram Technologies Inc. HIPAA policy. Additionally:

- PHI transmitted over the Internet is encrypted, and all access is protected by passwords.
- Computer display terminals are exited out to a login screen if the user leaves the terminal. Entry into the system is password protected. Passwords are not to be shared.
- Employees will not discuss PHI in a public area.
- The highest levels of Certified Amazon Web Service encryption are used for all messaging and storage