AudibleHealthAI

Quick Start Guide

Intended Use

AudibleHealth AI (respiratoryscreening.com) is a clinical decision support software (CDSS) intended for screening for tuberculosis, COVID-19, and/or pneumonia through the utilization and classification 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 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.

****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 call your healthcare provider.

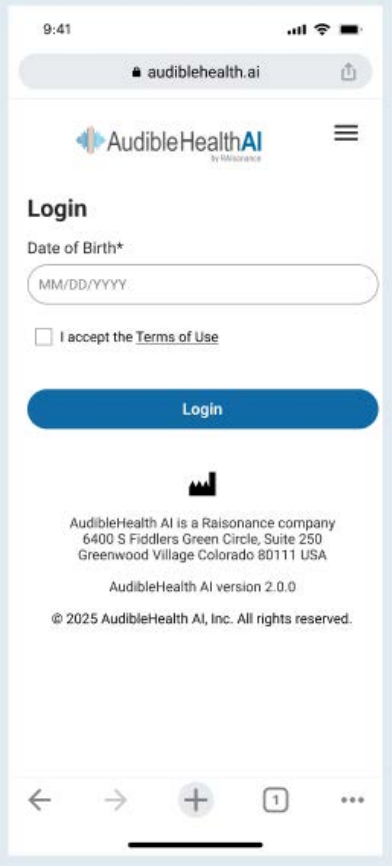
Compatibility

The AudibleHealth AI (respiratoryscreening.com) web app can be used on smartphones running iOS (version 17.7 or newer) and Android (version 12 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.

Screens

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

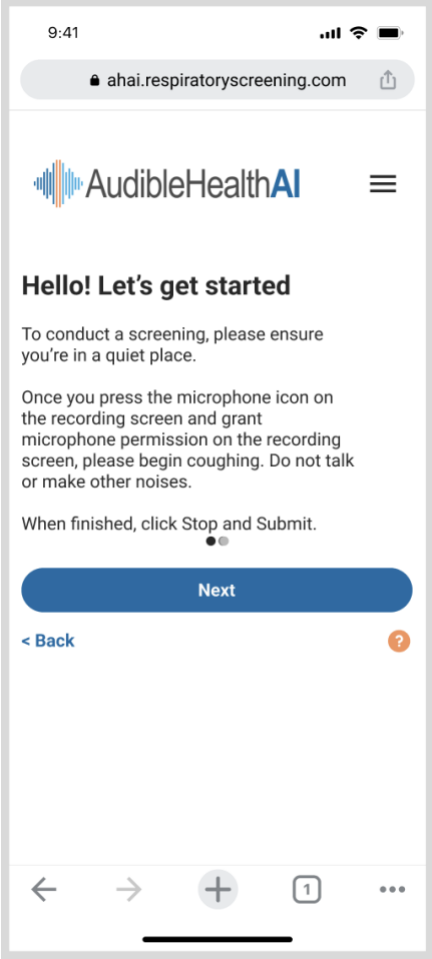


When your payment is complete, you will receive a confirmation screen.

