For healthcare providers · Direct Link

# Instructions for Use

**These instructions for use are for healthcare providers who intend to prescribe an AudibleHealth AI screening test by sending a message with a link. If you are a patient, please review one of our Quick Start Guides for patients.**

| | |
|---|---|
| Version<br>6 | Applies to<br>App v2.5.0 |
| Effective<br>TBD | UDI-DI (GS1)<br>00199284438224 |
| GMDN<br>64033 | Language<br>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/ifu/direct-link

Please read all instructions carefully before using this device.

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.

# 02

## Contraindications

Use of the AudibleHealth AI device for screening is contraindicated for the following persons:

- 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.

# 03

## Warnings and precautions

**How safety information is shown**

⚠ **WARNING** — Could result in serious harm or an incorrect clinical decision if not avoided.

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

ⓘ **NOTE** — Supporting information that helps you administer the test.

## Warnings

⚠ **WARNING**

The AudibleHealth AI only provides screening information, not diagnostic, treatment, or management information. Results should be clinically correlated.

## Precautions

ⓘ **CAUTION**

Patients experiencing breathing difficulties or shortness of breath may require more than one attempt to achieve a successful FCV submission for analysis. If breathing difficulties persist or worsen, the patient should stop coughing and seek other means of testing.

## Potential complications / adverse events

Submission of cough samples for analysis by an AI/ML clinical decision support software is a low-risk procedure. Potential complications may occur during or following FCV collection, including but not limited to light-headedness or shortness of breath.

⚠ **WARNING**

Although the device has been tested and performed adequately in clinical studies, it is possible that the device could provide an incorrect screening result.

# 04

## Compatibility

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

# 05

## Device 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.

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.

### Device packaging or presentation

The user interface for this device is offered as a web application (app) for Android version 13 through the current version and iOS version 18 through the current version. The app is the only packaging for this device. To use the app, a healthcare provider must send a link to the user's phone. Once the link is selected, the web app will open automatically. This web app is only available as a point-of-care-use product. Only healthcare providers and organizations with appropriate credentials may prescribe this app for screening.

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# 06

## Infection control

Although the software cannot become contaminated itself, submission of a cough requires the user to cough in their environment. Since coughing is one of the most common ways respiratory illnesses spread from person to person, utilizing high-quality infection control procedures is a key safety consideration when using AudibleHealth AI. First and foremost, follow facility protocol for disinfecting equipment. If there is no facility protocol or a patient is using a personal smartphone, here are some recommendations to assist in infection control:

- Ensure that the patient and healthcare workers wear an N95 quality mask during cough collection where appropriate.
- Where possible, providing a special cough collection location that is separated from others if indoors, or ideally is located outdoors.
- Thoroughly wipe down any devices used for cough collection or surfaces that may have been exposed to droplets or aerosolized particles with disposable, anti-bacterial, alcohol-based wipes. This includes smartphones as well as other medical equipment, supplies, etc., where appropriate.
- Use a UV light sanitizing tray to decontaminate phones and tablets by placing the device in the decontamination tray for several minutes. These devices are clinically proven to eliminate 99% of bacteria, even in the tiny spaces and crevices found in phones and tablets.

- Ensuring that the healthcare or community health worker wears disposable gloves and changes them between patients in case any particles are transferred

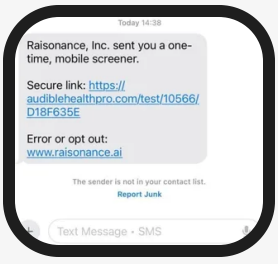
# 07
# Using AudibleHealth AI

### 7.1
## Sending a test

In order to send a test to a smartphone, you must have an account with a distributor or have the ability to send tests integrated with your electronic health record. Separate instructions are available for sending a test based on which option your administrator has chosen. Please refer to these instructions to send a test to a patient.

