

Steth IO®

User's Guide

Document Number: 11-00-UM-1000-00

Revision E

Release Date: October 12, 2018

Version: 1.4 for iPhone

www.stethio.com

© 2018 Steth IO, All rights reserved.

An updated list of US and International Patents (granted or pending) is available on our website.

Steth IO

1. Legal Disclaimers

Steth IO is a tool to be used in healthcare for physical examination of individuals. This device does NOT provide a clinical diagnosis and can only assist the examiner in arriving at a clinical diagnosis. When necessary, it is recommended that clinical expertise should supersede any examination findings suggested by the device.

Caution: Federal law restricts this device to sales by or on the order of a physician.

2. Contents

Legal Disclaimers	2
Introduction	4
Product Description	5
Components of the Steth IO System	5
General Device Product Specifications	5
Performance Characteristics	5
Environmental Specifications	6
User Interface	6
Intended Use	6
Indications for Use	6
Intended User	6
Intended Use Environment and Targeted Patient Population	6
Limitations of Use	7
Contraindications	7
List of Cautions and Warnings	7
General Safety Precautions	7
Warnings	7
Steth IO Device and Software Installation	7
Device Installation	7
Downloading and unlocking the Software	8
Software Registration and Unlocking	8
Confirm Registration	9
Software Sign-In	9
Registration Example	9
Using the Steth IO	9

Device Placement	9
Heart Sounds	10
Lung Sounds	10
Recording and Visualizing Sounds	11
Replaying the Sounds	11
Annotating an Exam	12
Cropping, Highlighting and Deleting Segments	12
Ending and Saving an Exam	13
Examination Storage Management	13
Associating an Exam with a New Name	13
Associating an Exam with an Existing Name	14
Adding Photograph to an Exam	14
Editing Exams	14
Deleting Exams and Segments	14
Accessing Stored Examinations	14
Transmitting Exam Reports	15
Storage, Cleaning, and Maintenance	15
Storage	15
Cleaning	15
Maintenance	15
Customer Service	16
Warranty	16
Troubleshooting	16
Appendix	17
Symbols used for system or package labeling	17
Explanation of Symbols	17

3. Introduction

We want to thank you for choosing Steth IO which can assist you in arriving at a clinical diagnosis during auscultation. Steth IO is a unique device that can convert your smartphone into a digital stethoscope. Greatest of care was taken in designing and manufacturing your Steth IO. An enclosure for designated smartphones and certain handheld computers, this device enables you to hear and visualize amplified sounds from the heart and lungs.

Please read these instructions prior to using this device and save them for future reference.

4. Product Description

Steth IO is an acoustic device that is used in conjunction with a smartphone to collect heart and lung sounds. Steth IO attaches to the back of the smartphone and contains an acoustic waveguide that channels sound from Steth IO stethoscope to the smartphone's microphone, while also acting as a protective covering for the phone. Steth IO smartphone application software performs real-time analysis so the user can hear the sounds using headphones, and visualize the sound using the on-screen phonocardiogram. The device is capable of recording sound and phonocardiogram data, allowing healthcare providers to capture biological sounds and send the data to other healthcare providers or for review at a later time. Steth IO is intended for use as a diagnostic aid, enabling the healthcare provider to identify sounds and any abnormalities that may be present.

4.1. Components of the Steth IO System

	<p>Steth IO Device Steth IO device shown with the installed smartphone.</p>
	<p>Steth IO Software The software application is available for download from a designated software repository. A special link to download the software will be provided with the purchase of the system.</p>
	<p>Smartphone and Headphones The smartphone for which the Steth IO device was purchased, and as indicated on the device packaging, will have to be supplied by the user. The smartphone must be running the latest operating system for the smartphone. To hear the biological sounds during auscultation with Steth IO we recommend using a pair of headphones with a frequency response of 30Hz-20kHz. Adjust the volume on your smartphone to your preferred level of comfort to listen to your auscultation findings.</p>

5. General Device Product Specifications

5.1. Performance Characteristics

Device is designed to guide audio from skin surface to the microphone.

This device does not have a limited shelf-life because of low likelihood of time-dependent product degradation.

5.2. Environmental Specifications

When in conflict with the Environmental Specifications of the intended smartphone, adhere to the stricter Environmental Specifications.



