AudibleHealthAI
by RAIsonance

For patients · Self-Referral

Quick Start Guide

Version 7	Applies to App v2.5.0
Effective TBD	UDI-DI (GS1) 00199284438224
GMDN 64033	Language English

Applies to AudibleHealth AI app v2.5.0 and its subsequent maintenance releases (v2.5.x).

View the latest version online:
https://help.audiblehealth.ai/quick-start/self-referral

01

Intended use

AudibleHealth AI (respiratoryscreening.com) is a Clinical Decision Support Software (CDSS) intended to support healthcare providers in screening for tuberculosis, COVID, and/or pneumonia through the evaluation of a forced cough vocalization. The test is intended for point-of-care use by a healthcare provider to screen adults 18 years of age or older. AudibleHealth AI does not provide a definitive diagnosis and is not intended to be a standalone diagnostic tool. As a CDSS, it is intended for use in conjunction with risk assessment, radiography, and other medical diagnostic evaluations to assist the clinician in making individual patient management decisions.

Precautions/Contraindications

You should not use this screening test if you have any of the following conditions:

- Recent acute traumatic injury to the head, neck, throat, chest, abdomen, or trunk
- Patent tracheostomy stoma
- Recent chest/abdomen/trunk trauma or surgery, recent/persistent neurovascular injury, or recent intracranial surgery
- Persons unable to cough voluntarily
- Medical history of cribriform plate injury or cribriform plate surgery, diaphragmatic hernia, external beam neck / throat / maxillofacial radiation, phrenic nerve injury/palsy, radical neck / throat / maxillofacial surgery, vocal cord trauma or nodules
- Persons with aphasia may have difficulty in producing an FCV in the time allotted by the app and have not been evaluated as a population.

Coughing on your smartphone can increase the number of germs on your phone. After you complete your screening, it is recommended that you clean your phone to reduce the risk of spreading a disease.

> **NOTE**
> Patients experiencing breathing difficulties or shortness of breath may require more than one attempt to achieve a successful cough submission for analysis. If breathing difficulties persist or worsen, stop coughing and contact your healthcare provider immediately.

02

Compatibility

The AudibleHealth AI (respiratoryscreening.com) web app can be used on smartphones running iOS (version 18 or newer) and Android (version 13 or newer) operating systems and is compatible with the following web browsers: Google Chrome, Safari, Samsung Internet, and Android Chrome.

Please be sure your smartphone is using one of the compatible browsers listed above.

03

Screens

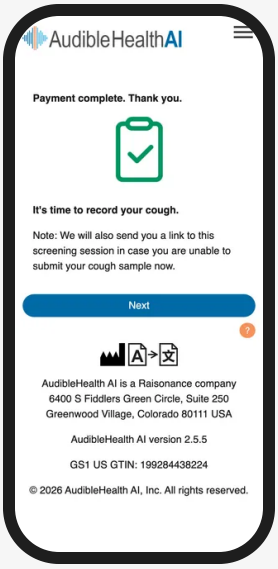
The following is a walk-through of the screens as you will see them, with explanations about them, their function, and how they relate to the overall flow of the AudibleHealth AI user experience.

Step 1

Payment Confirmation Screen

When your payment is complete, you will see the payment confirmation screen below.

Click the “Next” button.

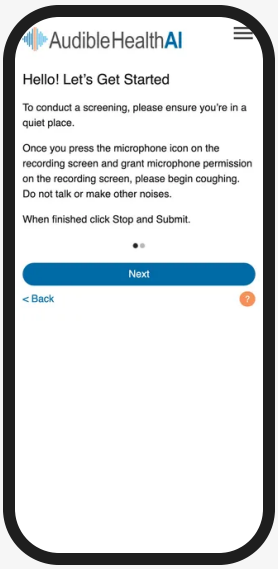


Payment Confirmation Screen

Step 2

Hello! Let’s get started Screen

Please carefully read the Hello! Let’s get started screen to get an overview of the cough submission process. Once you’ve finished reading, press “Next” to proceed to the Coughing Tips Screen.

