For healthcare providers · Field Screener

Instructions for Use

These instructions for use are for healthcare providers who intend to administer an AudibleHealth AI screening test as a field screening on a central smartphone that is used to test multiple patients. If you are a patient, please review one of our Quick Start Guides.

Version 5	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/ifu/field-screener

Please read all instructions carefully before using this device.

01

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 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.

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Device packaging or presentation

The user interface for this device is offered as a web application (app) for Android versions 13 through the current version and iOS versions 18 through the current version. The app is the only packaging for this device. To use the app, the clinician opens the Field Screener web app, logs in, registers the patient/subject and then asks the patient/subject to complete the cough submission. 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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Intended use/clinical applications

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.

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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.

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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.

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Warnings

WARNING

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

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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.

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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.

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

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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

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Instructions / directions

> **NOTE**
>
> These Instructions for Use (IFU) are for healthcare providers who will be using the AudibleHealth AI field screener as the mechanism for direct screening. If you are not a healthcare provider or are using a different method for sending tests, please refer to the appropriate IFU or Quick Start Guide.

The first screens encountered are simply registration and selection of the screener type. You will see a specific note indicating when you have begun use of the actual medical device.

Login

1. Upon accessing the AHAI Field Screener web app, you will see a login page. Login using the email address and password you would use for TestHub.
2. Your account administrator should have ensured you are aware of your login credentials. If you do not have login credentials, speak to your account manager or system administrator.

Registration / sending a test

1. After login, you will see a screen with the **Available Screener Types** available in your inventory.
2. Select the Screener Type you wish to use for your patient. After the Screener Type is selected, you will see a checkmark next to it, and you will be able to select *Start Field Screenings* to

proceed. (If you do not see the Screener Type you wish to use, contact your account manager or system administrator who is responsible for replenishing your inventory.)

3. After you have selected the Screener Type, you will be prompted to enter a unique identifier. Follow your organization's policy for the appropriate Medical Record Number or other identifier to use. Select *Continue* to proceed.

4. The next screen will ask for a few details on the patient. Gender and Smoking Status are required and can be selected from the drop-down menus. First Name and Last Name are optional fields. Follow your organization's policy on whether to utilize these fields. Select *Submit & Start Screening* to proceed.

FCV collection and testing instructions

> **NOTE**
> You are now entering the user interface for the medical device.

1. The first screen identifies that you are entering AudibleHealth AI and that it is a respiratory screening. Select *Proceed* to continue.

2. The following 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.

    a. The manufacturer information and the software version number are on the **Hello! Let's Get Started** screen for reference.

    b. 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.

    c. 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. For more information, refer to the Infection Control section of this document.

3. After selecting *Next*, you are ready to have the patient submit a cough sample. To submit an FCV for analysis, you or the patient should tap the microphone button once, and the patient should cough for at least 15 seconds. 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 when the patient coughs.
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.

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*.

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

    a. 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 meet the required sound quality standards, ensuring you receive the most accurate screening result possible for your patient.

b. 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.

c. If the patient receives the **Oops!** or **More Coughs Needed!** screen, try to 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.

7. If the device is not able to evaluate the patient's cough sample after 3 attempts, the 5-minute break screen will appear. Waiting 5 minutes before another attempt helps prevent voice strain from frequent coughing.

8. If the device is able to evaluate the patient's cough and provide a screening result, a **Success!** message is displayed. Select *Done* to proceed to the results and leave the medical device user interface.

9. If you have to stop screening the patient at any time, you can resume screening a patient by repeating the registration steps and entering the same medical record number. This will ensure that all submissions are attributed to the same patient.

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Results

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:

- Tuberculosis - Sensitivity: 91%, Specificity: 80%
- COVID-19 - Sensitivity: 96%, Specificity: 87%

- Pneumonia - Sensitivity: 94%, Specificity: 87%

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).

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.

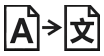
Test results for reportable diseases will be reported to the appropriate public health authorities by AudibleHealth AI, Inc., in accordance with local, state, and federal requirements.

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Explanation of symbols used in product labelling

This is governed by the law of the nation where 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

Symbol	Meaning	Reference
	Translation	ISO 15223-1, 5.7.8

App Icon:

AudibleHealth AI app icon

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Warranty

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

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Manufacturer

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

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

GS1: 00199284438224 GMDN: 64033