Operational Temperature: -30°C - +45°C



Operational Humidity: 5% to 95% (Relative, Non-Condensing)



Storage Temperature: -30°C - +45°C



Storage Humidity: 5% - 95% (Relative, Non-Condensing)

5.3. User Interface

The device attaches to the smartphone device as a protective cover. The user interface is the stethoscope attachment which is placed on regions of interest on the subject. All interface to the software and device interaction is performed via software running on the smartphone device.

6. Intended Use

6.1. Indications for Use

Steth IO Stethoscope and Phonocardiogram are intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, and lungs with the use of selective frequency ranges. It has been tested for use on adults undergoing a physical assessment.

6.2. Intended User

Steth IO is intended to be used by Healthcare Providers. There are no additional training requirements for use of the Steth IO device.

6.3. Intended Use Environment and Targeted Patient Population

Steth IO is intended to be used in Medical Facilities, Hospitals, Outpatient Clinics, and Physician Offices. Steth IO can be used on any person undergoing a physical assessment. The targeted patient population consists of all types for which the healthcare provider would utilize a stethoscope.

6.4. Limitations of Use

Steth IO may be ineffective in hearing or visualizing biological sounds over thick garments or on individuals with a biological mass index (BMI) of greater than 45.

Steth IO may not be effective in environments with excessive ambient noise.

6.5. Contraindications

Steth IO should not be used over open skin lesions if present at site of examination.

7. List of Cautions and Warnings

7.1. General Safety Precautions

- The device is not operable except for use in conjunction with the Steth IO software application.
- Do not immerse the device in cleaning agents or other liquids.
- Do not attempt to sterilize the device in an autoclave or glass sterilizer.
- Do not operate the device while charging the smartphone.
- Do not use the device if there is visible physical damage to the case, diaphragm or other smartphone.
- Clean the device between uses as described in 13 Storage, Cleaning, and Maintenance.
- Do not use the device for any purposes other than described in the indications for use.
- Do not modify the device except where described in this manual as in replacing the diaphragm.
- Consult your smartphone or handheld computer manufacturer's instructions regarding electrical and radio-frequency interference.

7.2. Warnings

- The device should not be used for patients with pacemakers
- The device can only assist in formulating a clinical diagnosis. When the findings suggested by the device are uninterpretable or not in accordance with your clinical findings we recommend using a traditional stethoscope for confirmation.
- Supplied software is optimized for use with the accompanying hardware and hence the software should never be used without the accompanying hardware.
- Device cannot identify and hence should not be used to detect ischemic heart conditions
- Do not use the device near magnetic resonance imaging devices.
- Keep out of reach of individuals who are incapable of properly using the device.

8. Steth IO Device and Software Installation

8.1. Device Installation

Gently insert your smartphone into the Steth IO device with the screen facing outward and the microphone port of the smartphone aligned with the audio port of the device. The audio port is highlighted below.



8.2. Downloading and unlocking the Software

Obtain access to the software repository using the App Store on your iPhone. That will allow you to download Steth IO software application that works in conjunction with your device to visualize and hear biological sounds during auscultation. The application is available for download in the App Store for the iOS version.

If you have difficulties accessing the software repository to download contact us at support@stethio.com

Installing Steth IO software on the smartphone will place the app's icon on the home screen of the smartphone. Access the app via the icon.

8.3. Software Registration and Unlocking

Software registration is a required step to securely store auscultation exams on your smartphone. Please ensure you have access to the internet via Wi-Fi or your cellular carrier. Follow the instructions on the screen to complete registration.

8.4. Confirm Registration

You will receive an email to your registered email account. Follow the link provided to confirm your account and registration.

Once your account is confirmed and Steth IO software is successfully installed on the smartphone, you can select Sign In to access the full application. See the log-in screen below.

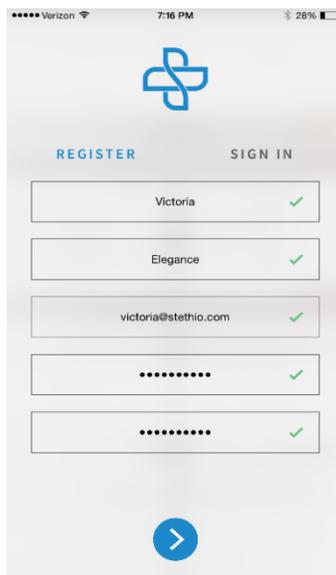
8.5. Software Sign-In

After signing in, the home screen appears. You can access your account settings to change your password, logout and learn about Steth IO via the gear icon at the bottom right corner. As shown in the home screen below.