### 7.2
## Opening the link

1. Once you have ensured that the smartphone receiving the test is compatible with the one-time test web app (see COMPATIBILITY (§4 Compatibility) above), you will send a link via SMS (text message) or WhatsApp message as per instructions referenced above.
2. When the patient selects the link within the text message, the smartphone will automatically be taken to the web browser with the web app open.




Text message

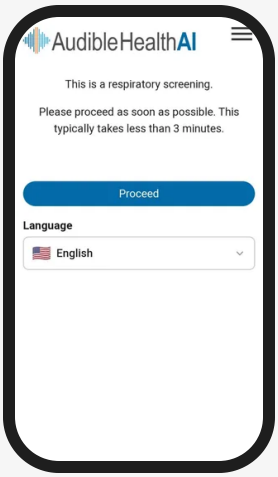
7.3

## Login

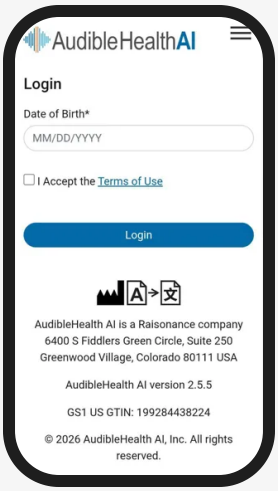
1. When the web app opens, the patient will be informed that the test is a respiratory screening and be presented with a screen to select the preferred language to be used within. The user should select *Proceed* to continue.

2. Then the patient will enter their date of birth (two digits for the month, two digits for the day, and 4 digits for the year), accept the Terms of Use, and select *Login*.

> **NOTE**
>
> The Terms of Use is in a link, which the patient can select and review if they choose.




Language




Login

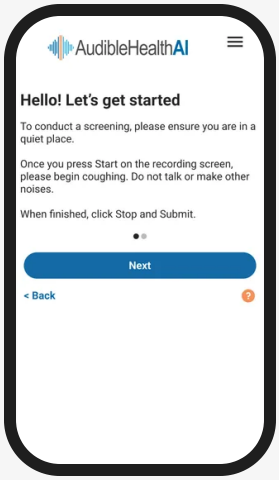
7.4

## FCV collection and testing

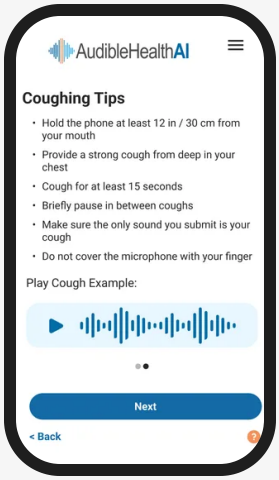
1. After login, the first two screens provide a brief tutorial, reviewing the test process and helpful tips for a successful FCV collection. Once the patient has finished reading these (or you have explained them to the patient), the *Next* button will continue the process.

**NOTE**

Patients can also listen to an example of a good-quality cough by selecting the *play triangle* at the bottom of the second instruction screen.




"Hello! Let's get started"




"Coughing Tips"

2

**CAUTION**

In addition to the sound considerations below, please consider the environment from an infection control perspective prior to preparing the patient to cough. The facility protocol should be followed based on the patient's symptoms and clinical suspicion. Please see the Infection Control (§6 Infection control) section of this document for further information.

3 To submit an FCV for analysis, you or the patient should tap the *microphone button*, and the patient should cough for at least 15 seconds. You will have to give the web app permission to use the smartphone's microphone.

To optimize FCV quality:

a. You (or the patient) will need to reduce any background noise in your space, such as turning off the television or radio and turning off or moving away from loud appliances or air conditioning units.
b. Silence the phone before submission.
c. Find the microphone on the smartphone. The phone should be held along the sides so that no fingers are over the microphone while the patient is coughing.

d. Whoever is holding the phone should not move it or their fingers. This may add extra noise and interfere with a successful submission.

e. Do not allow the patient to talk, eat, chew gum, or make noises other than the cough during the submission.

f. Hold the phone at least 12 in / 30 cm from your mouth.

g. Ensure you start coughing as soon as you click Start.

