HTS-01 User Manual

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Mimi Health Hearing Test

Model HTS-01

The Mimi Health Hearing Test (HTS-01) intended use is to provide audiometric hearing screenings as support for decisions in relation to the medical diagnosis of hearing health including hearing impairment and hearing-related disorders.

The device provides guided instruction for self-administered air-conduction testing by the consumer in a quiet or sound-controlled environment. By increasing access to hearing screening when compared to traditional audiometry, the use of HTS-01 may lead to earlier self-referral for comprehensive medical diagnostic evaluation of hearing status by a qualified health professional.

HTS-01 does not supersede or replace a decisive diagnosis by a qualified health professional, does not allow direct diagnosis and is not intended to be used for monitoring, treatment or alleviation of any disease or disability. A diagnostic evaluation should be pursued if concerns about hearing sensitivity persist, independent of test results generated by the HTS-01.





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User Manual

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Overview

Software name Mimi Health Hearing Test Product ID HTS-01 Manufacturer Mimi Hearing Technologies GmbH Boxhagener Str. 82 10245 Berlin, Germany Valid from HTS-01 v1.13.0 (January 7, 2022) Software versions and up. Client SDK: v4.13.0 (iOS) and v5.0.0 For the latest manual download, see https://mimi.health/hts-01/user-manual (Android) Mimi Health Hearing Test (HTS-01) is a software Software description designed to provide testing for hearing abilities for users on consumer electronic devices, as support for medical diagnosis for hearing health and hearing disabilities (disease or impairment), where users, who receive results indicating deterioration in hearing health or have related concerns are encouraged to refer to a medical professional for a related diagnosis. The software consists of features that ensure the functionality of the hearing test once HTS-01 is placed within a host mobile application. HTS-01

Intended use

The HTS-01 intended use is to provide audiometric hearing screenings as support for decisions in relation to the medical diagnosis of hearing health including hearing impairment and hearing-related disorders. The device provides guided instruction for self-administered air-conduction testing by the consumer in a quiet or sound-controlled environment. By increasing

is distributed as a medical device to selected partners, which then integrate HTS-01 into their respective host mobile applications under strict instructions and with a defined interface, which are furthermore ensured by validation and

The HTS-01 is a medical device by its own functionality, with an independent intended

purpose from the mobile application.

verification procedures.

	access to hearing screening when compared to traditional audiometry, the use of HTS-01 may lead to earlier self-referral for comprehensive medical diagnostic evaluation of hearing status by a qualified health professional.
	HTS-01 does not supersede or replace a decisive diagnosis by a qualified health professional, does not allow direct diagnosis and is not intended to be used for monitoring, treatment or alleviation of any disease or disability. A diagnostic evaluation should be pursued if concerns about hearing sensitivity persist, independent of test results generated by the HTS-01.
Indications	Medical conditions intended to be assessed by HTS-01 include mild to moderate hearing loss. However, individuals whose hearing is expected or documented to be within normal limits can also use HTS-01 to learn more about their hearing.
	People with severe to profound hearing loss do not fall under the targeted population of HTS-01, because of the SPL output limitations on most consumer electronic devices.
Contra-indications	Individuals with suspected or documented severe to profound hearing loss are excluded from the target population of HTS-01, because maximum SPL output limitations on most consumer electronic devices would result either in inaccurate assessment of their hearing sensitivity and consequently little to no benefit for this population.
	While there are no known medical contraindications for use with HTS-01 as a medical device software (MDSW), HTS-01 is intended to be used with various hardware components, specifically consumer electronic mobile devices and headphones. The use of HTS-01 in conjunction with hardware components is not advised when medically contraindicated. Medical contraindication for use with headphones might include cases of chronic

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suppurative otitis media, infection-causing otalgia, outer ear laceration or abrasion, foreign object in ear canal or other otologic concern where the use of headphones could potentially exacerbate an underlying medical condition. In the event that an otologic condition is suspected, self-referral to competent medical authority is strongly advised in lieu of completing testing with HTS-01.

Intended users of HTS-01 are lay people 18 years of age or older who desire to perform a mobile hearing test in order to screen their general hearing sensitivity. Intended users are expected to be proficient at interacting with touch screen applications without professional training in associated technology or healthcare industries in order to use HTS-01 inside a partner mobile application.

The target users of HTS-01 are individuals: (a) with mild to moderate hearing loss, (b) without suspected hearing loss curious to learn more about their hearing status.

Individuals with suspected or documented severe to profound hearing loss are excluded from the intended target population of HTS-01 because maximum sound pressure level (SPL) output limitations on most consumer electronic devices would preclude an accurate assessment.

Specifications of the clinical benefits to be expected The device provides guided instruction for self-administered air-conduction testing by the consumer in a quiet or sound-controlled environment. By increasing access to hearing screening when compared to traditional audiometry, the use of HTS-01 may lead to earlier self-referral for comprehensive medical diagnostic evaluation of hearing status by a qualified health professional.