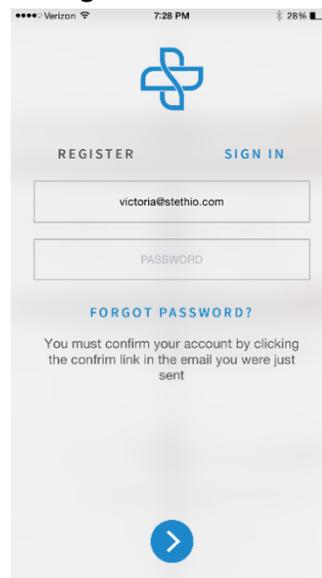
At this point, your device and software are installed and ready for use.

8.6.

Registration Example



Log-In Screen



Home Screen

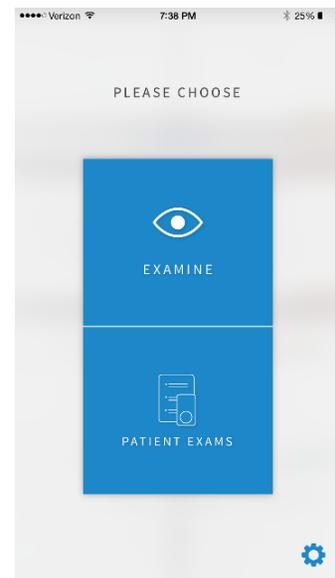


Figure 1: Registration, Login, and Home Screen

9. Using the Steth IO

9.1. Device Placement

With the device installed on the smartphone, the software installed, user account registered, and the headphones plugged in or paired, the device is ready for use. To begin,

touch “Examine” on screen. Holding the Steth IO device in hand, place the stethoscope against the anatomic area of interest (heart or lung) to listen to biological sounds.

9.2. Heart Sounds

Start recording by selecting the examination type. Use the heart icon for heart sounds as shown in Figure 1. Heart icon will turn RED. Heart icon will invoke digital filters to highlight heart sound frequencies making them audible and visible on the screen. During the heart exam the software will analyze the presence of heart sounds for determining the heart rate* and the calculated heart rate will be displayed on the screen.

*Note: Clinical determination of the heart rate is highly recommended.

In the heart exam mode the cardiac sounds will be displayed as a phonocardiogram tracing to enable the examiner to identify the first and second heart sounds along with other extra heart sounds like the third or fourth heart sounds. In addition, the phonocardiogram should be able to detect murmurs in systole or diastole. Graphic representation of the cardiac sounds can aid the examiner in arriving at a clinical diagnosis.

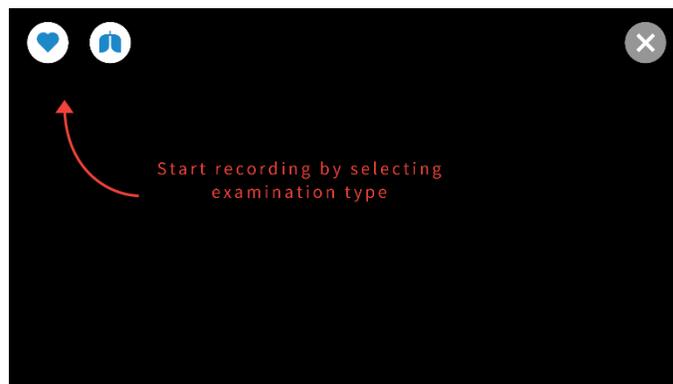


Figure 2 - Begin recording screen. Figure shows heart and lung symbol icons.

9.3. Lung Sounds

Start recording by selecting the examination type. Use the lung icon for other biological sounds. Lung icon will turn RED. Lung sound icon will invoke specialized filters to highlight lung sounds making them audible and visible on the screen.

9.4. Recording and Visualizing Sounds

When the examination type is chosen, Steth IO starts recording sounds while simultaneously displaying them as a phonogram on the screen. The recording can be continued until stopped by touching anywhere on the screen. Note that a single recording can be a maximum of 60 seconds long only. Each time an exam is initiated by choosing the exam type a new segment is recorded within the exam and during the recording of a segment corresponding icon will be lit red to indicate active recording. The segments in each exam will be sequentially numbered and marked accordingly by a heart icon for the heart exams and lung icon for lung exams.