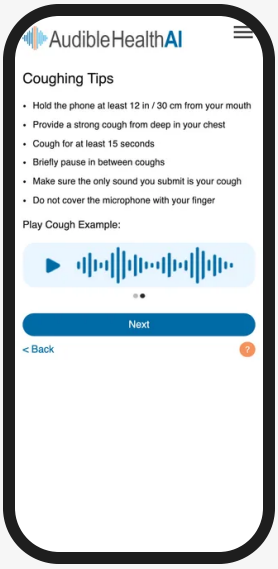


Hello! Let’s get started Screen

Step 3

Coughing Tips Screen

Please carefully read the items listed in the Coughing Tips screen. Being familiar with these items will help you know how to complete a cough submission successfully. If you would like to hear an example of a good cough submission, you can tap the triangular play icon, where it indicates “Play Cough Example”.



Coughing Tips Screen

Step 4

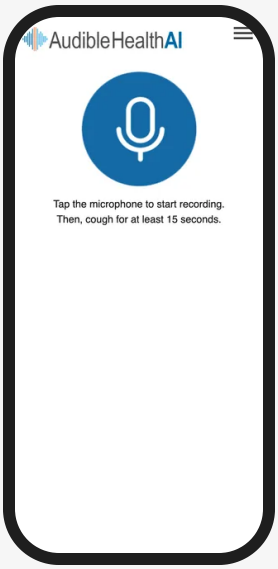
Ready to Record and Recording Screens

You are now ready to submit your cough. On the Ready to Record screen, tap the microphone icon once, then grant microphone permission when the pop-up request appears.

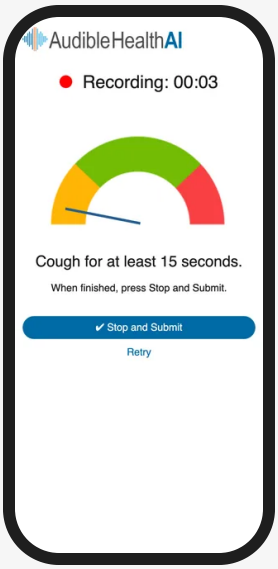
Next, you will see the Recording screen. This is where you will begin coughing and should continue with a series of forced coughs for at least 15 seconds. The needle on the meter will move while you are coughing. This helps you see whether your cough volume is within an acceptable range. If the needle is in the green, your cough is the right volume.

After you've finished coughing, tap "Stop and Submit".

> **NOTE**
>
> You should only tap the "Retry" option if you know the sound quality in the recording was poor (i.e., a siren sounded when you were trying to cough).



Ready to Record Screen

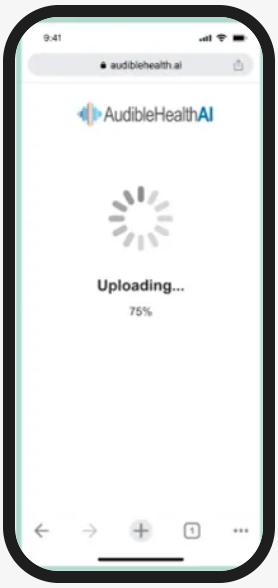


Recording Screen

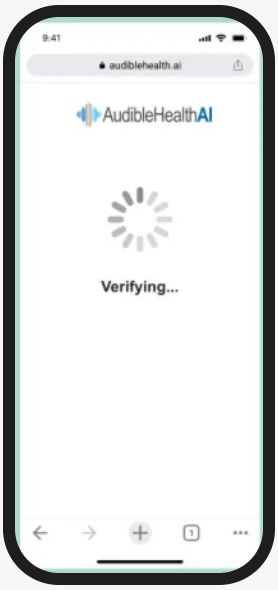
Step 5

Analyzing and Success! Screens

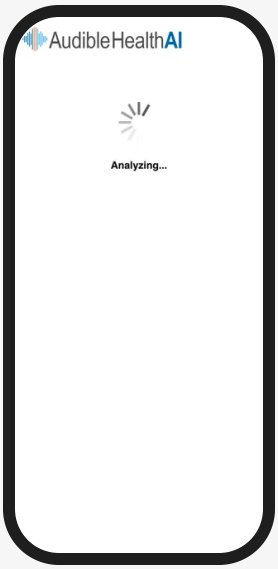
After you submit, you will see the Uploading, Verifying, and Analyzing screens. These screens show the status of your cough sample as the network sends it to the cloud. If you have a good network connection, these screens will progress immediately. If you have a slower network connection, you may see these screens take longer to progress.



