AudibleHealthAI
by RAIsonance

For field clinicians · Field Screener

Quick Start Guide

Version **4**	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/field-screener

01

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/Contraindications

You should not have a patient/subject use this screening test if they 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 a shared, clinic phone can increase the number of germs on the phone. After you complete your screening, it is recommended that you clean the 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, request the patient/subject stop coughing and contact you immediately.

02
Compatibility

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.

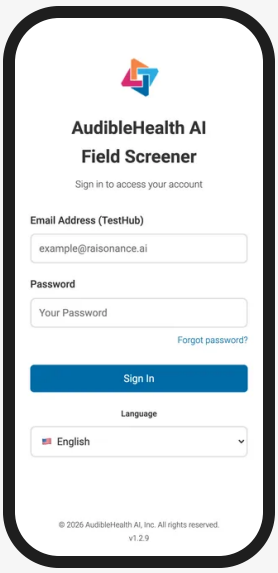
03

Screens

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

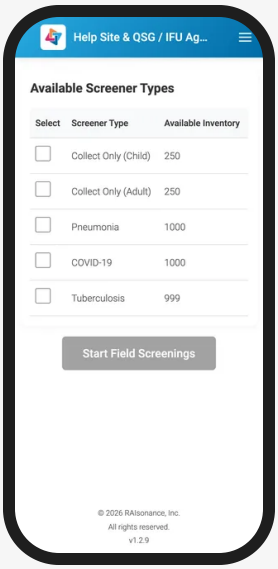
Before beginning, you will need to log in with your email and password. The administrator for your account should have this established prior to use of the web app. If you do not have login credentials, you will need to speak to your account manager / system administrator.

> **NOTE**
> The first few screens are simply registration and selection of the screener type. You will see another note when you begin use of the actual medical device.

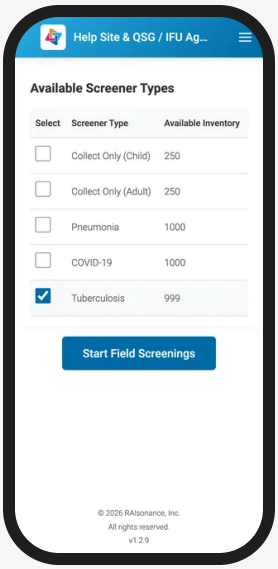


Login

After you log in, you will see the screener types available for you to use based on your organization's inventory. When you select the screener type you want, a checkmark will appear, and you will be able to select Start Field Screenings.

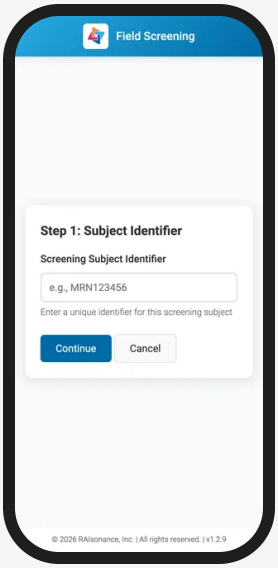


Available Screener Types



Available Screener Types

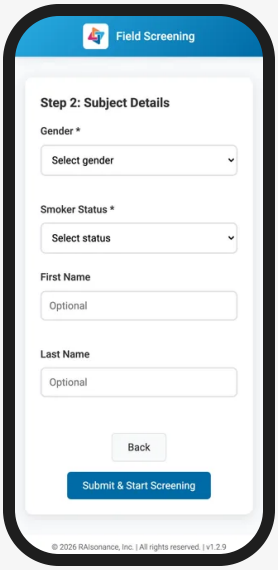
This screen allows you to enter the appropriate unique identifier to track the identity of the patient. You will follow your organization's policy for the appropriate Medical Record Number or other identifier to use. Then select Continue.



Step 1: Subject Identifier

This screen collects the patient's gender and smoking status. When selected, each of these fields will provide a drop-down of options. You will follow your organization's policy on whether to

enter the patient's First and Last Name. The fields are optional. When finished, select Submit & Start Screening.