Click the “Proceed” button

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

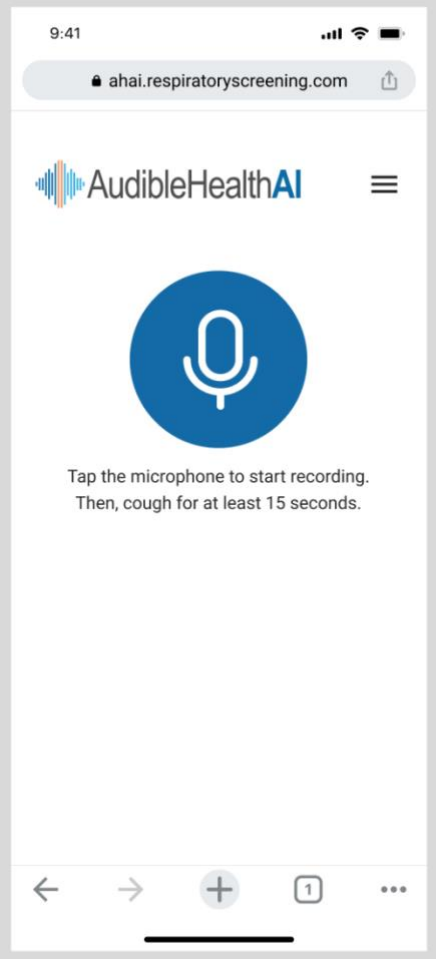
"Hello! Let's get started" Screen



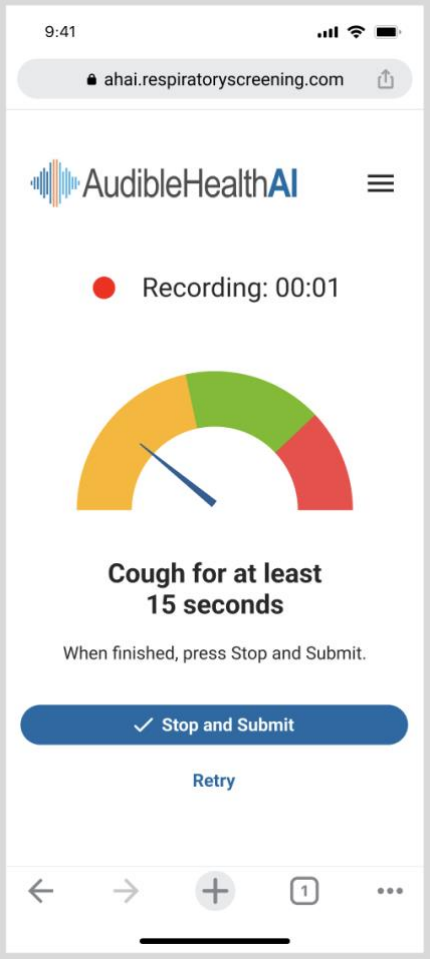
"Coughing Tips" Screen

- 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.
- Please read each of these screens carefully so that your cough submission will be successful.

