AudibleHealthAI
by RAIsonance

For patients · Direct Link

Quick Start Guide

How to complete your cough screening on this phone, step by step.

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/direct-link

01

Is this test right for me?

How safety information is shown

⚠ **WARNING** — Could result in serious harm if not avoided.

ⓘ **CAUTION** — Could result in minor harm or an unusable test if not avoided.

ⓘ **NOTE** — Information that helps you complete the test.

Intended use

AudibleHealth AI 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 and contraindications

WARNING

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.

CAUTION

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

What you need

The AudibleHealth AI 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.

Coughing tips

- To conduct a screening, please ensure you are in a quiet place
- Hold the phone at least 12 in / 30 cm from your mouth
- Provide a strong cough from deep in your chest
- Cough for at least 15 seconds
- Briefly pause in between coughs
- Make sure the only sound you submit is your cough
- Do not cover the microphone with your finger

03

Step by step

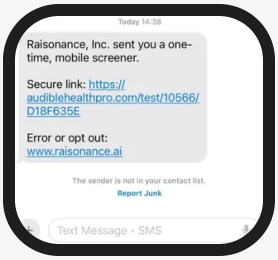
The following is a walk-through of the screens as you will see them, with explanations.

Step 1

Open your test link

When your provider sends you a screening test, you will receive a text message or WhatsApp message that looks similar to this one. When you click on the link, your web browser will

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



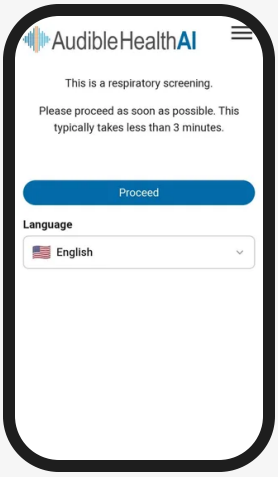
Text message

Step 2

Choose your language

This is the first screen that you will see in the web browser. Please select your preferred language and choose Proceed.

> **NOTE**
>
> If you see a different screen when the web browser opens, please see the Troubleshooting the Link for Screening (§4 Troubleshooting the Link for Screening) section for further information.



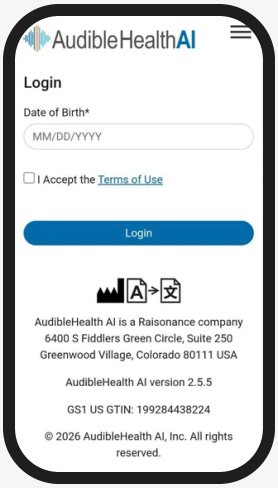
Language

Step 3

Log in with your date of birth

Please log in using your date of birth, using 2 digits for the month, 2 digits for the day, and 4 digits for the year.

You will need to accept the Terms of Use to proceed. If you would like to review the Terms of Use, you may select that link. Please note that you can also see the manufacturer information and the version of the screening test you are using on this page.



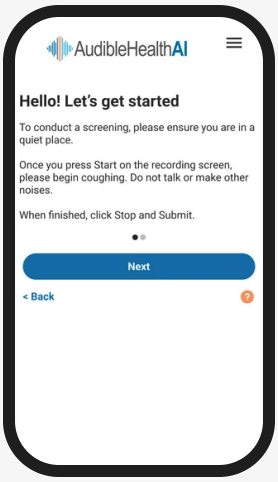
Login

Step 4

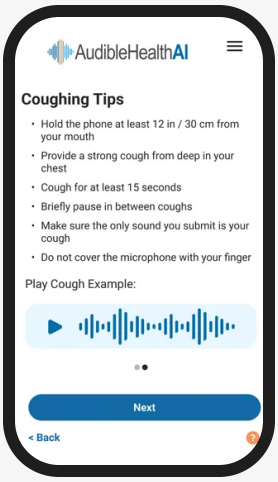
Read the instructions

Please read the Get Started screen, followed by Coughing Tips, before beginning.

- Press 'Next' to navigate these screens.
- If you would like to hear an example of a good cough submission, you can touch the "play" triangle on the Coughing Tips screen.
- Please read each of these screens carefully so that your cough submission will be successful.