9.5. Replaying the Sounds

Recorded exams can be replayed in a loop by tapping the green PLAY button (See Figure 2) and stopped by tapping the gray STOP button.

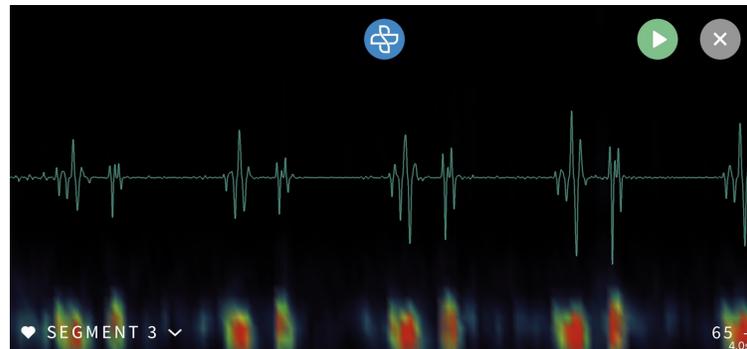


Figure 2: The exam screen after a segment has been recorded. The Steth IO icon on the top-middle is used to access the assisted intelligence feature. The Play button on the top right can be used to replay the recording

9.6. Assisted Intelligence (BETA)

Steth IO provides an analysis feature where the exam sound file is analyzed on a cloud-based system to help the examiner with the interpretation of the result. This Assisted Intelligence feature is automatically triggered once a heart exam segment is completed. The results can be viewed by pressing the Steth IO icon on the top of the screen once the icon starts glowing (See Figure 2).

Please note that this feature is in BETA TESTING currently. Also note that the results of the Assisted Intelligence are based on an algorithmic interpretation of the phonocardiogram and requires a clinical examination to confirm. This must be interpreted by a qualified physician.

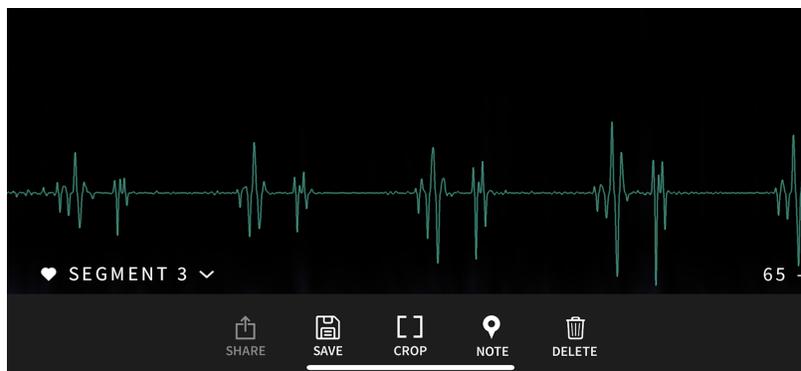


Figure 3: The Exam screen showing the Segment menu on the bottom. The Segment menu can be accessed by pressing on the Segment text on the bottom right of the Exam screen after an Exam has been completed.

9.7. Annotating an Exam

Recorded examinations can be annotated using the Note button which is available in the Segment menu (See Figure 3). Pressing the annotate button will allow an examiner to mark points of interest on the visual representation of the recording with pre-defined acronyms and add free text with up to 300 characters.

9.8. Cropping, Highlighting and Deleting Segments

The Segment menu will allow the examiner to crop “[]” a segment to exclude extraneous sound and visual signals. After selecting the length of the segment to be cropped, press the check box on the top of the screen to crop. This will allow the examiner to edit the exam down to the signals of interest. A segment can also be deleted by tapping the Delete button on the Segment menu.

9.9. Saving & Sharing an Exam

Once a segment has been recorded, the recorded exam segment can be shared with another user by pressing the share button on the Segment menu. The exam can be shared through various options available on the iPhone - Airdrop, Message, Email, etc. The shared exam is available as a stethio file which can be opened by the Steth IO app on another device.

The examiner can also press the Save button on the Segment menu. The saved examination with all its corresponding segments will be stored on the smartphone storage, and can be accessed through the Patient Exams screen.