Necessary qualifications for users In contrast to traditional air-conduction pure-tone audiometry which requires professional administration of testing, HTS-01 is intended to be used directly by naïve (non-professional)

Patient target group and intended users

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Sterilization, final assembly, calibration, cleaning and disinfection

users on consumer mobile devices without guidance or intervention from healthcare personnel. Users are expected to exhibit basic smartphone and app-use literacy to access and complete test flow.

The Pure Tone Threshold (PTT) test requires a set of headphones for which manufacturer-determined correction factors have been calculated. A list of recommended headphones is populated during the test setup. If headphones for which biologic calibration factors are not known are used for testing, test results will be flagged as potentially inaccurate. It is outside of the intended use to proceed with the PTT without a set of recommended headphones. If you do not have a set of recommended headphones for the PTT test, the Masked Threshold (MT) test is recommended instead. The MT test allows you to test your ears with most sets of properly working headphones.

Any reconditioning procedures not applicable.

Storage, transport, durability not applicable.

Maintenance and repair

not applicable; however, some errors are addressed in the Troubleshooting section.

Precautions

Before using this product, please read and save the enclosed instructions of use.

USING DAMAGED HARDWARE CAN CAUSE UNEXPECTED BEHAVIOR LIKE SUDDEN LOUD NOISE OR INACCURATE RESULTS. Do not use HTS-01 with hardware that produces unexpected noises (crackle, hiss, etc.), or with a damaged cable or connection, or any other indicator of damaged hardware. Do not use HTS-01 with hardware contaminated speaker meshes or with earplugs that do not fit correctly into the ear.

TESTING IN A LOUD ENVIRONMENT CAN CAUSE INACCURATE RESULTS. HTS-01 is intended for use in a quiet environment. Find a quiet place to test your ears for accurate results.

ACCESSIBILITY SETTINGS CAN AFFECT THE ACCURACY OF YOUR RESULTS. The test should not be completed with System Accessibility Features for audio. These features include Volume Balance, Sound Amplification, or anything that affects the audio output of your device. Disable these from your System Settings before beginning a test.

The following links are included to help you locate the information you need. Settings may differ depending on your device - contact your device manufacturer for further support with regards to these features.

For iOS Products (iPhone, iPad):

support.apple.com/en-gb/guide/iphone/i ph3e2e2cdc/ios

For Android Products:

https://support.google.com/accessibility/ android/answer/9157755

Continued on next page \rightarrow

AUDIO SETTINGS CAN AFFECT THE ACCURACY OF YOUR RESULTS. The test should not be completed with system features or apps and services that affect audio. These features include volume limits, Equalizer (EQ) settings, third party services (for example Dolby Atmos, Samsung AdaptSound) or anything that affects the audio output of your device. Disable these from your System Settings before beginning a test.

The following links are included to help you locate the information you need. Settings may differ depending on your device - contact your device manufacturer for further support with regards to these features.

For iOS Products (iPhone, iPad):

https://support.apple.com/en-ie/guide/ip hone/iph5643d2c85/ios

For Samsung Products (e.g. S9, S9+, Note9, and Galaxy S10)

https://www.samsung.com/us/support/a nswer/ANS00080318/

AN INCOMPLETE OR INTERRUPTED TEST WILL PROVIDE INACCURATE RESULTS. HTS-01 requires your full attention from start to finish. Find a quiet place to test your ears for valid results. Valid results can be provided only if the attention is focused on the test during the whole duration of the test. If you pause the test for a long time, restart the test for valid results.

CHANGING HARDWARE DURING THE TEST CAN CAUSE AUDIO DISTORTION AND INACCURATE RESULTS. The test should be completed with the same hardware from start to finish. Changing headphones during the test may lead to inaccurate results.

TESTING IN THE WRONG OPERATING ENVIRONMENT MAY AFFECT ACCURACY. The test should only be completed in a supported environment. The iOS SDK does not support testing when running within an iOS app on Apple silicon based macOS. Settings may differ depending on your device. Contact your device manufacturer for further support with regards to these features.

Getting started

Prerequisites

Combination with other devices, including accessories: HTS-01 is a medical device software by its own functionality with an independent intended purpose from the host mobile application and has no accessories.

To complete the Mimi Hearing Test and generate a Hearing ID, you will need:

1. An Android or iOS device	 HTS-01 software is supported on smartphones and tablets using the following platforms: Minimum Android version: Android 5.0 (API21) or later Minimum iOS version: iOS 12 or later
2. Headphones	 HTS-01 software is supported on standard headphones or headphones that come with your device. HTS-01 allows you to test your hearing with two testing paradigms - the Masked Threshold (MT) test and the Pure Tone Threshold (PTT) test. The MT test can be taken with any standard wired or Bluetooth headphones. The PTT test requires calibrated headphones. A list of calibrated headphones will be available during the test setup. Ensure that your headphones are working correctly before starting the test. ▲ USING DAMAGED HARDWARE CAN CAUSE UNEXPECTED BEHAVIOR LIKE SUDDEN LOUD NOISE OR INACCURATE RESULTS.
3. A quiet environment	A quiet place is required to complete testing with HTS-01. Try to create a space where you can sit in silence without interruption for the duration of the test.You will need roughly 6 minutes to test both ears using the PTT test and 3 minutes for the MT test.