"Hello! Let's get started"

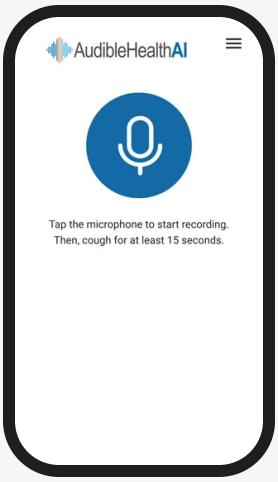


"Coughing Tips"

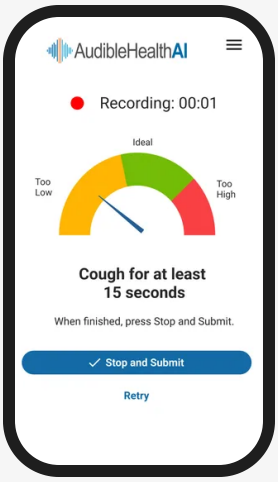
Step 5

Record your cough

- After you have read all the instructions, you are ready to submit your cough.
- Tap the microphone when you are ready to start coughing. Cough for at least 15 seconds.
- Then select Stop and Submit when you are finished.
- "Retry" should only be used if you know the sound quality will be poor (i.e., a siren sounded when you are trying to cough).
- The needle on the meter will move when you are coughing. This is to show you if the volume of your cough is in an acceptable range. If the needle is in the green, your cough is at the right volume.



Ready to Record

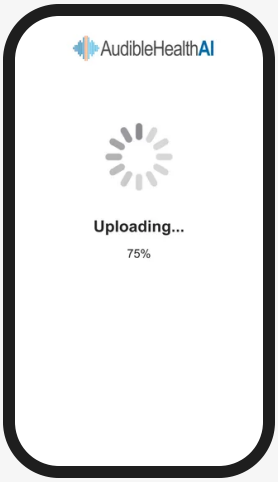


Recording

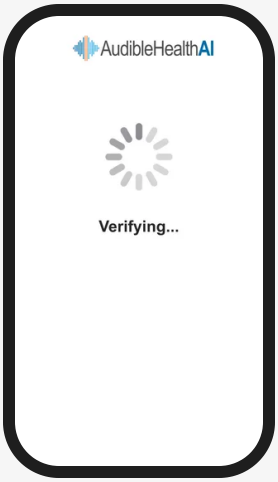
Step 6

Wait while your cough is processed

After you submit, you will see the Uploading, Verifying, and Analyzing screens. These screens let you know 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”



“Verifying”



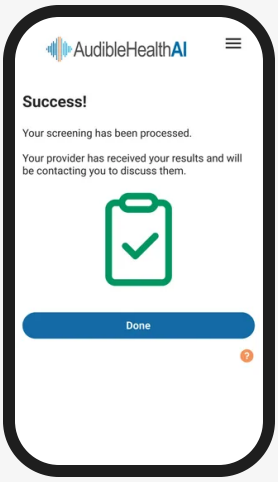
“Analyzing”

Step 7

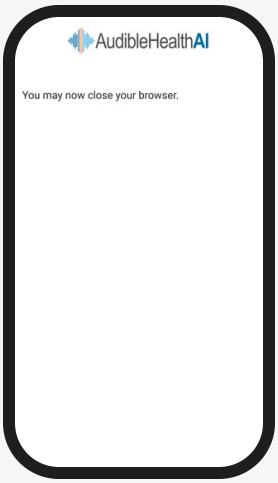
Success

When you submit a successful cough, you will see the Success! screen. If you are using your personal smartphone, you may select "Done" and close out of the web browser at this time.

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



"Success"



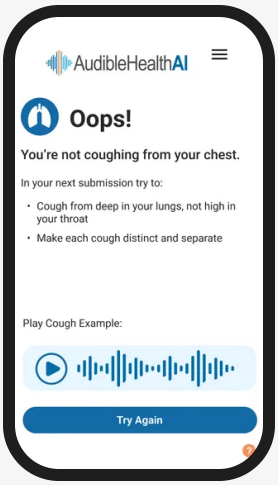
"Close Browser"