“Uploading” Screen

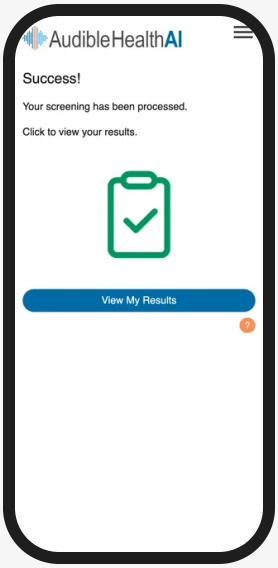


“Verifying Screen”



“Analyzing” Screen

Tap the “View My Results” button to see your Screening Results Summary with your Provider Information.



“Success” Screen

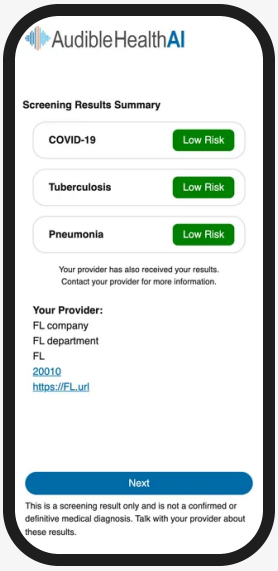
Step 6

Screening Results Summary and Close Browser Screens

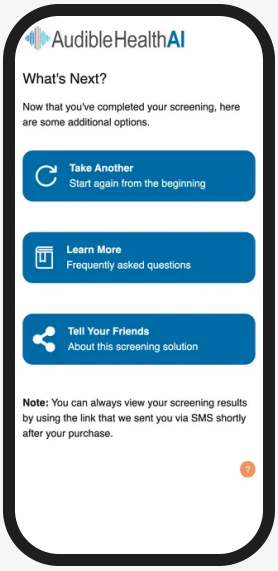
The Screening Results Summary Screen with your Provider Information displays your results and the specific provider to whom they are sent.

Once you're done viewing this information on your personal smartphone, you may tap the "Done" button. You will then see a new browser screen that simply alerts you that you may now close that mobile browser tab.

If you are using a smartphone provided by your healthcare provider, you may instead return it to the provider representative at this time.



Screening Results Summary Screen



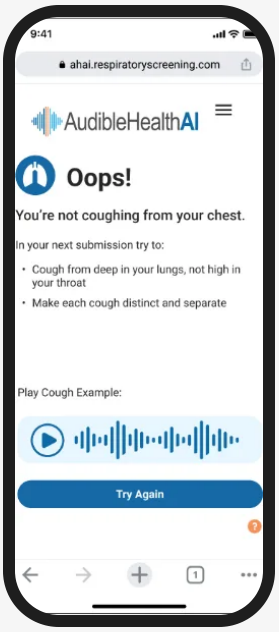
Close Browser Screen

Step 7

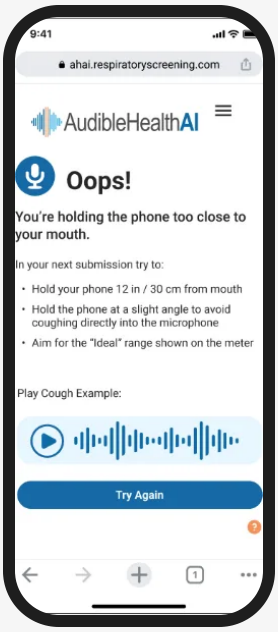
Cough Submission Error Screens

If there is a problem with the sound quality of your cough that caused you to have NO usable coughs for screening, you will see one of these Oops! Screens after the Analyzing screen. These screens provide tips that are specific to the problem with your cough sample, as well as provide another opportunity to listen to the sample cough.

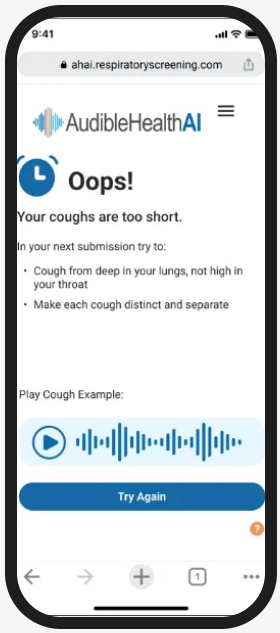
With these Oops! Screens, when you tap “Try Again”, you will be taken back to the Ready to Record Screen shown in Step #4.