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Setup and Configuration Information

During your first session with Mimi, you will have the opportunity to create a new Hearing ID or log in with your existing account. To begin, simply take a hearing test and view your insights. To save your progress, **Sign Up** to create an account.

This is the initial state of the app if it has never been used before. To return the app to this state at any time, see **Removing your Hearing ID from this device** in the User Manual Tutorials.



Depending on the configuration of the selected partner host application, intended users can access different testing paradigms, either the Masked Threshold (MT) test, or the Pure Tone Threshold (PTT) test, or both the PTT and MT tests together in a given host application.

Test your hearing in noise

The MT hearing test tests your ability to differentiate a signal in background noise, simulating an environment in which your ears must navigate a crowded area. This test allows you to test your ears with any properly functioning headphones, with no need for calibration. HTS-01 turns your hearing data into insights, to help you reflect on your hearing health. This test is available in select partner applications, depending on the configuration of the partner app. The MT test will give you understandable results in about three minutes.

Test your hearing in silence

The PTT hearing test will give you understandable results in about six minutes. This paradigm tests a wide range of frequencies (125-12,000 Hz). We turn your auditory data into tangible insights to help you reflect on your hearing health. This test is available in select partner applications, depending on the configuration of the partner app. In addition, users are provided with a hearing grade based on the better ear following the World Health Organization (WHO) classification for hearing loss, along with a brief explanation of their results. Unlike the MT test, the PTT test requires calibrated headphones.

Your Hearing ID

Mimi's Hearing ID is a unique representation of your hearing ability and how it changes over time. Save your Hearing ID to your Mimi Account to seamlessly move your data between any device enabled with Mimi.

Your Hearing ID

Ever wondered how well you hear?

Take a test with Mimi and learn about your

hearing ability

Log in with Mimi

Main User Interface Components

Profile header



- The Profile Header reflects your Hearing ID. If you have not yet created a Hearing ID, you will see the onboarding state. From here you have the options to Create a Hearing ID or Log In with an existing Mimi Account.
- 2. Once you have completed the hearing test, your results are displayed in the **Profile** header. The result displayed depends on the type of hearing test taken. If multiple results are available, you can swipe left and right on this header to view more.
- If you have an incomplete Hearing ID or your results could not be calculated, you will see the We Don't Know Yet State.

For more information on this message, see the Troubleshooting section.

Create Hearing ID card

This card can only be seen if you have not yet set up a Hearing ID or taken the hearing test.

Here you can find some information about a Hearing ID and launch HTS-01.



Save your Hearing ID card

Once you have taken the hearing test, this card will allow you to save your Hearing ID by **Signing up with Mimi.**

Your hearing in noise card

On this card, you are provided with more information about your hearing in noisy environments. You can see more information on other hearing grades by tapping **Read More**.

This card will not appear until you have completed the **hearing in silence** test. This test is only available in certain regions.

Your hearing in silence card

On this card, you can see some more information about your hearing in silence. You can see some more information on other hearing grades by tapping **Read More.**

This card will not appear until you have completed the **hearing in silence** test. This test is only available in certain regions.



You	r hea	ring in	noise		
Your distir noise at mi	test re nguishi e, and y d to hiç	sult sho ng impo ou migh jh freque	ws that yo rtant sour it miss son encies.	ou may ha nds in bao ne acous	ave trouble okground stic details
Read	i more				
	<u></u>				
			Fair		



Already have an account? card

After you have taken the hearing test, you can log in to your account if you have not done this already. If you do not have a Hearing ID, you can create one from the **Save your Hearing ID** Card.

Keep your Hearing ID up-to-date card

Your Hearing ID is a reflection of your hearing ability, which is likely to change over time. Retake the HTS-01 regularly to keep your Hearing ID up to date. You can do this using the **Test your ears again** button.

Your Mimi account card

On this card, you can see the email address associated with your mimi account.

Your Hearing ID card

Here you can see some more information about your account, including the date of your most recent hearing test and your year of birth.

Your Hearing ID
Last hearing test You haven't done a test yet.

Your Mimi account

Manage account

ruby@mimi.io

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Tutorials

Create a Hearing ID

The HTS-01 is a quick, reliable way to explore your hearing ability. The instructions are displayed onscreen, so you'll never lose track of the next steps.



If you have used Mimi previously, you may instead see the **User Profile**. If you have taken a test before or logged in with an existing account, for more information on how to retest your ears skip to the section **Test your ears again**. To return the app to this state, see the section on **Reset your Hearing ID**.



1. Tap Get started

This is the initial state of the app if it has never been used before. If you have used the app previously, you will not see this screen, but instead, you will see the **Existing User** profile. To return the app to this state, see the section on **Removing Your Hearing ID from this device**.



