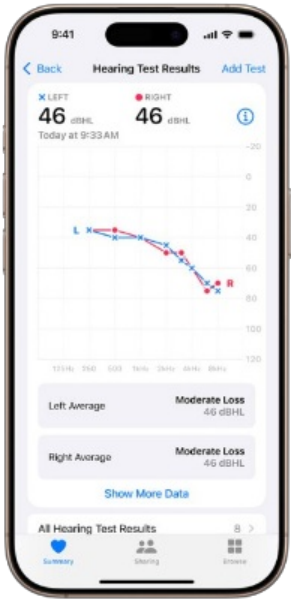
# Apple Hearing Test Feature Instructions



**Apple Hearing Test Feature Instructions**



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## INDICATIONS FOR USE

The Apple Hearing Test Feature is a software-only mobile medical application that is intended to be used with compatible wearable electronic products. The feature is an over-the-counter air-conduction hearing assessment intended to profile hearing ability and to produce an audiogram without the assistance of a hearing healthcare professional. The Apple Hearing Test Feature is intended for use by individuals 18 years of age or older.

## INTENDED PURPOSE (EU)

The Apple Hearing Test Feature is a software-only mobile medical application that is intended to be used with compatible wearable electronic products. The feature is an over-the-counter air-conduction hearing assessment intended to profile hearing ability and to produce an audiogram without the assistance of a hearing healthcare professional. The Apple Hearing Test Feature is intended for use by individuals 18 years of age or older.

### Target Population and Intended Users

The feature is indicated as an over-the-counter air-conduction hearing assessment to profile hearing ability and produce an audiogram for individuals 18 years of age or older.

## PRECAUTIONS AND WARNINGS

- The Apple Hearing Test Feature is intended for individuals 18 years of age or older
- Do not perform the hearing test in a noisy environment. Choose a quiet room or area away from intrusive sounds such as street noise, TV audio, loud fans, noisy appliances, etc.
- Do not speak, chew gum, eat or drink during the test, as this may impact test results
- Exposure to loud noises within the last 24 hours or the presence of congestion can impact test results
- The Apple Hearing Test should not supersede any medical advice provided by your hearing healthcare professional.
- Hearing health is comprised of many factors. If you have any of the problems listed below, you should consider consulting with a hearing healthcare professional:

    - You saw blood, pus or fluid coming out of your ear in the past 6 months
    - Your ear feels painful or uncomfortable
    - You have a lot of ear wax or think your ear canal may be obstructed
    - You frequently experience dizziness or have a feeling of swaying and spinning (called vertigo)
    - Your hearing changed suddenly in the past 6 months
    - Your ability to hear changes: it gets worse and then better again
    - You perceive worse hearing or ringing/buzzing in only one ear
- If you remain concerned after using the Hearing Test Feature, consult with a hearing healthcare professional

## CUSTOMER SUPPORT

This information and other labelling, including the user instructional brochure, are available on the internet at: **https://www.apple.com/legal/ifu**. You may also call Apple Support through the 'Contact Apple Support' option in the 'About Hearing Test Feature' screen or write to **medicalcompliance@group.apple.com** or One Apple Park Way, Cupertino, CA 95014 to request a paper copy of this information and other labelling.

## SECURITY

Apple recommends that you add a passcode (personal identification number [PIN]), Face ID or Touch ID (fingerprint) to your iOS compatible devices (e.g. iPhone, iPad) to add a layer of security. It is important to secure the iOS device since you will be storing personal health information. Users will also receive additional iOS update notifications on the device, and updates are delivered wirelessly, encouraging rapid adoption of the latest security fixes. Please visit **https://support.apple.com/guide/security/welcome/web** for iOS Security Guide that describes Apple's security practices available to all our users.

In the event that you suspect or would like to report any security issues with your device, please visit the Apple Support web page, which describes how to get help with your security issues (**https://support.apple.com/111756**).

## USING THE HEARING TEST FEATURE

### Setup

- The Hearing Test Feature is compatible with AirPods Pro 2 when paired to an iOS device (e.g. iPhone, iPad). For region availability and device compatibility information, please visit **https://www.apple.com/uk/airpods.pro/feature-availability/**
- Update iPhone/iPad and AirPods Pro 2 to latest iOS and Firmware
- Make sure your AirPods Pro 2 are paired to your iPhone/iPad
    - For more information on pairing your AirPods Pro to your iPhone, please visit **https://support.apple.com/kb/HT207010**.
- Insert the AirPods Pro 2 into the corresponding ears with the stems facing downwards. A snug fit makes sure that background noise doesn't affect your test results and that the test is accurate.
- Access the Hearing Test Feature in one of the following ways:
    - Open Settings → [Name of your AirPods Pro 2] → Tap Take a Hearing Test
    - Open Health app → Tap Browse at the bottom right → Tap Hearing → Tap Hearing Test Results → Tap Take Hearing Test
    - AirPods Pro Setup Prompt → when you initially set up your AirPods Pro 2, the feature will ask you to take an initial hearing test