9.10. Ending and Saving an Exam

Once the examination is completed it can be closed by touching the  button on the right corner screen.

10. Examination Storage Management

Steth IO can be used to auscultate a person as a regular digital stethoscope and exams do not have to be saved by default. When desired, all the segments in an examination for a particular patient can be saved by pressing the Save button. This will prompt the examiner to specify a patient name and a date of birth for the exam.

10.1. Saving the Exam with a New Patient Name

In the Exam Summary screen, which appears after the examiner presses Save, add a patient's name to the field on the screen and press the “+” button to add a new patient with the associated exam. In the next screen, the date of birth, gender, and any other notes about the patient can also be added. The segments in the exam will be numbered sequentially within each exam and will have a heart or lung icon depending on the types of recorded segments within that particular exam. For example: a segment will have both

the heart and lung icons if heart and lung exams were recorded or a single icon if only one type of exam was recorded.

10.2. Associating an Exam with an Existing Name

Typing a name in the field with magnifying glass will prompt existing names which may be associated to an exam. Any number of exams can be added under each name, limited only by storage capacity on the device.

10.3. Adding Photograph to an Exam

To improve the identification of a patient, Steth IO software allows you to associate a photograph of a patient to a named exam. Select an exam from the list, tap the "Portrait" icon gives the options to "TAKE PHOTO", "CHOOSE FROM LIBRARY", or "CANCEL" to cancel the action. If a new photo is taken using the device you will be prompted to use the photo. The photograph selected will be saved in place of the generic "Profile Image" icon.

10.4. Editing Exams

An exam saved under a name can be edited by tapping the pencil icon on the top right hand corner of the screen. This will allow the name associated with the exam to be renamed.

10.5. Deleting Exams and Segments

Each examination may contain more than one segment depending on the number of segments originally recorded. Tapping the pencil icon will bring "red circles" next to each segment and a "DELETE" button at the bottom of the screen.

To delete a segment with in an exam tap the red circle next to a segment and a "DELETE" button will appear next to that particular segment which will allow you to delete the segment.

Tapping the red "DELETE" button at the bottom of the screen will delete an entire exam. You will be promoted for confirmation with "Are you sure?" giving you an option to Cancel the action or proceed to Delete the exam.



11. Accessing Stored Examinations

From the home screen, saved examinations can be viewed by tapping "PATIENT EXAMS". Tapping a name on the list will open the exam and the list of segments within. Each segment can be viewed by tapping on the segment which will open the recorded sound and the associated visual record. The "PLAY", "STOP", and "EXIT" buttons will be active. If necessary you can also CROP "[]", , annotate or "DELETE" a segment.

The list of Patient Exams also contains a set of Demo exams with gray bar next to the exam from a variety of patients indicating normal and abnormal heart and lung conditions.

12. Transmitting Exam Reports

A saved examination on the smartphone can be sent to another person responsible for care via email or another method. Open an exam and tap on Share button at the upper right hand corner. Chose to Email or Export. In case of Email, a HIPAA warning alert indicates you should only send the record to individuals responsible for care. The transmitted email report will contain:

- Time and Date of the Exam
- Patient Name
- Segment Number
- Duration of the recording
- Type of digital filter utilized
- .wav file of the exam
- Visual phonogram of the recorded sound
- A stethio file which can be opened in another device with the Steth IO app.

13. Storage, Cleaning, and Maintenance

13.1. Storage

Do not store the unit in:

- Locations exposed to direct sunlight
- Locations subject to high temperatures and high humidity
- Wet or damp locations where water may get on the unit
- Dusty locations
- Near fires or open flames
- Locations exposed to strong vibration
- Locations exposed to strong electromagnetic fields.

13.2. Cleaning

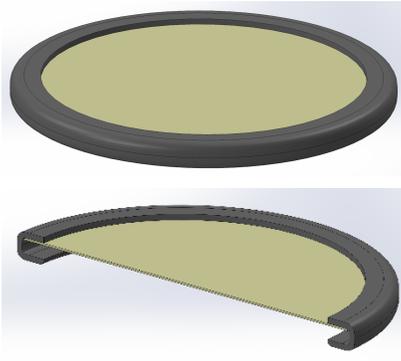
- Do not store or operate the device in extreme temperatures.
- Do not drop the device.
- Use alcohol wipes to clean the exterior surfaces of the device taking care not to get alcohol onto the installed smartphone.
- The device should be cleaned before and after using on each patient to reduce the risk of infection transmission.
- Do not submerge the device in any liquid.
- Notice: Do not subject the device to any sterilization.