Your Hearing ID



2. Tap Test your ears

Once you have finished reading the onscreen instructions, tap **Test your ears** to begin the test flow.

Your Hearing ID	
Create Hearing ID	
Learn more about your hearing ability.	
1 Find a quiet place	
2 Take the hearing test	
3 Get insights about your hearing	
Test your ears	
Log in with Mimi	
CE About Disclaimer	

3. Select the Masked threshold test

4. Find a quiet place

The MT test measures the quietest sounds you can hear in noisy environments.

HTS-01 must be taken in a silent place.

Once you have found the quiet place, tap **OK**.



5. Enter your year of birth

The year of birth helps us to understand your expected hearing ability, and calculate accurate results.

Choose your year of birth by swiping up or down to scroll through the date picker.

Tap Next to continue.

<	Get set up
	When were you born?
	your unique hearing ability.
	1989
	1989
	1990
	1991
	1993
	Next

6. Connect headphones

Connect the headphones that you will use for the test. You can use wired or bluetooth headphones for this test. The **Next** button remains inactive until the headphones are connected.

USING DAMAGED HARDWARE CAN CAUSE UNEXPECTED BEHAVIOR LIKE SUDDEN LOUD NOISE OR INACCURATE RESULTS. Indicators of damaged headphones include unexpected noises (crackle, hiss, etc.) or if the cable must be held in position to ensure a clean signal, for example.





7. Set up your device

Turn on **Do Not Disturb**, and turn off **Audio Effects**.



8. Set the volume for the test

Tap **Play noise** to begin playback.

Using your headphones, set the volume slider to a low volume, and slowly increase to find a level that is comfortable for you. It is important that the signal volume remains comfortable (i.e. not too quiet, but not too loud).

When you are ready, tap Next.

<	Get set up
	Select a volume that is loud yet comfortable
	Use the slider below or the volume buttons on your device to adjust the volume.
	Play noise
	Next

9. Get familiar with the sound of the Hearing Test

On this screen you have the opportunity to familiarize with the noises you will hear during the test. Take some time to listen to these sounds and ensure you know what to expect once the test begins.

When you are ready, tap All set.



10. Try a practice round

Here you will be guided through a practice round of the hearing test.

Press and hold the button while you hear the beep. Keep your finger on the button until the beep disappears. There will always be a masking noisetry to ignore it, and listen for the beep even when it is very quiet. On-screen indicators will show a check mark when you do this correctly

NOTE: You can return to this screen and repeat the practice round at any time.



11. Test your first ear

After a 3-second countdown, the test begins on just one ear. The first ear is selected randomly to avoid any bias in the test data.

Press and hold the button while you hear the beep. Keep your finger on the button until the beep disappears. There will always be a masking noisetry to ignore it, and listen for the beep even when it is very quiet.

A status bar indicates your progress through the test.

You may pause the test at any time to take a break, or if you get interrupted, by tapping the

Pause Icon II in the top right corner. See step 14 of this manual for more information on pausing the test.

12. A short pause between ears

When your first ear is complete, you will see this confirmation screen.

Tap Next to continue the test on the second ear.



Hearing test
Great work
Now let's test your other ear.
Restart test
Next

13. Test your second ear

Press and hold the button while you hear the beep. Keep your finger on the button until the beep disappears. There will always be a masking noisetry to ignore it, and listen for the beep even when it is very quiet.

A status bar indicates your progress through the test.

If you need to stop or interrupt the test at any time, see step 14 of this manual to pause the test.

14. Pausing the test

Pause the test at any time by tapping the **Pause Icon II** in the top right corner.

There are 5 options on the Pause Menu:

1. Resume

Resume the test from where you left off. Use this to simply continue the test.

2. Practice again

If you are unsure how the test works, you can exit the test at any time and return to the practice round.

NOTE: Your test data for this session will be lost

3. Restart this ear

Restart the test if you are distracted or interrupted during the test. NOTE: Your test data for this ear will be

4. Skip this ear

lost.

Skip testing an ear if you have no hearing in one ear or for any other reason. NOTE: If you skip the first ear during the test, this option will not appear on the second ear.

NOTE: Your test data for this ear will be lost.

5. Exit test

Exit the test at any time NOTE: Your test data for this session will be lost.

ī	Exit test
bb.	Skip this ear
Ð	Restart this ear
•	Practice again
	Resume



15. Finish the test

Once you complete the test we will begin processing your results and display your grade.

Continue to the next section for more information on viewing your test results on the **Profile**.





1. Tap Get started

This is the initial state of the app if it has never been used before. If you have used the app previously, you will not see this screen and instead see the **Existing User** profile. To return the app to this state, see the section on **Removing Your Hearing ID from this device**.



2. Tap Test your ears

Once you have finished reading the onscreen instructions, tap **Test your ears** to begin the test flow.