- Follow the onscreen instructions
  - Indicate if you are 18 years of age or older
    - **NOTE**: The Hearing Test Feature is intended for individuals 18 years of age or older
  - Indicate if you are currently experiencing allergies, a cold, or infection in your ears or sinuses, or if you have been in a loud environment like a concert or construction site in the last 24 hours
    - **NOTE**: Please note that congestion or exposure to loud sounds can impact the accuracy of your hearing test results. You should consider waiting until the congestion has resolved or for 24 hours after exposure to loud sounds to allow your hearing to recover
- Find a quiet place to take the test. The Hearing Test Feature will check the AirPods fit in each ear and measure the background noise level before proceeding to the test.
  - **NOTE:** The Hearing Test Feature will turn on 'Do Not Disturb' mode to help minimise any distractions
  - **NOTE:** If the Hearing Test Feature determines that the AirPods do not have an acceptable fit in your ears, you may need to adjust your AirPods to get a snug fit or try changing the ear tip sizes. Your AirPods Pro 2 come with various sized ear tips (XS, S, M, L). For more information on changing your ear tips on your AirPods Pro, please visit **https://support.apple.com/HT210633**
  - **NOTE:** A very quiet room will allow you to get a more accurate result. The test will be paused if your surroundings get too loud. To continue, wait for the noise to stop, move to a quieter location or take the test at a quieter time
- You may exit the Hearing Test Feature at any time by tapping "Cancel".

### Taking the hearing test

- When the hearing test starts, your AirPods will play a series of tones
- You will tap the screen when you hear a tone. You will have more than one chance to hear each tone
- Follow the onscreen instructions to complete the hearing test session
  - **NOTE**: The hearing test session will be paused if the Hearing Test Feature detects loud noises near you. To continue, wait for the noise to stop, move to a quieter location or take the test at a quieter time. You can end the test, but all progress will be lost
  - **NOTE**: The hearing test session will be paused if one of your AirPods is removed during the Hearing Test Feature use. To continue, place your AirPods back in your ear. You can end the test, but all progress will be lost
  - **NOTE**: If the hearing test is paused for too long, the test will automatically end and will need to be restarted.

### Hearing test result

- Once the test has successfully completed, you will receive your hearing test result, which includes a hearing loss classification for each ear
  - The hearing test result classification is based upon the four-frequency pure tone average (4PTA), which is the average of the hearing thresholds at 500 Hz, 1 kHz, 2 kHz and 4 kHz
  - The complete audiogram with values at each of the measured hearing thresholds (250 Hz, 500 Hz, 1 kHz, 2 kHz, 3 kHz, 4 kHz, 6 kHz and 8 kHz) can be found by selecting Show Details. The audiogram will also be saved in the Hearing category of the Health app
  - The different hearing loss classifications based on the World Health Organization (WHO) guidelines and

the 4PTA value range can be seen in the table below:

| Classification | 4PTA Value Range |
|---|---|
| Little to No Loss | Up to 25 dBHL |
| Mild Loss | 26 – 40 dBHL |
| Moderate Loss | 41 – 60 dBHL |
| Severe Loss | 61 – 80 dBHL |
| Profound Loss | Above 80 dBHL |

- **NOTE:** The Hearing Test Feature has an upper measurement limit of 85 dBHL. If your hearing loss exceeds the limits of the test and you would like to better understand your hearing loss, you should consult with a hearing healthcare professional
- **NOTE**: It is recommended that you take a new hearing test every 12 months to assess your hearing

## SAFETY AND PERFORMANCE

The Hearing Test Feature was validated in a clinical study with 202 subjects aged 18 years or older across the spectrum of hearing loss classifications. The study measured the subject's hearing using the Hearing Test Feature against a traditional reference pure tone audiometry test conducted by an audiologist. The enrolled subjects contained a representative distribution across each of the following categories: Little to no loss (Up to 25 dBHL), Mild Loss (26–40 dBHL), Moderate Loss (41–60 dBHL) and Severe to Profound Loss (61–85 dBHL). Subjects were also enrolled based on specific age and sex targets representative of the intended user population.

Results from the clinical study demonstrate equivalence between the Hearing Test Feature and a professionally-obtained audiogram from an audiologist when using the reference pure tone audiometry test. Comparing the results of all available audiograms showed that the estimated median absolute deviation (MAD) of the 4PTA and eight frequency pure tone average (8PTA) values between the Hearing Test Feature and reference tests was 1.81 dbHL (95% CI: 1.49, 2.30) and 1.75 dBHL (95% CI: 1.59, 1.92), respectively. Further, the overall per cent agreement in the hearing loss classification of the subject's best ear between the two groups were 86.4% for the identical classification and 100% within +/-1 classification.

No device-related adverse events were reported in the study.
The study was conducted with no protocol deviations or missing data that would impact the results. Overall, the clinical study provides reasonable assurance of safety and effectiveness for the Hearing Test Feature.