04

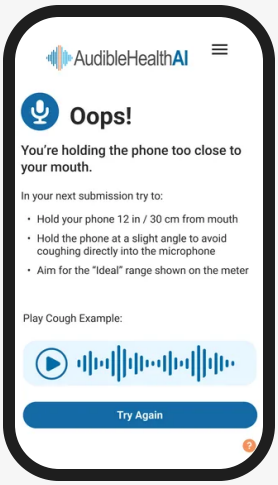
If something goes wrong

Oops! screens

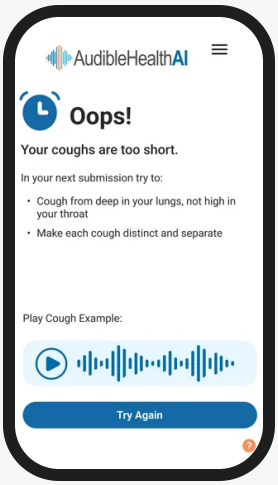
If there is a problem with the sound quality of your cough that caused you to have no usable coughs for screening, you will see one of these Oops! Screens, which will provide tips that are specific to the problem with your cough sample, and another opportunity to listen to the sample cough.



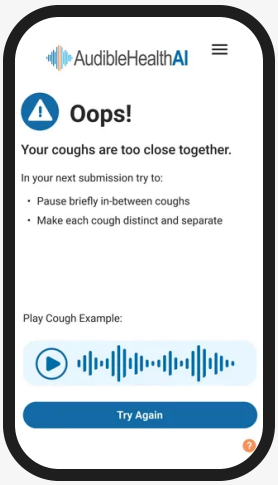
Oops! screen



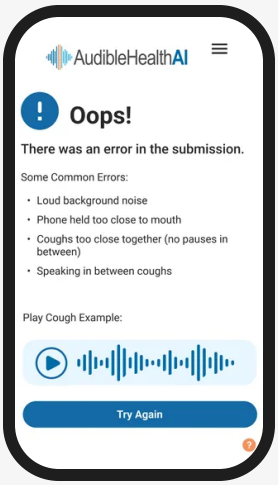
Oops! screen



Oops! screen



Oops! screen

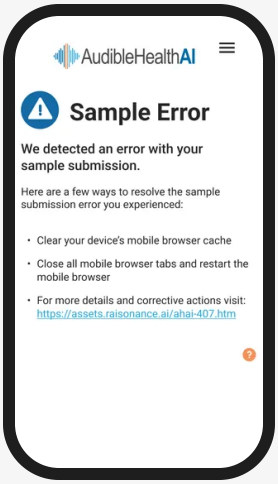


Oops! screen

When you select Try Again, you will be taken back to the Ready to Record Screen above.

Transmission error

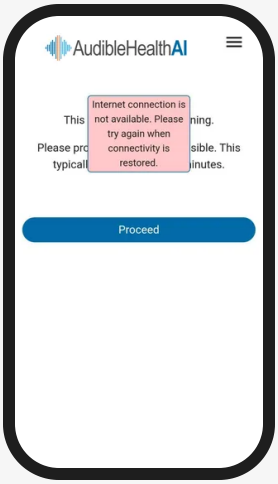
If there is an error in the transmission of your cough sample, you may see this screen. Please clear your browser cache and close your browser.



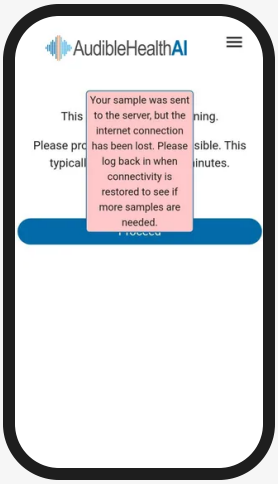
Transmission Error

Connectivity error

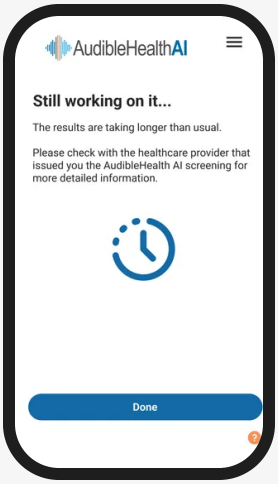
If your internet connection is lost, you may see one of these messages. If the connection was lost before your cough sample was sent, try again once your connection is restored. If the connection was lost after your cough sample was sent, log back in with the same link once your connection is restored to see whether more samples are needed. If your results are taking longer than usual, you may see the Still working on it… screen; please check with the healthcare provider who issued your screening for more information.