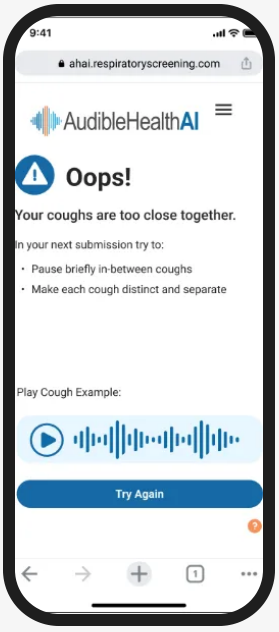
Oops! (1 of 6)



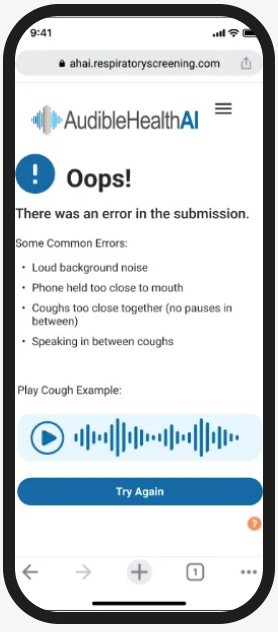
Oops! (2 of 6)



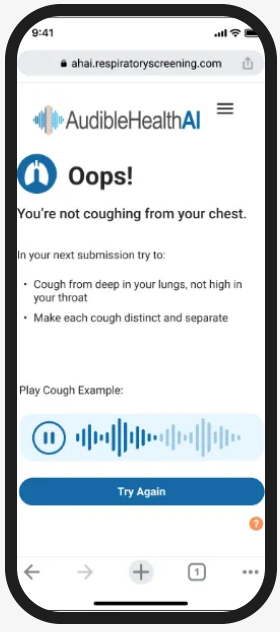
Oops! (3 of 6)



Oops! (4 of 6)



Oops! (5 of 6)

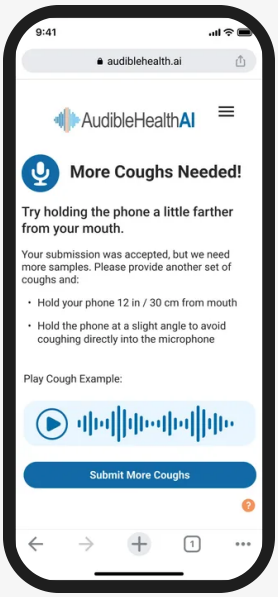


Oops! (6 of 6)

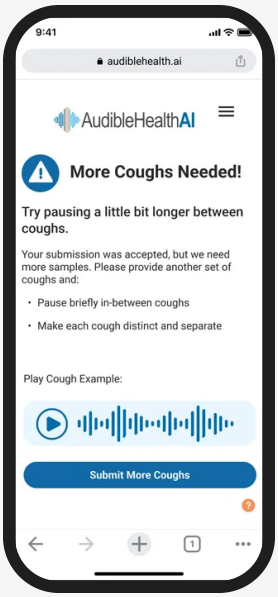
Step 8

More Coughs Needed! Screens

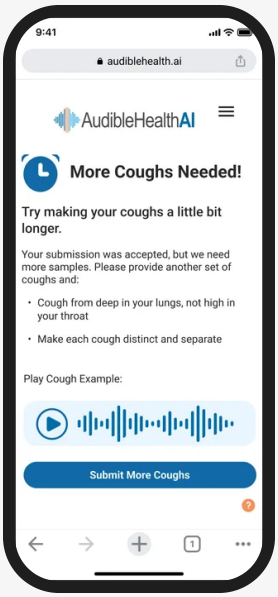
If there is a problem with the sound quality of some of your coughs that caused you to have fewer than the 10 required, usable coughs for screening, you will see one of these 'More Coughs Needed!' Screens. These screens indicate that some of your coughs were successful, but we need more. These screens provide tips specific to the problem with your coughs in your cough sample, as well as provide another opportunity to listen to the sample cough