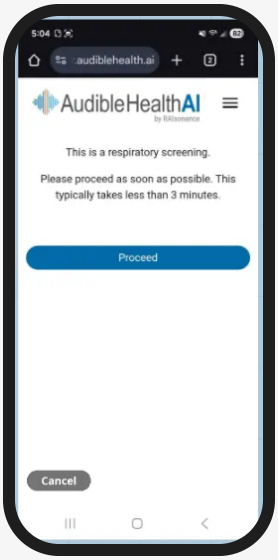


Step 2: Subject Details

> **NOTE**
>
> This screen represents entry into the web app that serves as the user interface for the medical device.

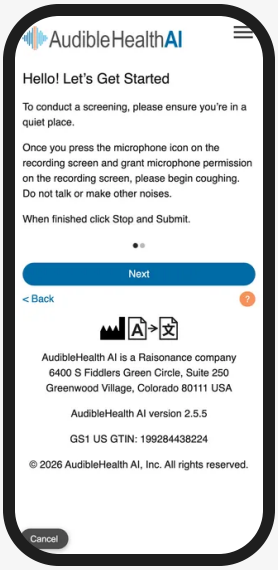
Select Proceed to continue.

You will notice the option to Cancel in the bottom left-hand corner on this and subsequent screens. Choosing Cancel will abort the testing process completely for the current patient and take you back to the Home Screen with the Available Screener Types.

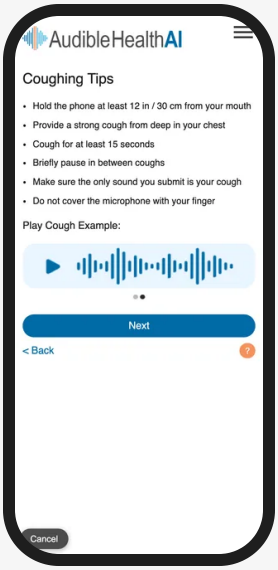


This is a respiratory screening.

Please read the Get Started screen, followed by Coughing Tips, to the patient before beginning to give them the best opportunity to successfully submit a cough sample.



"Hello! Let's get started" Screen

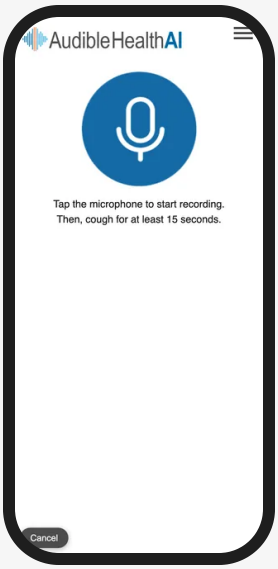


"Coughing Tips" Screen

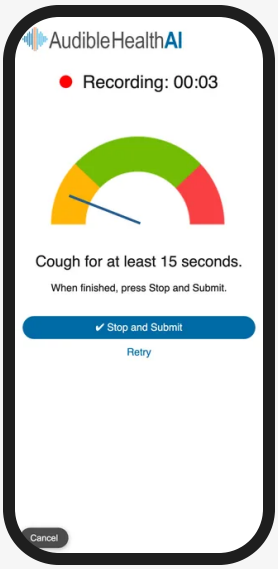
- Press 'Next' to navigate these screens.
- If you would like to hear an example of a good cough submission, you can touch the "play" triangle on the Coughing Tips screen.

NOTE

Manufacturer information and the Software version number for the medical device, and device unique identifier are found on the Get Started screen.