Ready to Record Screen



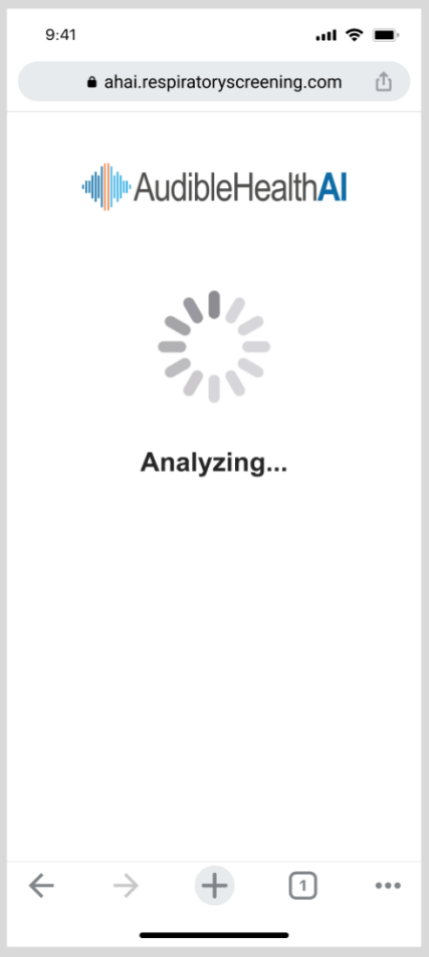
Recording Screen



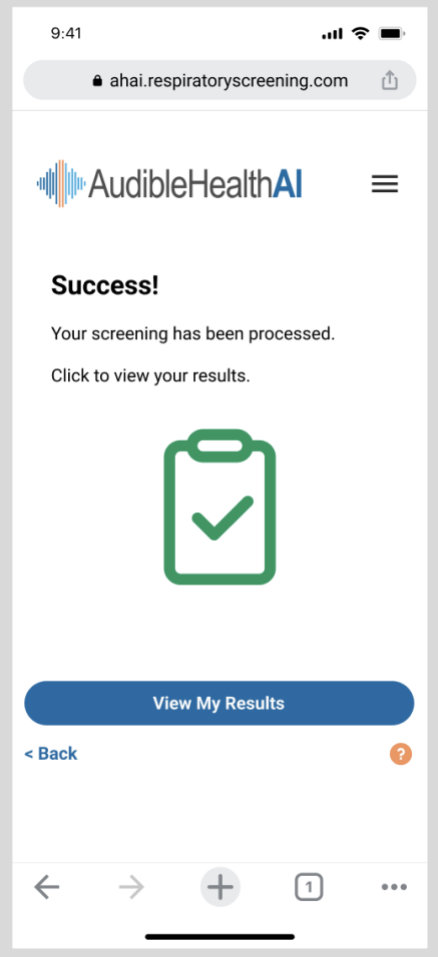
- After you have read all the instructions, you are ready to submit your cough.
- Tap the microphone when you are ready to start coughing. Cough for at least 15 seconds.
- Then select Stop & Submit when you are finished.
- "Retry" should only be used if you know the sound quality will be poor (i.e.,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

After you submit, you will see the Analyzing screen.

"Analyzing" Screen

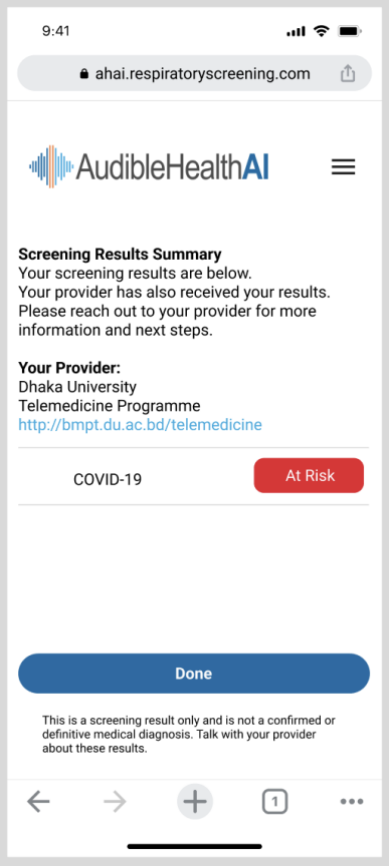


"Success" Screen

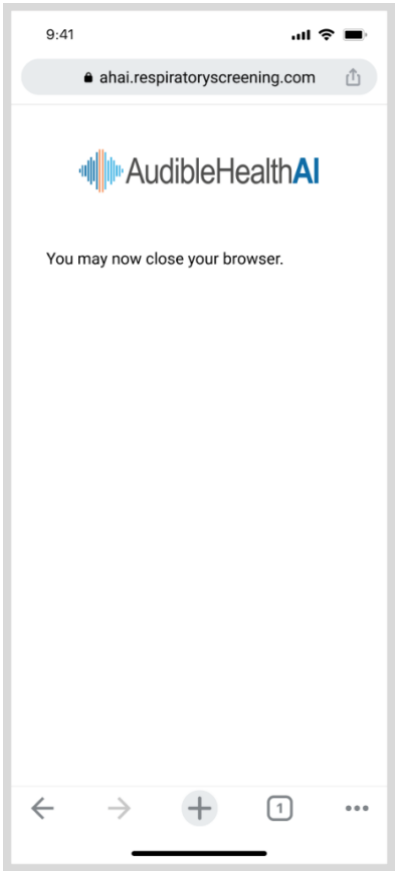


When you submit a successful cough, you will see the Success! Screen.

