

Regulatory Information

Medical Device Name

Stethophone Pro

Version

3.8.1

For iPhones: XS, XS Max, XR, SE 2nd generation, 11, 11 Pro, 11 Pro Max, 12, 12 Pro, 12 Mini, 12 Pro Max, 13 mini, 13, 13 Pro, 13 Pro Max, SE 3rd generation, 14, 14 Plus, 14 Pro, 14 Pro Max, 15, 15 Plus, 15 Pro, 15 Pro Max, 16, 16 Plus, 16 Pro, 16 Pro Max, 16e, 17, Air, 17 Pro, 17 Pro Max

Not compatible with iPad

Release Date

May 2026

Unique identification code (UDI)

(01)00860011561736(8012)[3.8.1]

Manufactured by

Sparrow Acoustics Inc.
2416 Natura Dr.

Lucasville, Nova Scotia
Canada, B4B 0X3

Intended Use / Indications for Use

Stethophone Pro is an electronic stethoscope that enables detection, amplification, filtering, and transmission of auscultation sound data (heart and lungs), whereby a clinician at one location can listen to the auscultation sounds of a patient acquired on site or at a different location. Stethophone Pro is intended for use on adult patients. Stethophone Pro is not intended for self-diagnosis and not intended to be used as a sole means of diagnosis.

Stethophone Pro can be used in clinical and nonclinical environments.

For Rx-only: Stethophone Pro is intended to provide decision support to clinicians in their evaluation of patients' heart sounds. The software analyzes heart sounds and phonocardiograms and can automatically detect murmurs that may be present, sound timing and character, including S1, S2, and the absence of a heart murmur. The interpretations of heart sounds offered by the software are not diagnoses and are meant only to provide decision support to the clinician, who may use the result in conjunction with their own evaluation and clinical judgment.

For OTC: When used without access to the automatic analysis feature or under supervision of healthcare professional, Stethophone Pro is also intended to be used by lay users.

Directions for Use

- Do not use Stethophone for any purpose other than specified in the Indications for Use.
 - **For all users:** All features are available to every user except for automated analysis results.
 - **^{Rx}_{ONLY} For prescription use only:** Access to automated analysis results is only available for professional use or under supervision of a licensed healthcare practitioner.
 - Stethophone cannot diagnose, prevent, mitigate, treat, or cure any health conditions and can only be used for diagnostic decision support. Stethophone is not intended to be used as the sole means for diagnosis. Stethophone is not intended for self-diagnosis.
 - Stethophone is not a substitute for professional medical advice: any information or results provided by Stethophone require medical evaluation by a clinician. If you are experiencing chest pain, pressure, tightness, shortness of breath, or any other sensations that you suspect may be a medical issue, call emergency services.
 - Stethophone can only be used on specified smartphone models.
 - Remove any cables, chargers, and smartphone cases prior to listening in real time or recording sound.
 - Disable Sound Recognition, Headphone Accommodations, and Voice Isolation for your smartphone before real-time listening or recording, as these features may affect microphone input. Compatibility with these features and hearing aids has not been evaluated.
 - For effective sound capture, press the bottom of the smartphone to the skin so that there are no gaps.
 - Wireless headphones are required to listen in real time or during recording. Any standard headphones can be used for listening to recorded sound.
 - Record sound in a quiet place.
 - Listening through clothes is not recommended. It may reduce Stethophone effectiveness.
 - An Internet connection is required in order to record and send examinations, and listen to recordings.
 - Familiarize yourself with User Guide before using Stethophone. There are no additional training requirements for the use of Stethophone.
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Safety Precautions

- Do not use over damaged skin areas.
 - Clean the smartphone before each use in accordance with [Apple Inc. cleaning guidelines](#) or [the USA government recommended cleaning rules for mobile phones](#).
 - It's recommended to switch off other applications, especially graphics-intensive or processor-intensive, while using Stethophone to avoid increased GPU usage. If for any reason you find your smartphone too warm at some point, temporarily pause the usage of Stethophone. Follow [Apple Inc. recommended instructions for temperature management](#).
 - Follow [Apple Inc. recommended product safety instructions](#) including:
 - Do not use on patients with pacemakers, implantable cardioverter-defibrillators, and cardiac resynchronization therapy devices.
 - Do not use near magnetic resonance imaging (MRI) devices.
 - Do not press to the body while charging the smartphone.
 - Do not use if the smartphone has visible physical damage.
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Cybersecurity Precautions

- Only authorized users can access Stethophone.
 - Two-factor authentication will be triggered every 30 days.
 - You need to authorize every new smartphone for Stethophone use.
 - Installing antivirus on smartphones is recommended for your data protection.
 - Ensure you have the right to send examination data to others.
 - Do not share your Stethophone credentials with anyone.
 - You will be logged out after 10 minutes of inactivity.
 - When Stethophone is open, do not leave your smartphone unattended and unlocked.
 - Log out of Stethophone when you are not using it.
 - If the system becomes unavailable due to networking, cloud, or connection problems, you will be shown a message. No further action is required. When the connection is available, the application will continue working as intended. Stethophone remains available for use regardless of the connection status.
 - Stethophone is being monitored on a regular basis for potential threats that may result in cybersecurity incidents, such as unauthorized use of the system as a gateway to other systems, unauthorized use of another user's account, unauthorized use of the system, or execution of malicious code that destroys or steals data. If a cybersecurity incident affects the application or Personal Health Information loss is identified, you will be informed about the incident via email and, if necessary, given instructions on how to proceed.
 - Manufacturer constantly maintains the appropriate security level of the application. When new versions are released, we will inform you to update your application.
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