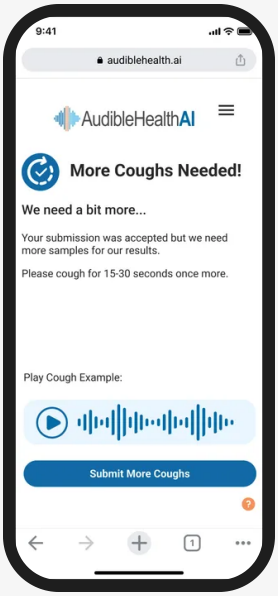
More Coughs Needed! (1 of 5)



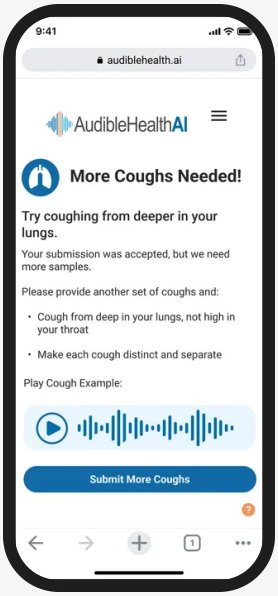
More Coughs Needed! (2 of 5)



More Coughs Needed! (3 of 5)



More Coughs Needed! (4 of 5)



More Coughs Needed! (5 of 5)

NOTE

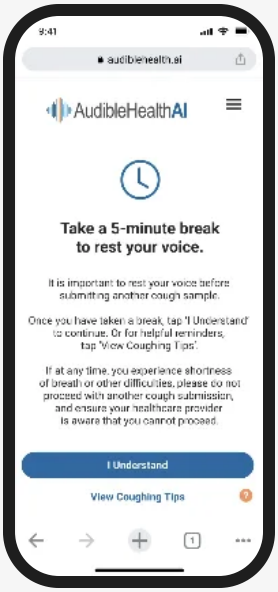
Neither the Oops! or More Coughs Needed! screens are related to the screening result. These screens are simply related to the audio of your cough submission to provide an accurate screening result to your healthcare provider.

Step 9

Break Screen

If you submit 3 cough samples that are not of adequate sound quality (or do not add up to 10 total usable coughs for screening), you will see the 5-minute break screen. You will have to wait 5 minutes to submit another cough to prevent voice strain.

After 5 minutes, you will be ready to attempt another cough submission. If this happens, you may use the same link from your text messages to complete your cough submission. Shown below is the screen you see when you should take a break to rest your voice.



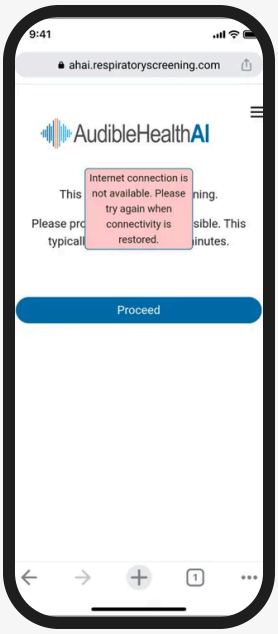
Break Screen

Step 10

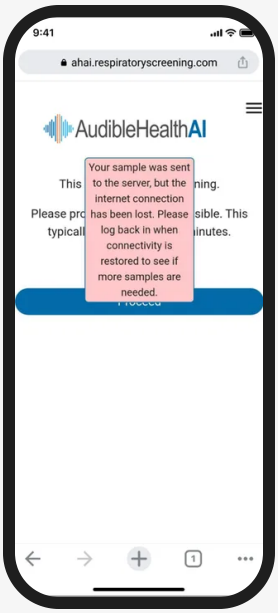
Connectivity Error Screens

Unfortunately, if there is a disruption in the internet connection during the transmission of the cough sample, the screening cannot be completed. If this occurs, you will see one of these screens.

If there is an error in the transmission of your cough sample, you may see one of the Connectivity Error screens. Please clear your browser cache and close your mobile browser.



Connectivity Error (1 of 2)

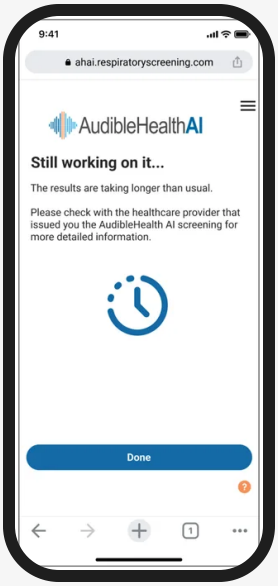


Connectivity Error (2 of 2)

Step 11

Still working on it Screen

If the screener result is still processing after a couple of minutes, you may see the “Still working on it…” screen. If this is the case, simply tap “Done” and consult with your provider, as they will have access to your results and be able to relay them to you as soon as processing is complete.