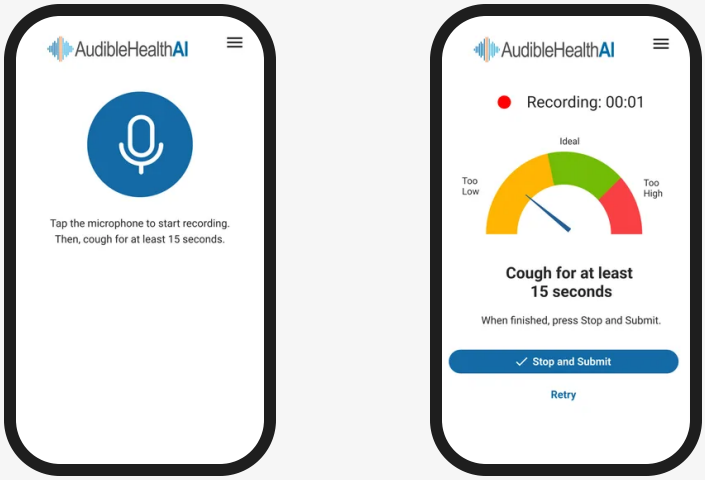
h. Encourage the patient to provide a strong cough from deep in their chest.

i. The patient should cough for at least 15 seconds and briefly pause between coughs. (The patient can listen to the example cough to understand this pause.)

j. The volume of the cough should be at about the level someone would normally talk on a smartphone.

k. Make sure the only sound you submit is the cough.

4 While the patient is coughing, you will see a meter that moves with the cough. Encourage the patient to try to move the needle to the green area with each cough. You will also see a timer that will help you determine whether the patient coughed for at least 15 seconds.




Ready to Record | Recording

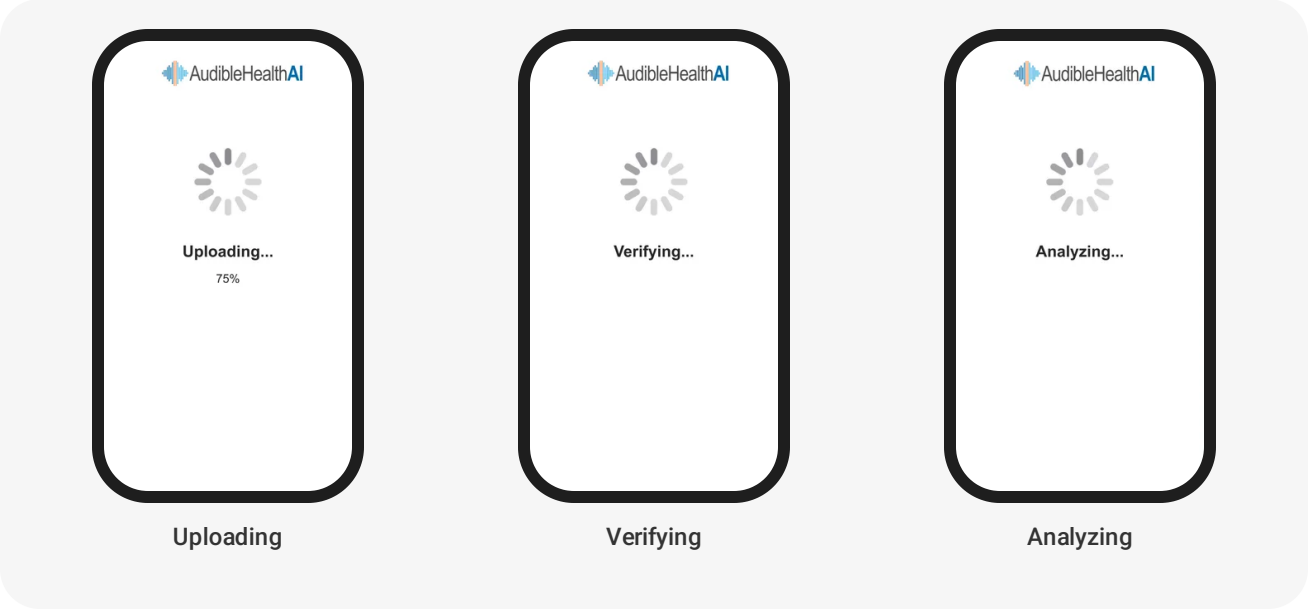
5 If an unexpected noise occurs or there is a problem with the submission, you may select *Retry* to retry the FCV collection. If there are no concerns about the cough submission, select *Stop and Submit*.