Provider-Results Screen



"Close Browser" Screen

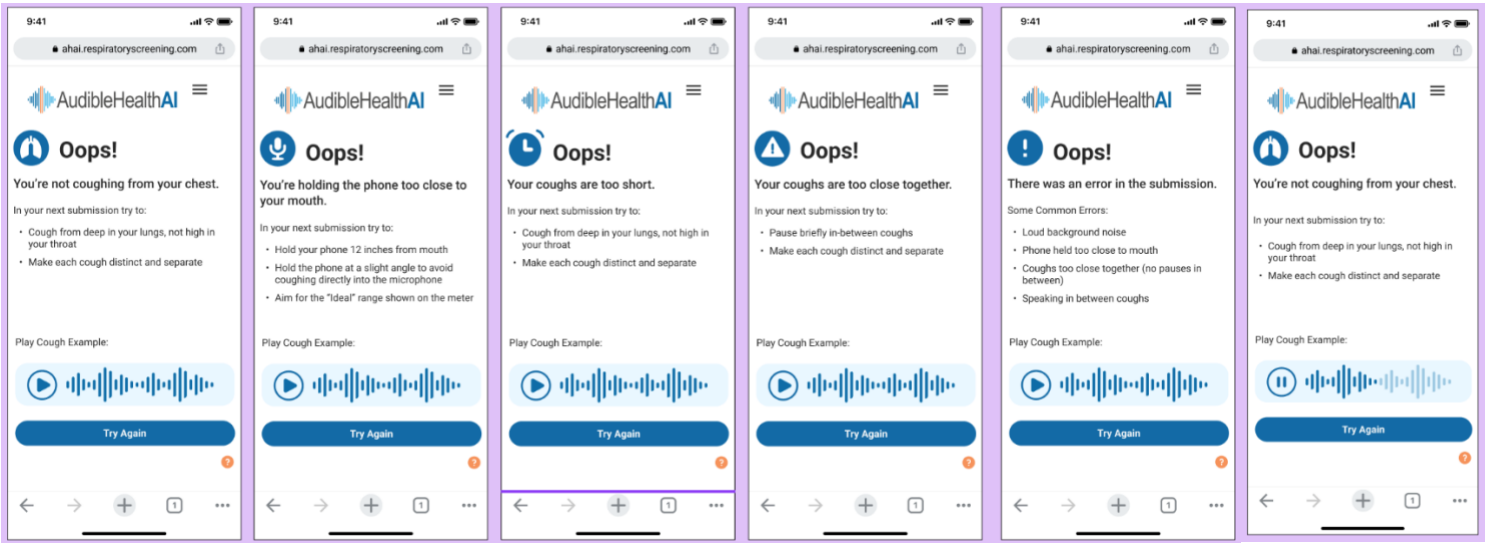


A screen will then appear with your results and the provider to which they are sent. If you are using your personal smartphone, you may select "Done" and close out of the web browser at this time.

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

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.