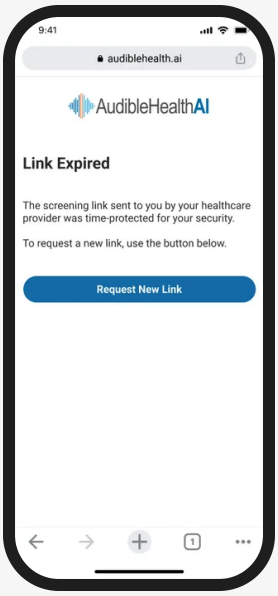


Still working on it…

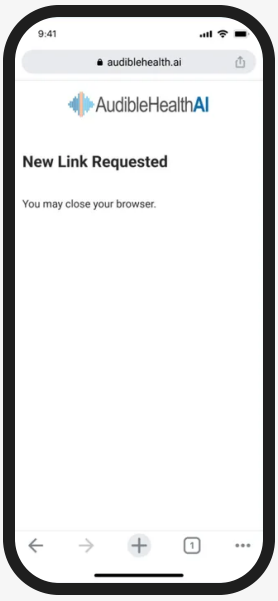
Step 12

Troubleshooting the Link for Screening

The link for the screening test will expire in the timeframe set by the healthcare provider or institution that prescribed the screening. If you tap an expired link, the mobile web browser will open, but you will see the following Link Expired screen. You may request a new link by tapping on the “Request New Link” button. When you see the second screen, you may close your mobile browser and await further instructions from your healthcare provider.



Link Expired Screen



New Link Requested

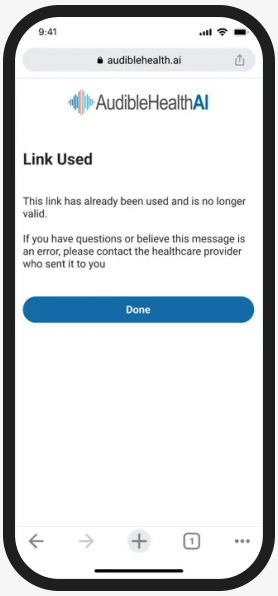
Step 13

Link Already Used

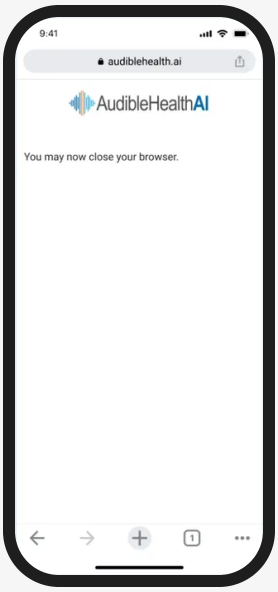
If you tap an existing screening link (perhaps one you used in an earlier session), you will see a screen indicating that the link has already been used. At that point, simply tap the “Done” button. You will then be met with a new screen that simply alerts you that you may now close the mobile browser tab at this time.

If you are using a smartphone provided to you by the healthcare provider, you may instead return the smartphone to the provider representative at this time.

If you have a concern that you have not been able to receive or use a link to a new screening you expected from your provider, please contact your provider to confirm.



"Link Used" Screen



Close Browser Screen

04

Cybersecurity information

Security Requirements

- Minimum mobile operating system requirements - Android 13 or higher in mobile and iOS 18 or higher in mobile with a mobile browser (Android, Chrome, Samsung Internet, or Safari)
- Regardless of mobile device, users should have the latest available security patches, up-to-date operating system software, and browser software as made available via the auto-update
- Secure 4G, 5G, or Wi-fi access network to the Internet (i.e., not public Wi-fi)
- Minimum bandwidth (512 kbps of upload and download)
- Working microphone

Additional Security Recommendations:

If you do not have an indication of a secure session or a valid site certificate, you should not proceed. Our application currently does not require geolocation; if requested, do not accept it. As a

general practice, users should ensure their devices are not compromised.