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## 7.5

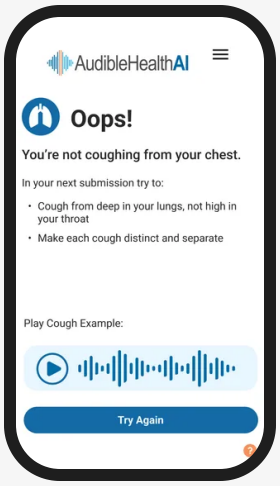
## Processing and error screens

6. While the FCV is being processed, three screens will show the process: **Uploading, Verifying,** and **Analyzing**.

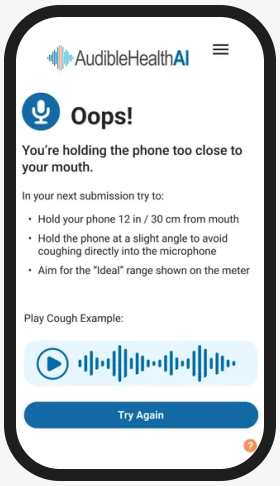



Uploading Verifying Analyzing

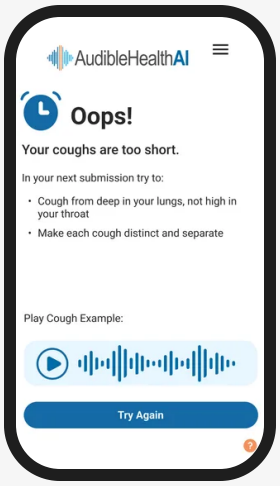
7. 
   - If a submission contains zero coughs that could be used for screening, the patient will see the **Oops!** screen and be prompted to try again. This is not related to the screening results. The audio processing system is designed to reject coughs that do not have the appropriate sound quality to ensure you receive the most accurate screening result possible for your patient.
   - If a submission contains some coughs that were usable for screening, but not the full 10 that are required, the **More Coughs Needed!** screen will appear, asking for another cough submission. Again, this is not related to the screening results.



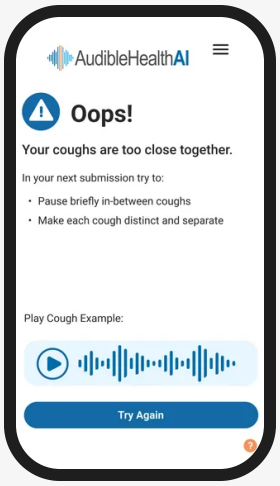

Oops! screen



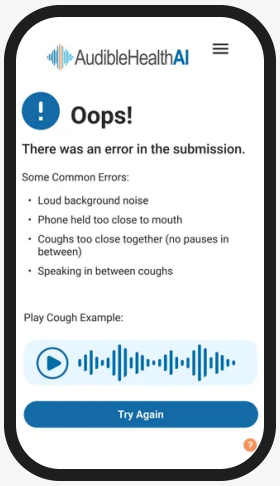

Oops! screen



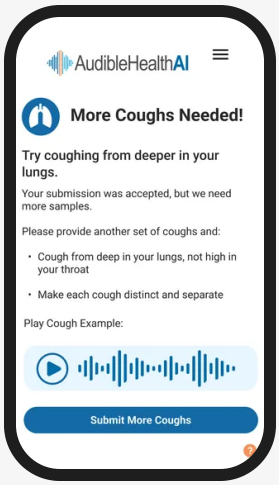

Oops! screen




Oops! screen




Oops! screen




More Coughs Needed!