13.3. Maintenance

Steth IO hardware is not expected to require any periodic service or maintenance. The diaphragm and the retainer ring may require periodic replacement depending on usage.

The diaphragm and the retainer ring can be replaced without requiring any special tools. To replace the diaphragm, situate the diaphragm in the groove of the retainer ring. With the diaphragm in place, align the lip of the retainer ring with the groove along the rim of

the bell of Steth IO. Apply firm pressure with your fingers along the retainer ring to snap the retainer ring along with the diaphragm into place. Your Steth IO is ready for use as before.



Diaphragm assembled into the retainer ring.

Illustration to show the lip of the retainer ring to be aligned with the groove along the rim of the Steth IO bell.

Experiencing difficulties or have questions on use? Please contact us at support@stethio.com.

14. Customer Service

14.1. Warranty

We are confident that you will be happy with the purchase of your Steth IO. Our hardware has a warranty against manufacturer's defects for a period of one year from the date of original purchase. This warranty does not cover regular wear and tear. Periodic updates for the Steth IO software will be provided to the original purchaser for as long as they own the Steth IO device. This warranty is not transferable.

Questions or Comments? Please contact support@stethio.com.

15. Troubleshooting

Problem	Solution
I cannot hear the auscultation.	<p>Verify the headphones are paired or are plugged in correctly and the audio jack for the headphones is plugged in completely.</p> <p>Verify the device is installed properly.</p> <p>Verify that the correct examination modality is selected (heart or lung).</p> <p>Verify that the volume on the smartphone is not muted.</p>

	Ensure that the volume is turned up adequately enough to make the sounds audible using headphones.
I cannot hear the sound of interest or there is a lot of noise in the auscultation.	Verify the device is installed properly and is fitting securely on the smartphone. Verify that the correct examination modality is selected (heart or lung). Ensure that the device is sitting flush on the patient.
I need to change my email.	Contact support@stethio.com

16. Appendix

16.1. Symbols used for system or package labeling

	Manufacturing Lot Number
	Temperature limits to which the device can be exposed
	Relative humidity limits for the operation of the device

16.2. Explanation of Symbols

	The icon for Steth IO mobile application
	Heart filter
	Lung filter
	Active heart recording
	Active lung recording
	Play recording
	Stop play / Stop recording

	Assisted Intelligence
	Insert annotation / note (at location of track bar)
	Settings (leads to <i>Support</i> , <i>Buy Steth IO</i> , <i>About Steth IO</i> , and <i>Account</i> screens)
	Delete (to permanently remove an examination, patient, segment)
	Close
	Accept
	Forward
	Back
	Edit (patient name, patient assigned to exam, edit note)
	Reject edit
	Accept edit
	Search (indicates where you begin typing patient's name to select from list / field can also be used to enter a new patient's name)
	Profile image (if selected, can be replaced with photo of patient)
	Exam contains both heart and lung recordings
	Exam contains only lung recordings

	Exam contains only heart recordings
	Annotation that indicates the first heart sound
	Annotation that indicates the second heart sound
	Annotation that indicates an extra heart sound
	Annotation that indicates an additional extra heart sound
	Annotation that indicates an Early Systolic Murmur
	Annotation that indicates a Late Systolic Murmur
	Annotation that indicates a Mid Systolic Murmur
	Annotation that indicates a Holosystolic Murmur
	Annotation that indicates an Early Diastolic Murmur
	Annotation that indicates a Mid Diastolic Murmur
	Annotation that indicates a Late Diastolic Murmur
	Annotation that indicates a Holodiastolic Murmur
	Annotation that indicates inspiration

	Annotation that indicates expiration
	Annotation that indicates wheezing
	Annotation that indicates cackles

Steth IO™ and  are registered trademarks of StratoScientific Inc. dba Steth IO

Steth IO™ Device is designed in the USA

Steth IO is protected under the domestic and international patents listed on our website.

Questions or Comments? Contact us at support@stethio.com

RouteMyData History

[Click to see the approval history \(account needed\).](#)