Your Hearing ID
Create Hearing ID
Learn more about your hearing ability.
1 Find a quiet place
2 Take the hearing test
3 Get insights about your hearing
Test your ears
Log in with Mimi
CE About Disclaimer

3. Select the **Pure tone threshold test**

The PTT test measures the quietest sounds you can hear at different frequencies.





4. Allow Microphone Access

In order to continue, the PTT test needs microphone access to check if the environment is quiet enough before beginning.

Tap **Allow** to grant access to the microphone.



5. Find a quiet place

HTS-01 must be taken in a silent place.

Once you have found the quiet place, tap **All set**.





6. Enter your year of birth

The year of birth helps us to understand your expected hearing ability, and calculate accurate results.

Choose your year of birth by swiping up or down to scroll through the date-picker.

Tap Next to continue.

7. Set up your device

Turn on **Do Not Disturb** and turn off **Audio Effects**.

8. Connect headphones

Connect the headphones that you will use for the test. You can use wired or bluetooth headphones for this test. The **Next** button remains inactive until the headphones are connected.

USING DAMAGED HARDWARE CAN CAUSE UNEXPECTED BEHAVIOR LIKE SUDDEN LOUD NOISE OR INACCURATE RESULTS. Indicators of damaged headphones include unexpected noises (crackle, hiss, etc.) or if the cable must be held in position to ensure a clean signal, for example.



9. Set the volume for the test

Set the volume slider to 50%.

When you are ready, tap Next.



10. Select your headphones

To take this hearing test you need headphones that are calibrated to your device. Using headphones that are not calibrated may affect your test results.

Tap Next to continue.

<	Ge	et set up	
S	Select yo	ur headphones	
Supporte	ed headpho	nes	0
Î	Apple Earpods		
	Apple Airpods		
1940	Apple Airpods Pro		\odot
Unsuppo	rted headp	hones	
Other h Uncalib	neadphones prated		
(i) Using result	uncalibrated	headphones may affeo mend using calibrated	et your
		Next	

11. Try a practice round

Here you will be guided through a practice round of the hearing test.

Press and hold the button while you hear the beep. Keep your finger on the button until the beep disappears. There will always be a masking noisetry to ignore it, and listen for the beep even when it is very quiet. On-screen indicators will show a check mark when you do this correctly

NOTE: You can return to this screen and repeat the practice round at any time.

12. Test your first ear

After a 3-second countdown, the test begins on just one ear. The first ear is selected randomly to avoid any bias in the test data.

Press and hold the button while you hear the beep. Keep your finger on the button until the beep disappears.

A status bar indicates your progress through the test.

You may pause the test at any time to take a break, or if you get interrupted, by tapping the

Pause Icon in the top right corner. See Step #15 of this manual for more information on pausing the test.



13. A short pause between ears

When your first ear is complete, you will see this confirmation screen.

Tap **Next** to continue the test on the second ear.



14. Test your second ear

Press and hold the button while you hear the beep. Keep your finger on the button until the beep disappears. A status bar indicates your progress through the test.

If you need to stop or interrupt the test at any time, see step #15 of this manual to pause the test

15. Pausing the test

Pause the test at any time by tapping the **Pause**

Icon II in the top right corner.

There are 5 options on the Pause Menu:

1. Resume

Resume the test from where you left off. Use this to simply continue the test.

2. Practice again

If you are unsure how the test works, you can exit the test at any time and return to the practice round.

NOTE: Your test data for this session will be lost.

3. Restart this ear

Restart the test if you are distracted or interrupted during the test.



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NOTE: Your test data for this ear will be lost.

4. Skip this ear

Skip testing an ear if you have no hearing in one ear or for any other reason. NOTE: If you skip the first ear during the test, this option will not appear on the second ear. NOTE: Your test data for this ear will be lost.

 Exit test Exit the test at any time NOTE: Your test data for this session will be lost.

16. Finish the test

Once you complete the test we will begin processing your results and display your grade.

Continue to the next section for more information on viewing your test results on the **Profile**.



Review Your Hearing ID

After taking the hearing test, Mimi processes the data so you can view your insights on the **Profile** tab. Here you will find useful information including a grade indicating your hearing ability, the date of your last test, and more information about hearing loss.



The Profile is displayed only after you have completed the hearing test. If you have not yet taken your first test, see **Create a Hearing ID**. Your Hearing Grade is the results of your latest test. For the most accurate insights keep your Hearing ID up to date by testing regularly.

Reviewing your results: **your hearing in noise** (MT paradigm)

1. View your results in the Profile header

The first place you see your result is in the **Profile** header. Here you can see your Hearing Grade and the date of your most recent hearing test.



2. Scroll down to the Results Card

Scroll down the profile until you see the **Your hearing in noise** card. In this view you can find much more detailed information about your hearing.

NOTE: You will only see this card if you have completed a test for your hearing in noise.



3. Tap Read more

Tap **Read more** to view more information about your Hearing Grade and other hearing grades.

Tap the $\stackrel{\text{i}}{=}$ menu in the top left to review your results from previous tests. You can delete a result by swiping left. To return to your current test results, tap the **X** button.