Connection lost before the sample was sent



Connection lost after the sample was sent

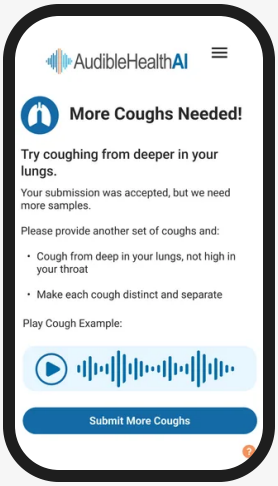


Still working on it…

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 10 usable coughs for screening, you will see one of these 'More Coughs Needed!' Screens.

These screens also include specific tips for addressing any identified audio problems and offer the option to review a sample cough.



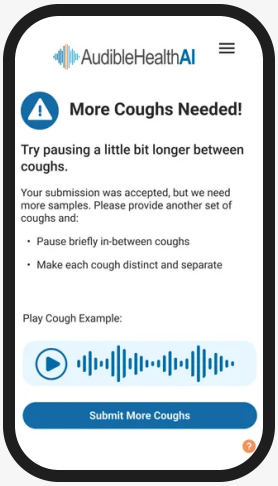
More Coughs Needed!



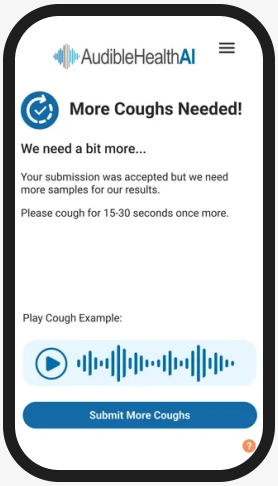
More Coughs Needed!



More Coughs Needed!



More Coughs Needed!



More Coughs Needed!

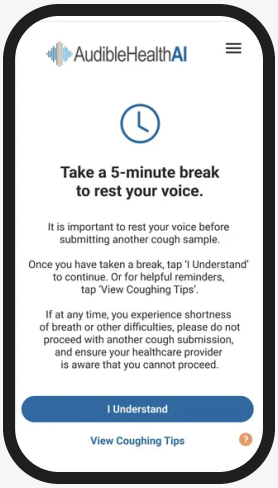
NOTE

Neither the Oops! Screens or the More Coughs Needed! Screens are related to the screening result. They are simply related to the audio quality necessary to provide an accurate screening result to your healthcare provider.

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.

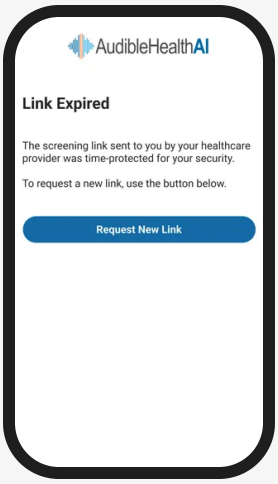
After 5 minutes, you will be ready to attempt another cough submission. If this happens, you may use the same link from your text messages to complete your cough submission. Shown below is the screen you see when you should take a break to rest your voice.



Break Screen

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 test. If you select an expired link, the web browser will open, but you will see the following screen. You may request a new link by selecting Request New Link. When you see the second screen, you may close your browser and await further instructions from your healthcare provider.



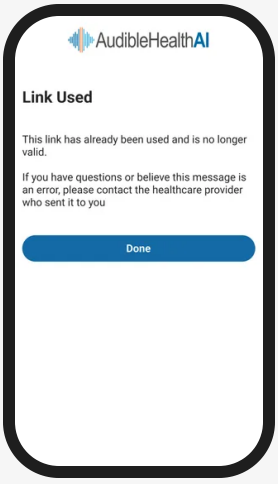
Link Expired



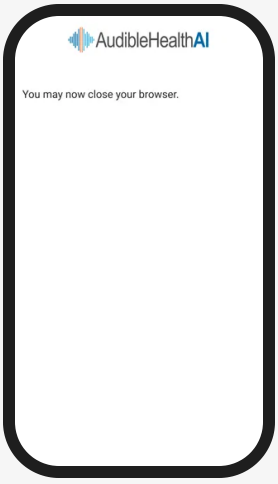
New Link Requested

CAUTION

If you select a link that has already been used, you will see the following screen. If you were not the individual who used the link or if you have questions, you should notify your healthcare provider immediately.



Link Used



Close browser

05

Clean your phone

CAUTION

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.

06

Keeping your device secure

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

WARNING

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 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 in terms of version. Webpages and internet communications should continue working, but with a reduction in performance and usability.

07

About this device

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 the 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 evaluating 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.

08

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