- Do not use a jailbroken device.
- Ensure your device is free from a virus or malware infection.
- We recommend using the internet more privately with iCloud Private Relay or a personal VPN connection.
- Use Safety Check software to determine compromised passwords or devices.
- Protect access to your device with biometric access (ex., Apple Face ID or a Strong Passcode) to access your device and your browser.
- If you find your iPhone or Android device and personal accounts are targeted by sophisticated remote attacks (targeted by some of the most sophisticated digital threats, such as those from private companies developing state-sponsored mercenary spyware) protect yourself with Lockdown Mode on your mobile device. Note: The lockdown mode may differ between iOS and Android devices, depending on the version. Webpages and internet communications should continue to work, but with reduced performance and usability.

05

Description

The AudibleHealth AI is a clinical decision support software (CDSS) that is comprised of an ensemble of software subroutines using Artificial Intelligence/Machine Learning (AI/ML) to support healthcare providers (HCPs) in screening for illness by evaluating forced cough vocalizations (FCV).

Components of the AudibleHealth AI are as follows:

- One-Time Test Web App Module
- Sound Processing Module
- Predictive Engines
- Laboratory Information Management System (LIMS) interface

The One Time Test Web App Module, which is the user interface seen by the end user, allows the end user to submit an audio file using a smartphone.

Technical description

The Sound Processing module has several components that ensure each FCV is of adequate sound quality and prepares the FCV to be evaluated by the AI/ML models. The first 50ms are trimmed from the beginning of the audio file as they do not provide data that assists in screening. A normalization step is used to scale the value of the signal to a uniform range (-14dBFS) to help with the de-clipping of the samples. If the audio file is in stereo sound (presented through two channels), it is converted to mono (one channel). The high-pass filter removes frequencies below a specific threshold from the file. A second normalization step is then performed to further scale the file to a better range (-6dBFS). Then the FCV passes through the wav2vec splitter, which turns the files into individual segments containing only one cough each. The duration filter ensures the quality of the splits by removing multi-cough segments and segments that are too short to be properly evaluated. If at least ten segmented coughs are usable after the completion of sound processing, the samples will be re-sampled to the sampling rates needed by the algorithm and sent to the AI/ML models. If there are not ten usable coughs, the user is prompted to submit a new FCV sample as described in the cough collection instructions.

The predictive engine consists of an ensemble of AI classifiers and a deterministic oracle. The classifiers are a group of deep convolutional neural networks (CNNs) trained to detect specific disease signatures in the cough sample, which gets converted from an audio file to an extremely data-rich spectrogram image. Another custom piece of software, known as a deterministic oracle, is connected to the ensemble to take in predictions from each CNN and deliver a final predictive score based on the data provided by the CNNs. Respiratory-related illnesses create specific disease signatures or patterns in the thousands of data points collected in each cough sample. This is due to the unique ways in which each disease affects the human respiratory system. Some diseases create additional mucus, cause changes in mucus viscosity, cause varying inflammation and cough harmonics, or produce conditions like airway constriction. By collecting many coughs from subjects who are confirmed positive for a specific disease and many coughs from people who are confirmed negative, AudibleHealth AI data scientists train AI/ML models that detect the specific patterns correlated to the target disease positives or negatives. After the CNN classifiers and the accompanying oracle have been trained and tested on a sufficient number of positive and negative samples, the predictive engine is capable of analyzing a new cough to determine whether the cough pattern matches the known signature for the target illness. For each illness, a separate ensemble of AI/ML models with their own accompanying oracle is trained, tested, and deployed. Each time the solution is used, the provider receives a numeric probability score between 0 and 100, indicating the likelihood that the sample does or does not correlate to the known disease being screened, with scores over 50 being considered

positive and scores below 50 being negative. Each predictive engine algorithm used for screening is a locked ML solution that is not continuously learning while in live production.

The LIMS interface is a laboratory industry-standard data transfer protocol for reporting and recording test results.

Thank you.

06

Manufacturer

This product is manufactured by: **AudibleHealth AI, Inc.**

6400 S. Fiddlers Green Circle, Suite 250 Greenwood Village, Colorado 80111 USA

Contact: https://help.audiblehealth.ai/

GS1: 00199284438224 GMDN: 64033