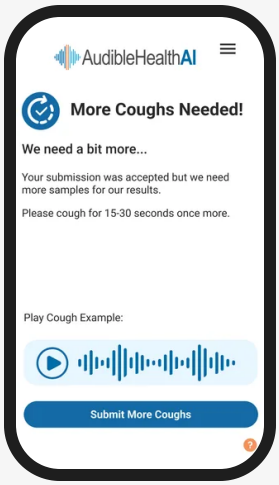

More Coughs Needed!




More Coughs Needed!




More Coughs Needed!




More Coughs Needed!

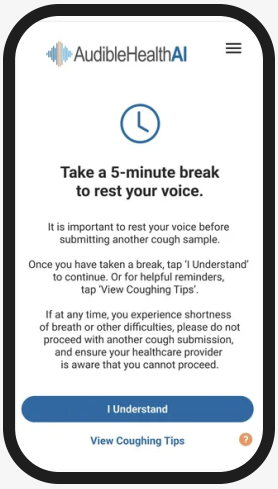
8 If the patient receives the **Oops!** or **More Coughs Needed!** screen, try to help the patient follow the specific instructions given on the screen. These screens are tailored to the audio issues detected by the audio processing system. Then select *Try Again* or *Submit More Coughs,* and the patient will be prompted to submit another cough sample.

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7.6

## Break screen

9 If the device is not able to evaluate the patient's cough sample after 3 attempts, a 5-minute break screen will appear. Waiting 5 minutes before another attempt helps to prevent voice strain from coughing many times. If you choose to have the patient wait 5 minutes, the patient will be able to use the same link in the text or WhatsApp message.




Break screen

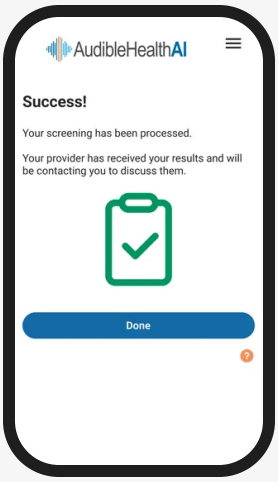
7.7

## Success

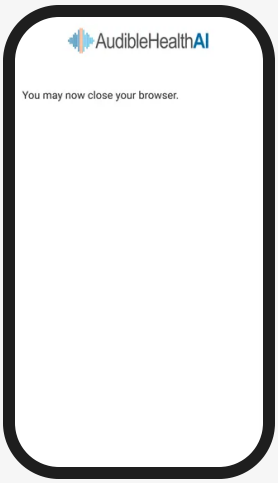
10. If the device is able to analyze the patient's cough and provide a screening result, a **Success!** message is displayed.

11. At that time, the patient can select *Done* and close the web browser. The smartphone should be sanitized at that time according to the facility policy to prevent the spread of infection.

12. The screening results will be transmitted to the system where the screener was ordered.




"Success"




"Close Browser"

08

## Results and interpretation

You will receive a screening result for each screener type you have selected within the system where the screener was ordered. Screening Results are presented as (1) *High Risk*, meaning that the chance the patient has the specified illness is 50% or greater, or (2) *Low Risk,* meaning that the chance the patient has the specified illness is less than 50%. The probability of illness is also displayed for reference.

In the most recent clinical study, the performance of the CDSS was as follows:

| Screener | Sensitivity | Specificity |
|---|---|---|
| Tuberculosis | 91% | 80% |
| COVID-19 | 96% | 87% |
| Pneumonia | 94% | 87% |

> ⚠ **WARNING**
>
> Despite these promising results, it remains possible that a screening result may be incorrect. All results are to be taken in the context of clinical judgment.