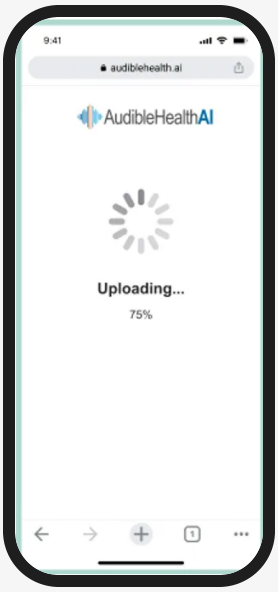
Ready to Record Screen



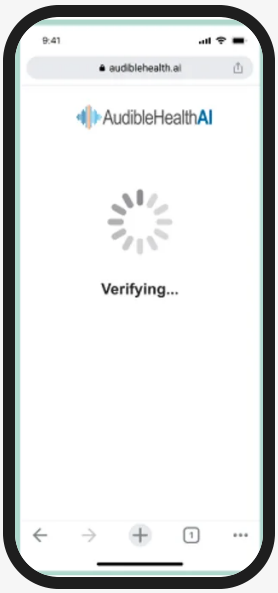
Recording Screen

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

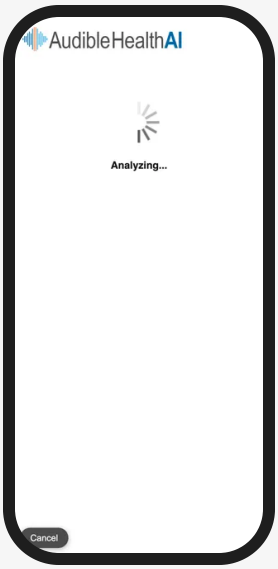
After you submit, you will see the Uploading, Verifying, and Analyzing screens. These screens show the status of your cough sample as the network sends it to the cloud. If you have a good network connection, these screens will progress immediately. If you have a slower network connection, you may see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



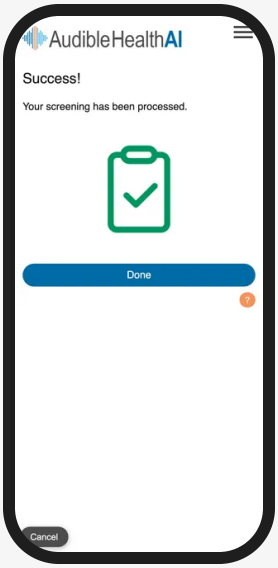
“Uploading” Screen



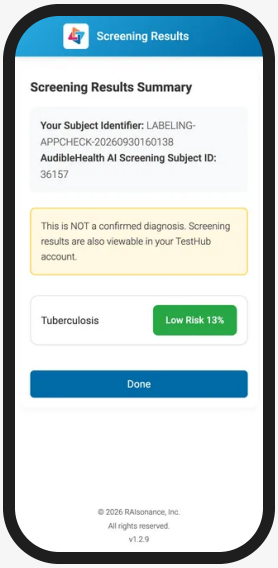
“Verifying Screen”



“Analyzing” Screen



“Success” Screen



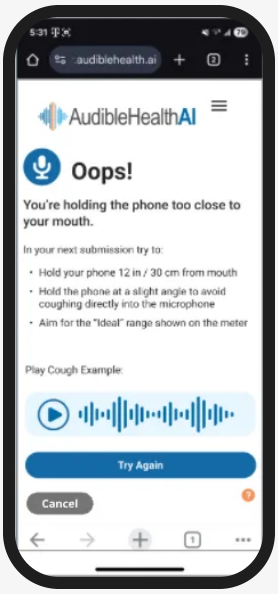
Screening Results

When you submit a successful cough, you will see the Success! screen. When you select “Done”, you are exiting the medical device user interface.

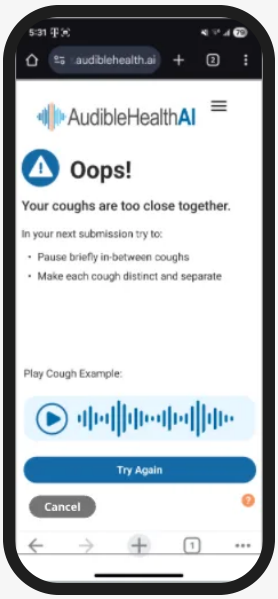
Depending on your organization’s policy, you may be taken to a results screen similar to the one shown to the right. Screening results will only be available for the specific screener types you selected.

If there is a problem with the sound quality of your cough that caused the sample 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 example cough.