Your hearing in noise	
Your test result shows that you may have trouble distinguishing important sounds in background noise, and you might miss some acoustic details at mid to high frequencies.	
Read more	
o o 🥑 o o	
Fair	

Reviewing your results: **your hearing in silence** (PTT paradigm)

1. View your results in the Profile header

The first place you see your result is in the **Profile** header. Here you can see your Hearing Grade and the date of your most recent hearing test.



2. Scroll down to the **Results** Card

Scroll down the profile until you see the **Your hearing in silence** card. In this view you can find much more detailed information about your hearing.

NOTE: you will only see this card if you have completed a test for your hearing in silence.



3. Tap the Hearing in silence card

Here you can view more information about your Hearing Grade and other hearing grades.

An audiogram displays a graph of your hearing ability. Scroll down to view further information on your Hearing Grade.

Tap the $\stackrel{\text{iei}}{=}$ menu in the top left to review your results from previous tests. You can delete a result by swiping left. To return to your current test results, tap the **X** button.

4. [Optional] Export your results

When viewing your results, you can tap the **Export**

Icon to export your results as PDF.

5. [Optional] Export your results: Enter a name

If you are logged into your account, you can enter or update the name that will appear on the report.

Then tap Continue.

A	udi	ogran	n				Û
	0	0					No loss
		R					
	20				-		-
B HL)	30						
p) sso	40						
iring L							
Hea	60						
	80						evere loss
	90						
		250		1k Erecuenc	3k	4k	8k
Yo	urav	erage h	nearing l	oss	y (F1Z)		
6		0.11					0
C	.)90	BHL	(R)	OB HL			
Α	udi	ogra	m				ر ال

Plea	ise enter your name data is personalized for the p	berson
to whom Name	the hearing test belongs to	
	Continue	
	Cancel	

6. [Optional] Exporting your results

Your export will begin shortly.

A system dialog will appear. The file can be saved directly to your device or attached to an email or other app of your choice for sharing.



niNi

Keep Your Hearing ID Up to Date

Your Hearing ID is a reflection of your hearing ability, which is likely to change over time. Retake the HTS-01 regularly to keep your Hearing ID up to date. You can do this using the **Test your ears again** button.



SYSTEM SETTINGS CAN AFFECT THE ACCURACY OF YOUR RESULTS. The test should not be completed with System Features for Audio. If you use any Accessibility Settings for Audio on your device, ensure these features are disabled and returned to default before beginning the test. Audio stream must be Stereo and Balance should be 50:50 Left and Right.



1. On your profile, scroll to the card called Keep your Hearing ID up-to-date



2. Tap Test your ears again

This will launch the test flow.

Here you may have the option to choose whether you would like to test **your hearing in noise** or **hearing in silence**. Note that all hearing test paradigms are not currently available in all regions.



3. Follow the onscreen instructions to retest your ears

Select a test type and get started.



Save Your Hearing ID

Whether you have previously used a Mimi Integrated Technology and you want to restore your data, or you have simply bought a new phone, you can store all of your hearing information on your Hearing ID to transfer seamlessly between products. Once you have created your Hearing ID, you can use your login details to log in to any Mimi-enabled device.



1. On the **Profile** scroll to the **Save your Hearing ID** card

NOTE: you must first complete the hearing test in order to save your Hearing ID. This card will not be visible before you take a test.

Save ye	our Hearing ID
,	Sign up or log in with Mimi to securely save your Hearing ID.
2 s	ign up Log in with Mimi

2. Tap Create account

On this card you can see some further information about creating a Hearing ID.

Tap Create account to continue.



3. Enter your name and email address

The email address you provide will be associated with your Hearing ID. Ensure that you can receive email to this account as this will be required for account verification.



4. Enter a password

Use a strong password for your Hearing ID. Your password must have eight or more characters and include upper and lowercase letters, and at least one number.

NOTE: store your password in a safe place, it will be needed for account access in future.



5. Review the Privacy Policy and Terms of Use

You must agree to the Privacy Policy and Terms of Use to create an account. To read these documents, simply click on **Privacy Policy** or **Terms of Use** or to open the documents.

If you are happy to proceed, check the boxes and tap **Finish**.



Mimi refers to Mimi Health GmbH and Mimi Hearing Technologies GmbH acting as joint controllers.

Decline



6. Verify your email

In order to finish setting up your account, you must verify your email address. You can launch your email app directly from the signup flow by tapping **Open my email.** Tap **Skip for now** to verify later.

User data may be lost if you do not verify your email to finish setting up your account. Your Hearing ID is not linked to your email address until your email address is verified.



1. Tap Log in from the Onboarding Header or from Already have an account? card

There are two options to launch the login flow. If you are using the app for the first time, tap **Log in with Mimi** in the **Profile** header.

If you have already created a Hearing ID, you can still log in from the login card.





2. Enter your email address and password

Enter the email and password specified during registration. If you cannot remember your password, see the Troubleshooting Section of this manual for assistance resetting your password.