Results are for screening for pulmonary tuberculosis infection in individuals who are symptomatic with a cough, COVID-19 illness, or pneumonia. *High risk* results are indicative of forced cough vocalization associated with the presence of the specified illness. Clinical correlation with patient history and other diagnostic information is necessary to determine the patient's infection status. *High risk* screening results do not rule out the possibility of co-infection with other bacteria or viruses (including other screener types offered that may not have been selected).

> ⚠ **WARNING**
>
> *Low Risk* screening results indicate a forced cough vocalization, which appears in someone who is confirmed negative for the illness. *Low Risk* results do not rule out infection with a different virus or bacteria and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. *Low Risk* results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with the illness, and should undergo follow-up testing if necessary for patient management.

Test results for reportable diseases will be reported to the appropriate public health authorities by AudibleHealth AI, Inc., in accordance with local, state, and federal requirements.

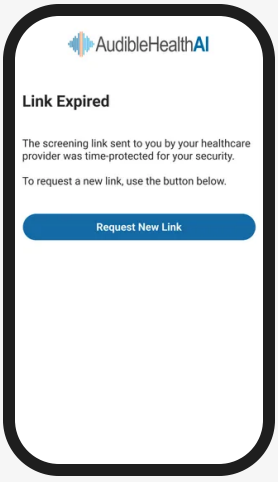
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09

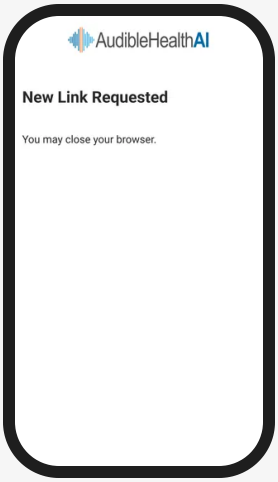
## Troubleshooting the One-Time Link

- The link you send to your patient expires after 14 days (or a shorter timeframe if requested by your administrator). If the patient attempts to access an expired link, a screen will appear in the web browser, noting the expiration. The patient will have the option to request a new link. You will be able to view the request in the system you use to send tests (as noted in Sending a Test (§7.1 Sending a test)).

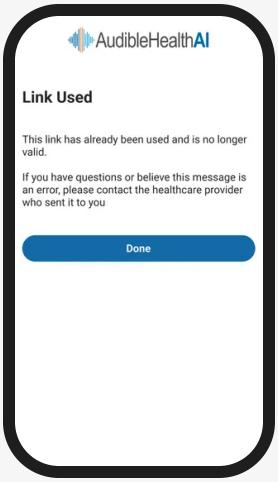
- The link will also expire as soon as it is used. If the patient attempts to access a link that has already been used, a screen will appear in the web browser, noting that the link has been used. The patient will NOT have an option to send a further request through the system if this occurs.



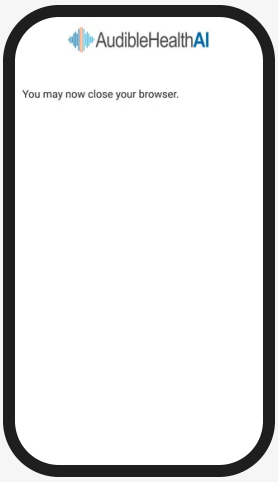

Link Expired




New Link Requested




Link Used




Close browser

# 10
# 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

> ⚠ **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.

# 11

# Explanation of symbols used in product labelling

This is governed by the law of the nation in which it is marketed (requirements and symbols may vary across countries and jurisdictions). Below are the pictures and their definitions, as they appear on the device label and packaging.

| Symbol | Meaning | Reference |
|---|---|---|
|  | Manufacturer | ISO 15223-1, 5.1.1 |
|  | Translation | ISO 15223-1, 5.7.8 |

App icon:

AudibleHealth AI app icon

12

# Manufacturer and warranty

## Warranty

No warranty, actual or implied, is offered for the AudibleHealth AI.

## 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