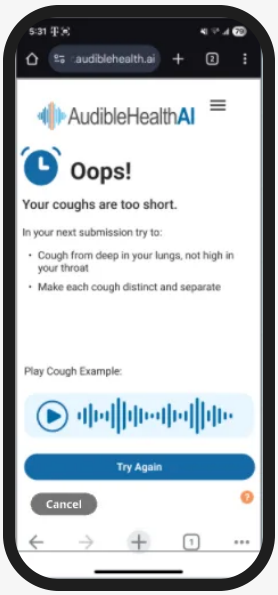
When you select Try Again, you will be taken back to the Ready to Record Screen above.



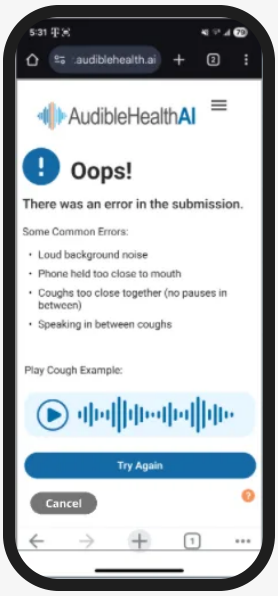
Oops! (1 of 5)



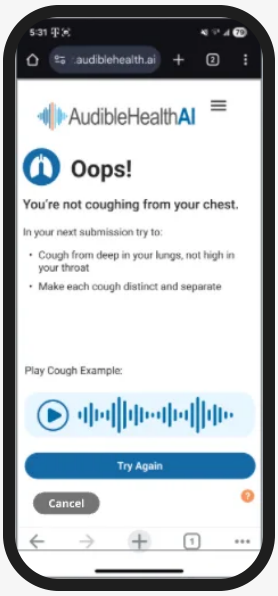
Oops! (2 of 5)



Oops! (3 of 5)



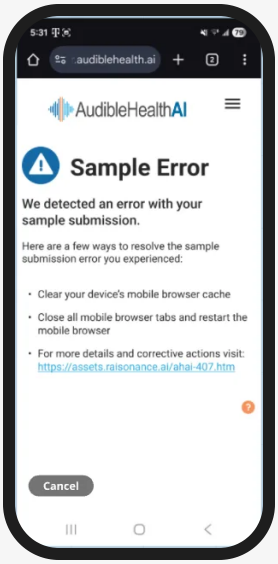
Oops! (4 of 5)



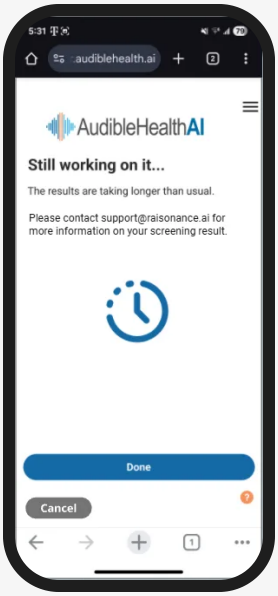
Oops! (5 of 5)

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

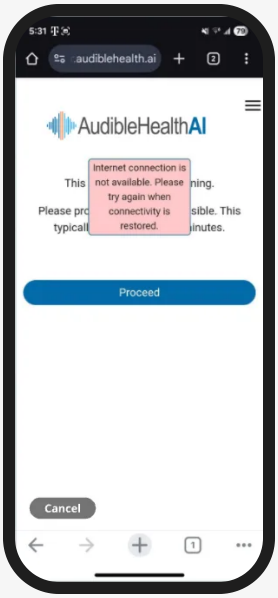
Unfortunately, if there is a disruption in the internet connection during the transmission of the cough sample, it cannot be completed. If that happens, you will see this screen. Select Cancel to submit another cough sample.