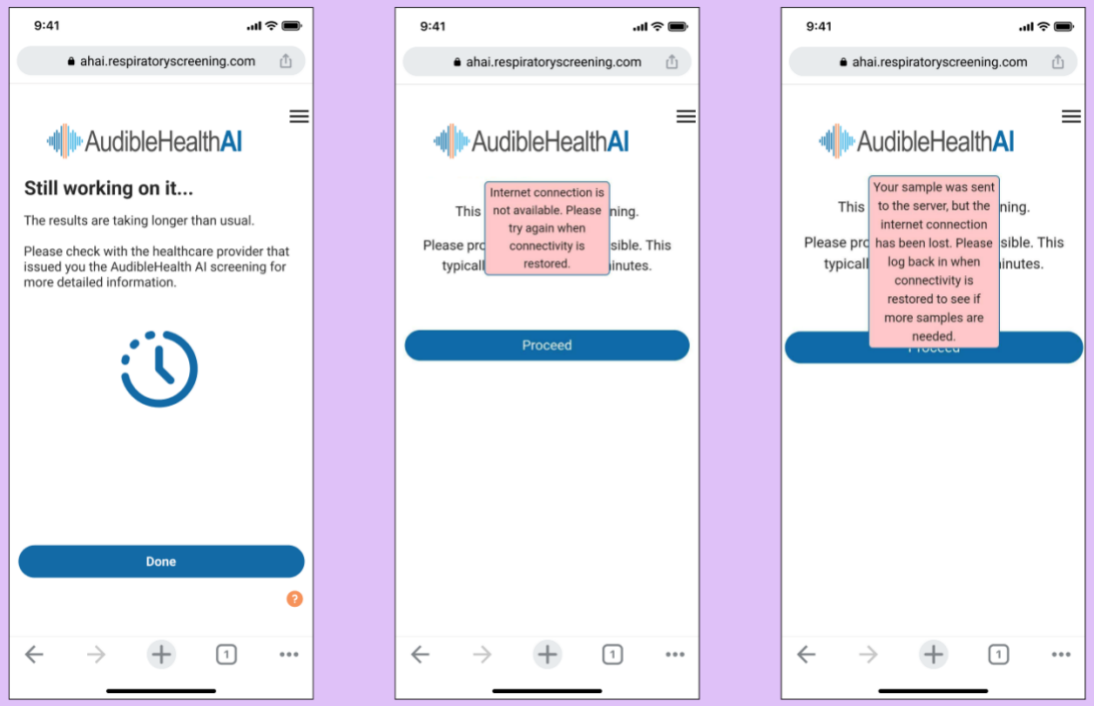
When you select Try Again, you will be taken back to the Ready to Record Screen above.



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.

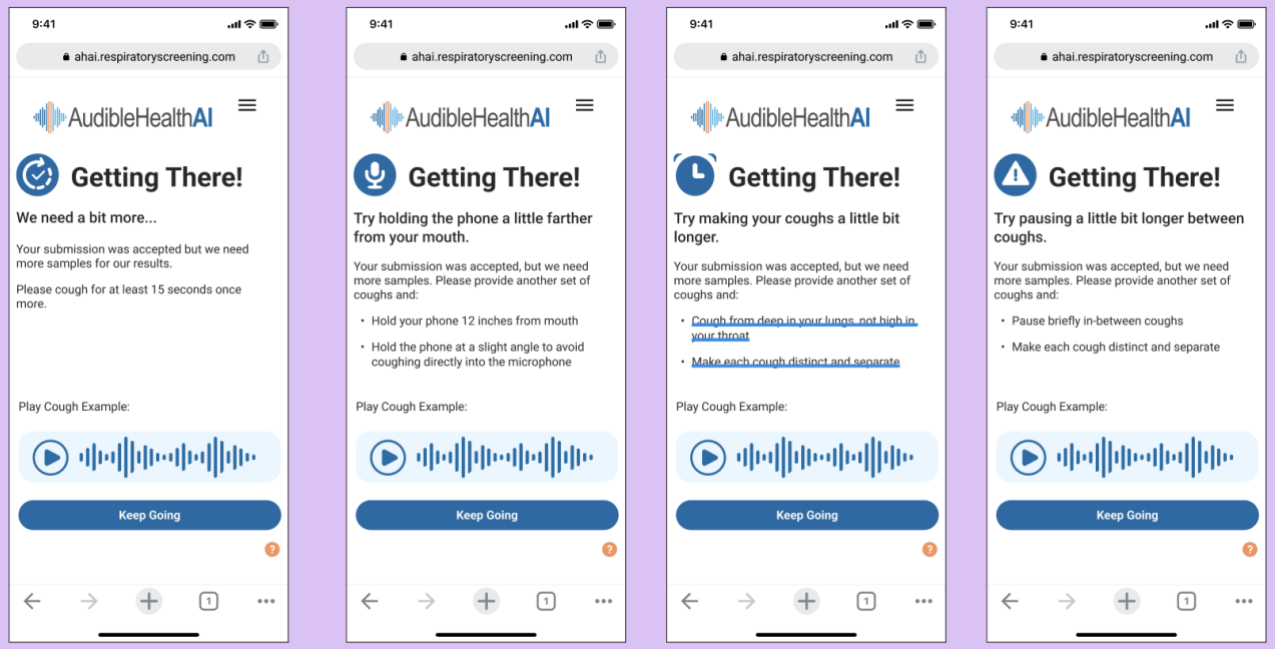
Unfortunately, if there is a disruption in the internet connection during the transmission of the cough sample, it cannot be completed. If that happens, you will see this screen. Select Try Again to submit another cough sample.