You can show/hide your password by clicking the icon with the crossed-out eye (\ge).

<	
Already have an account?	
Hearing Weilbeing.	
Email	
Password	2
Forgot password	1?
Log in	



1. Scroll to the bottom of the **Profile**

Here you will find a red button with an **X** mark. This button allows you to reset your Mimi App, removing your hearing data from the device.

If you previously logged into a Mimi account, you will see the option to **Log Out**.

If you have not yet created the Mimi account, you will only have the options to **Delete Hearing ID**.

NOTE: tapping **Delete Hearing ID** will discard all your data for this session. This data will be lost and cannot be recovered. To save your Hearing ID before removing it from this device, create the Mimi account.

Your Hearing ID		
Your hearing capacity in		
Silence		
Mild hearing loss Based on test taken on 24.08.2018		
Save your Hearing ID		
Sign up or log in with Mimi to securely save your Hearing ID.		
Log in with Mimi		
Your hearing in noise Your test result shows that you may have trouble distinguishing important sounds in background noise, and you might miss some acoustic details at mid to high frequencies. Read more		
Fair		
1.50		
Your hearing in silence Look at your latest audiogram and test results in more detail.		
Keep your Hearing ID up-to-date Remember to re-test your hearing ability regularly to track your hearing health over time.		
🗘 Test your ears again		
Your Hearing ID Last hearing test You haven't done a test yet. Year of birth 1985		
X Delete Hearing ID		



2. Tap Log out or Delete Hearing ID

This will clear the Hearing ID from the app and return HTS-01 to its initial state.

Troubleshooting

My hearing test was interrupted

In order to maintain the test environment, during the test you will be prevented from changing the volume, removing your headphones, and you will see an onscreen reminder if you have not interacted with the test in some time. During the **Hearing in silence** test, you will be interrupted if your environment becomes too noisy.

Device volume changed

Return the volume to its initial value as indicated onscreen to continue the test.

You can adjust the volume with your device Volume Keys or using the slider on screen.

Headphones disconnected

Reconnect your headphones to continue the test.

If you are using Bluetooth headphones, you will see the option to Troubleshoot further.

CHANGING HARDWARE DURING THE TEST CAN CAUSE AUDIO DISTORTION AND INACCURATE RESULTS. The test should be completed with the same hardware from start to finish. Changing headphone hardware during the test may lead to inaccurate results.

You've been inactive

You were inactive for too long. Remember to hold the button while you hear the beep and only let go when you no longer hear the beep.

To continue, tap Restart.

AN INCOMPLETE OR INTERRUPTED TEST WILL PROVIDE INACCURATE RESULTS. The HTS-01 requires







Restart

your full attention from start to finish. Find a quiet place to test your ears for accurate results. Reliable results can be provided only if the attention is focused on the test during the whole duration of the test. If you pause the test for a long time, restart the test for accurate results.

The test environment is too loud

Your test environment has become too loud. Try moving to a more quiet place for the best results.

This error will only appear during the **Hearing in silence** test (PTT paradigm). To test your hearing in silence, you will need a quiet place. The app first checks if your environment is quiet enough during the test setup, and will notify you during the test if your environment becomes too loud.

TESTING IN A LOUD ENVIRONMENT CAN CAUSE INACCURATE RESULTS. The HTS-01 is intended for use in a quiet environment. Find a quiet place to test your ears for accurate results.

Another app is using the device audio

Another app is currently using the device audio. This may occur when a phone call is in progress, or during any other type of audio playback.

To resume your test, quit any other app that is playing the audio, or otherwise end playback.







In order to compute your test results, Mimi requires a stable internet connection

Test Complete: Something went wrong

Once you have completed your hearing test, your results will be submitted and your insights will be calculated.

If you see an error message like the one pictured here, your test submission failed.

In order to calculate your test results, Mimi requires a stable internet connection. Please check your internet connection and try again.



My test results say "we don't know yet"

Occasionally, Mimi may not be able to identify your test results. This is usually because of internet connection issues, but may be caused by some data in your hearing test. Follow these steps to troubleshoot a **We don't know yet** result

Troubleshooting:

- Ensure that you have a good internet connection.
 If possible, try a different connection.
 HTS-01 requires an internet connection to calculate your results.
- Restart your device.
 Occasionally internet connection issues may not be resolved until your device is restarted.
- Retake the test.
 If there is a problem with your test results you may see this message. Try taking the test again. To verify if the problem is with your results, you will see a red banner.
- 4. If you still see this result, please reach out to support at hello@mimi.health



The test is too loud or hurts my ears

The HTS-01 should never cause physical discomfort or pain. Do not begin or continue the test if the audio is too loud or uncomfortable. Before starting the test, make sure you set your device volume at a comfortable level for you.