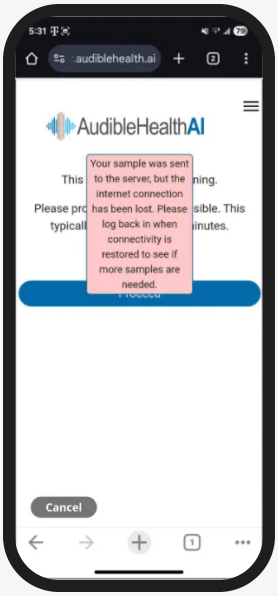
Transmission Error



Connectivity Error (1 of 3)



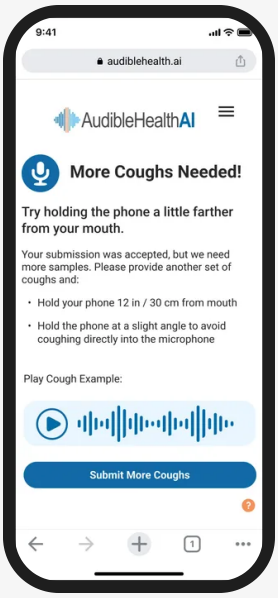
Connectivity Error (2 of 3)



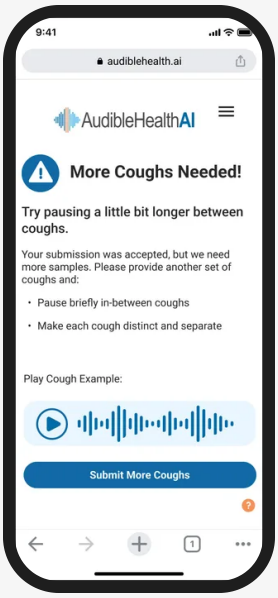
Connectivity Error (3 of 3)

If there is a problem with the sound quality of some of the coughs that caused the sample to have fewer than 10 usable coughs for screening, you will see one of these 'More Coughs Needed!' Screens.

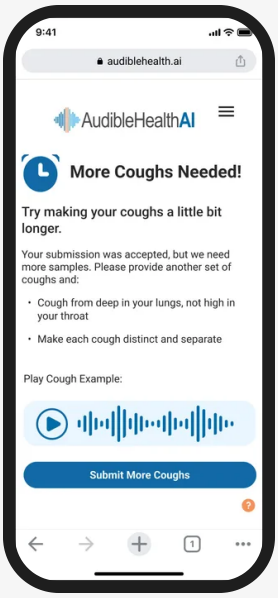
These screens also include specific tips for addressing any identified audio problems and offer the option to review a sample cough.



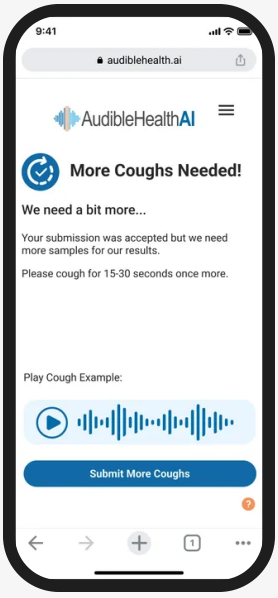
More Coughs Needed! (1 of 5)



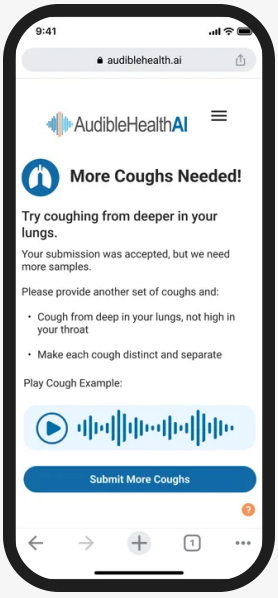
More Coughs Needed! (2 of 5)



More Coughs Needed! (3 of 5)



More Coughs Needed! (4 of 5)



More Coughs Needed! (5 of 5)

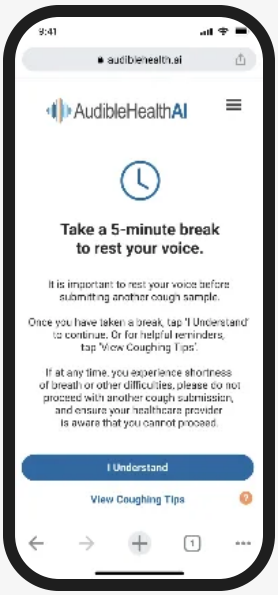
NOTE

Neither the Oops! 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.

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. Shown below is the screen you see when you should take a break to rest your voice.



Break 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 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 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 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 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