Connectivity Error



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 'Getting There!' Screens.

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



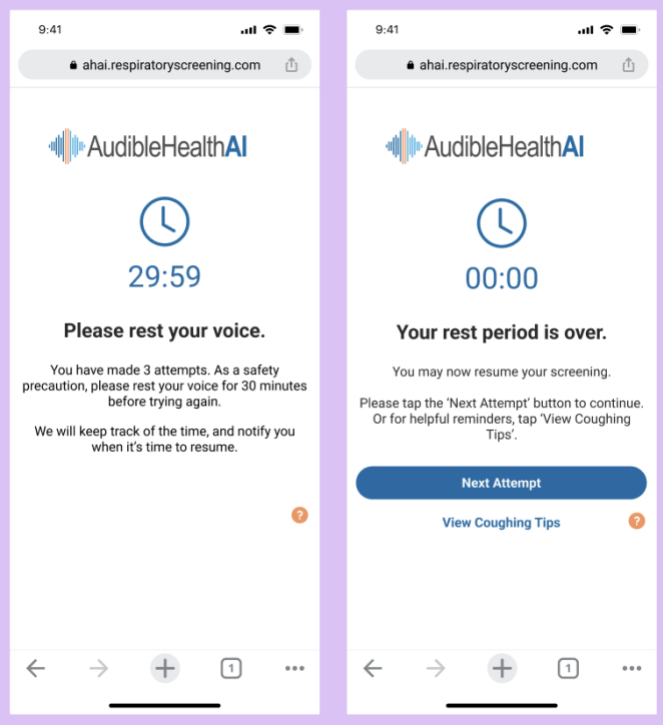
***NOTE:** Neither the Oops… Screens or the Getting There! Screens are related to the screening result. They are simply related to the audio quality necessary to provide an accurate screening result to your healthcare provider.

Time Out

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 30-minute time-out screen. You will have to wait 30 minutes to submit another cough to prevent voice strain.

After 30 minutes, you will be ready to attempt another cough submission. You may use the same link from your text messages to complete your cough submission if this happens. Shown below is this screen when you have time remaining before you can submit a sample, and the same screen when the wait period is complete.

Time Remaining No Time Remaining



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.

Cybersecurity Information

Security Requirements

- Minimum mobile operating system requirements - Android 12 or higher in mobile and iOS 17.7 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 in terms of version. Webpages and internet communications should continue working, but with a reduction in performance and usability.

Description

AudibleHealth AI (respiratoryscreening.com) is a Clinical Decision Support Software (CDSS) consisting of an ensemble of software subroutines that use Artificial Intelligence/Machine Learning (AI/ML) to analyze forced cough vocalizations (FCV) for screening purposes.

Components of the AudibleHealth AI are as follows:

- One Time Test Web App Module
- Sound Processing Module
- Predictive Engine
- 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.

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 analyzed. If at least ten segmented coughs are usable after the completion of sound processing, the samples will be resampled 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 section 6. When a new cough sample is submitted, the usable coughs from both samples are accumulated to reach the minimum of 10.

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.