If you feel the HTS-01 is too loud at any point, remove your headphones and stop listening immediately. To resolve the issue, try these steps to reduce the volume and create a more reliable environment for your test:

- During the test setup, ensure that the volume is set to an appropriate level. On the MT Test you can set it to a level that is comfortable. Take a few seconds to listen to the sound and ensure it is comfortable before you begin. On the PTT Test the volume should be set to 50%. If you are using uncalibrated headphones, this may sound loud. Use headphones that are calibrated for use with this test. If you do not have headphones calibrated for this test, we recommend our other test.
- 2. Try a different set of headphones broken or damaged headphones may cause a

faulty connection. Ensure you are using hardware that is fully operational. USING DAMAGED HARDWARE CAN CAUSE UNEXPECTED BEHAVIOR LIKE SUDDEN LOUD NOISE OR INACCURATE RESULTS.

3. Try testing on a different device - broken or damaged devices may cause a faulty

connection. Ensure you are using hardware that is fully operational. USING DAMAGED HARDWARE CAN CAUSE UNEXPECTED BEHAVIOR LIKE SUDDEN LOUD NOISE OR INACCURATE RESULTS.



1. Tap Log In from the onboarding header or from Already have an account? card

There are two options to launch the login flow. If you are using the app for the first time, tap **Log in with Mimi** in the **Profile** header.

If you have already created a Hearing ID, you can still log in from the login card.



6
Ever wondered how well you hear?
Take a test with Mimi and learn about your hearing ability.
Get started
Log in with Mimi
Already have an account? Minimum Fraction Provide the second s
Email
Password 🗞
Forgot password?
Login

Your Hearing ID



3. Enter your email address and tap **Submit**

You must enter the email specified during registration. Further instructions will be sent to this address.



4. Check your email

You will soon receive an email from Mimi. Follow the link in this email to reset your password.

If you do not receive an email, this is likely not the address you used to register. Try a different email address or create a new account.

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Your account can be deleted from Manage my Account.

- **1.** Log in to your account.
- **2.** Find the account card.
- 3. Tap Manage Account.
- 4. Tap Manage my Account.
- 5. Tap Delete my Account.
- 6. Read the on-screen information regarding deleting your account. NOTE: your user data will be removed permanently if you delete your account. It will not be possible to recover this information at a later date.
- 7. If you would still like to delete your account, tap Yes, I want to delete my account.
- 8. Your request will be processed.



I want to change my email

- **1.** Log in to your account.
- 2. Find the account card.
- 3. Tap Manage Account.
- 4. Tap Manage my Account.
- 5. Tap Change my email.



I want to review my consents or download my account data

- **1.** Log in to your account.
- 2. Find the account card.
- 3. Tap Manage Account.
- 4. Tap Manage my Account.
- 5. Tap My consents or Export all my data.

Technical and Performance Characteristics

The following tables collect the Masked Threshold (MT) and Pure-Tone Threshold (PTT) hearing tests parameters as defined in the respective hearing test scripts and engines. Note that the values defined here don't necessarily correspond to the actual behavior in terms of sound output.

Technical and Performance Characteristics of MT Hearing Test

Parameters	Observed HTS-01 MT specifications
Pulse Shape [ramp-on-ramp-off]	20, 100, 20, 120 ms
Initial level test tone	-55.0 dB FS (decibels relative to full scale)
Minimum tone level	approx15 dB FS
Maximum tone level	
(RMS-normalized)	
Level Masker noise	-20.2 dB FS
(RMS-normalized)	
Masker bandwidth	100 Hz BW at 500 Hz test tone
	200 Hz BW at 1 kHz
	320 Hz BW at 2 kHz
	320 Hz BW at 4 kHz
Difference between test tone and pink noise level	-40.3 dB FS
Level speed up	-5.084 dB/sec

Level speed down	5.02178 dB/sec
Overall duration	80.063 sec
Inactivity threshold	~8 sec
	~15 sec (timer)

Technical and Performance Characteristics of PTT Hearing Test

Parameters	Observed HTS-01 PTT specifications
Pulse Shape [ramp-on-ramp-off]	pulse repetition rate 220 ms silent state 110 ms steady state 90 ms 10 ms ramps Smooth ramps
Level speed up / down	+10 dB/sec up -10 dB/sec down
Start gain	-40 dB FS (decibels relative to full scale)
Contralateral noise level* [dB re-tone]	~-29 dB
Contralateral noise bandwidth [Oct]	
Overall duration	153 s
Keep-alive tone frequency	18900 Hz
Keep-alive tone level	-60 linear FS
Minimum level	-140 dB FS
Maximum level	0 dB FS



Inactivity threshold	12 sec
	20 sec

Symbols

The following symbols related to the medical device HTS-01 can be found throughout this manual and on the device itself:

Symbol	Explanation
CE	The CE-mark indicates that Interacoustics A/S meets the requirements of Annex II of the Medical Device Directive (MDD) 93/42/EEC
Ē	Year of manufacture
6	Manufacturer address
	User manual
	Precaution/caution
	Consult user manual
Der ser	Troubleshooting

Support

For additional questions or technical support, contact hello@mimi.health

Contact Information

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To request a physical copy of this manual, please contact hello@mimi.health