## CLINICAL BENEFIT (EU)

The Hearing Test Feature's intended clinical benefits include profiling hearing ability and producing an audiogram without the assistance of a hearing healthcare professional.

## BATTERIES AND CHARGING YOUR AIRPODS PRO 2

The Hearing Test Feature is compatible with AirPods Pro 2, which have rechargeable batteries. AirPods Pro are designed to have a battery life of approximately 6 hours on a single charge. The AirPods can be charged in the paired charging case. A quick charge of 5 minutes will provide roughly 1 hour of use, while 1 hour of charge will charge the AirPods completely.

The AirPods Pro 2 will provide an audible sign when the battery is getting low and requires charging. Please ensure that your AirPods Pro have sufficient charge before starting the Hearing Test Feature.

For more instructions on charging your AirPods Pro and the AirPods Pro case, please visit **https://support.apple.com/guide/airpods/devde25a4bbe/web**.

## TROUBLESHOOTING

If you experience difficulties in operating the Hearing Test Feature, refer to the troubleshooting guide below for a list of solutions.

**Problem**: The Hearing Test Feature won't let me proceed past Setup or the test keeps pausing

**Solution:**

- If the initial check identifies any problems with your AirPods Pro 2, please visit **https://support.apple.com/120991**
- Try rotating the AirPods to ensure that they are in the proper orientation (i.e. with the stems facing downwards until you get a snug fit)
- You need a quiet room for the Hearing Test Feature. Your environment may be too loud. To continue, wait for the noise to stop, try to find a different location that is quieter or take the test at a quieter time

**Problem**: The Hearing Test Feature tells me that the AirPods have a poor fit

**Solution:**

- Try rotating the AirPods to ensure that they are in the proper orientation (i.e. with the stems facing downwards until you get a snug fit)
- Try changing the ear tip to a different size. Your AirPods Pro 2 comes with different sizes of ear tips (XS, S, M, L) in the box

**Problem**: The Hearing Test Feature did not provide me with a result

**Solution:**

- You need a quiet room for the Hearing Test Feature. Your environment may be too loud. To continue, wait for the noise to stop, try to find a different location that is quieter or take the test at a quieter time
- The Hearing Test Feature may not have been able to generate your results based on your tapping pattern (e.g. delayed taps, inconsistent taps, multiple taps). Please tap as soon as you have heard a tone

## TECHNICAL SPECIFICATION

| | |
|---|---|
| Device Requirement | AirPods Pro 2 or later, excluding AirPods<br>iPhone Xs or later<br>iPad Pro (M4), iPad Pro 12.9-inch (3rd generation and later), iPad Pro 11-inch (1st generation and later), iPad Air (M2), iPad Air (3rd generation and later), iPad (7th generation and later) and iPad mini (5th generation and later) |
| Type and Class of Audiometer | Type 4, Air-Conduction |
| Stimulus Type | Pulsed tone |
| Test Frequency Range | 250 – 8000 Hz |
| Test Volume Range | 10 to 85 dBHL |
| Distortion | <2.5% THD Maximum |
| Response time window | ~2 – 3 seconds |

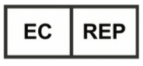
| Frequency (Hz) | RETSPL (dB SPL)1 | Mean Attenuation (dB)2 |
|---|---|---|
| 125 | – | 18.9 |
| 250 | 23.0 | 16.6 |
| 500 | 12.4 | 17.0 |
| 1000 | 8.7 | 19.5 |
| 2000 | 13.6 | 25.1 |
| 4000 | 12.2 | 23.7 |
| 8000 | 16.0 | 22.6 |

1. RETSPL values per ANSI ASA S3.6-2018 ‘American National Standard for Specification for Audiometers’
2. Mean Attenuation values per ISO 4869-1:2018 ‘Acoustics — Hearing protectors Part 1: Subjective method for the measurement of sound attenuation’

## EQUIPMENT SYMBOLS

Manufacturer

Read instructions before use



European Authorised Representative

Medical Device

099-46218 Revision C, September 2024, en_GB

Hearing Test Feature

Instructions for Use

Apple Inc.
One Apple Park Way
Cupertino, CA 95014, USA
United States
www.apple.com

EC REP Apple Distribution International
Hollyhill Industrial Estate,
Hollyhill, Cork,
Ireland
**Contact:** medicalcompliance@group.apple.com

CE 0123

## Documents / Resources

| | |
|---|---|
| | Apple Apple Hearing Test Feature [pdf] Instructions<br>Apple Hearing Test Feature, Hearing Test Feature, Test Feature, Feature |

## References

- Apple
- Apple
- Apple
- Take a Hearing Test with AirPods Pro 2 - Apple Support
- Charge AirPods, AirPods Pro, or AirPods Max – Apple Support (AU)
- Choose your AirPods Pro ear tips and use the Ear Tip Fit Test - Apple Support
- Connect your AirPods and AirPods Pro to your iPhone - Apple Support
- AirPods Pro 2 - Hearing Health Feature Availability - Apple (UK)
- User Manual

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