Hearing Aid Feature

Instructions for Use

Apple Inc.
One Apple Park Way
Cupertino, CA 95014, US
Australia
www.apple.com

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

CE 0123

INDICATIONS FOR USE

The Hearing Aid Feature is a software-only mobile medical application that is intended to be used with compatible wearable electronic products. The feature is intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. The Hearing Aid Feature utilises a self-fitting strategy and is adjusted by the user to meet their hearing needs without the assistance of a hearing healthcare professional. The device is intended for Over-the-Counter use.

(EU)

INTENDED PURPOSE

The Hearing Aid Feature is a software-only mobile medical application that is intended to be used with compatible wearable electronic products. The feature is intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. The Hearing Aid Feature utilises a self-fitting strategy and is adjusted by the user to meet their hearing needs without the assistance of a hearing healthcare professional. The device is intended for Over-the-Counter use.

Target Population and Intended Users

The feature is indicated to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment.

PRECAUTIONS AND WARNINGS

- **WARNING: If you are younger than 18 years old, DO NOT use this.**
    - You should go to a doctor, preferably an ear, nose and throat doctor (an ENT), because your condition needs specialised care. Over-the-counter hearing aids are only for users who are aged 18 years or older
- **The Hearing Aid Feature is for adults with signs of mild to moderate hearing loss. How do you know if you have this?**
    - You have trouble hearing speech in noisy places
    - You find it hard to follow speech in groups
    - You have trouble hearing on the phone
    - Listening makes you tired
    - You need to turn up the volume on the TV or radio, and other people complain it's too loud
- **Some people with hearing loss may need help from a hearing healthcare professional even after using this Hearing Aid Feature. How do you know if you need to see one?**
    - You can't hear speech even if the room is quiet
    - You don't hear loud sounds well — for example, you don't hear loud music, power tools, engines or other very noisy things
    - If this hearing aid does not help you enough, ask for help from a hearing healthcare professional
- **WARNING: When to See a Doctor**
    - If you have any of the problems listed below, please see a doctor, preferably an ear, nose and throat doctor (an ENT)
        - Your ear has a birth defect or an unusual shape. Your ear was injured or deformed in an accident
        - 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 you think something could be in your ear
- You get really dizzy or have a feeling of spinning or swaying (called vertigo)
- Your hearing changed suddenly in the past 6 months
- Your hearing changes: it gets worse, then gets better again
- You have worse hearing in one ear
- You hear ringing or buzzing in only one ear

- **Caution: The Hearing Aid Feature is not hearing protection.**
  - If you're in a loud place or experience overly loud sounds, whether short or long lasting, you should use the right kind of hearing protection. Apple has a separate Hearing Protection feature that is on by default on AirPods Pro 2 when paired with a compatible iPhone, iPad or Mac. See support.apple.com/120850 for total attenuation and more information.

- **CAUTION: The sound output should not be uncomfortable or painful**
  - You should turn down the volume or remove the AirPods Pro 2 if the sound output is uncomfortably loud or painful. If you consistently need to turn the volume down, you may need to further adjust the Hearing Aid Feature settings.

- **If you remain concerned, consult a professional**
  - If you try the Hearing Aid Feature and continue to struggle with or remain concerned about your hearing, you should consult with a hearing healthcare professional.

- **What you might expect when you start using Apple's Hearing Aid Feature**
  - A hearing aid can benefit many people with hearing loss. However, you should know it will not restore normal hearing, and you may still have some difficulty hearing over noise. Further, a hearing aid will not prevent or improve a medical condition that causes hearing loss.
  - People who start using hearing aids sometimes need a few weeks to get used to them. Similarly, many people find that training or counselling can help them get more out of their devices.

- If you have hearing loss in both ears, you might get more out of using hearing aids in both, especially in situations that make you tired from listening — for example, noisy environments.

- **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 Aid Mode' 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.**

- **Tell FDA about injuries, malfunctions or other adverse events**

  - To report a problem involving the Hearing Aid Feature, you should submit information to FDA as soon as possible after the problem. FDA calls them "adverse events", and they might include: suddenly worsening hearing loss from using the Hearing Aid Feature.

  - If problems occur with the AirPods (i.e. skin irritation in your ear or injury from the device, like cuts or scratches, or burns from an overheated battery, or pieces of the device getting stuck in your ear), or any other concern with the Hearing Aid Feature, please contact AppleCare at 1-800-275-2273 or https://support.apple.com/106932.

  - For any concerns with the Hearing Aid Feature, you can also submit information to FDA as soon as possible after the problem. Instructions for reporting are available at https://www.fda.gov/Safety/MedWatch, or call 1-800-FDA-1088 in the US.

- **EU**

  - This is a notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

  -

Contraindications

There are no known contraindications associated with use of the Hearing Aid Feature. Please refer to the warnings and precautions for further information.

SECURITY: Apple recommends that you add a passcode (personal identification number [PIN]), Face ID or Touch ID (fingerprint) to your iOS device (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.

USING THE HEARING AID FEATURE

The Hearing Aid Feature is compatible with other Apple Features, such as Conversation Boost, Loud Sound Reduction and more.

Set-Up/On-boarding

- The Hearing Aid 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/au/airpods-pro/feature-availability/

- Update iPhone/iPad and AirPods Pro 2 to latest iOS and Firmware

- Make sure your AirPods Pro 2 is paired to your iPhone/iPad

    - For more information on pairing your AirPods Pro 2 to your iPhone, please visit https://support.apple.com/HT207010

- Insert the AirPods Pro 2 into your ears

- Open Settings → [Name]'s AirPods Pro 2 → Under Hearing Health, tap Hearing Assistance → Set Up Hearing Aid Mode

- Follow the on-screen instructions

    - Confirm that you are at least 18 years old

        - **NOTE:** This OTC hearing aid is for users who aged 18 years and older. People who are younger than 18 years old with hearing loss should see a doctor, preferably an ENT, because they may need medical testing and management. Hearing loss can affect speech and learning, so professional fitting and continuing care are also important.

    - Choose a hearing test result (i.e. audiogram) to use to set up your Hearing Aid Feature

        - Any compatible audiograms saved in the Health app on your iOS device can be used to set up the Hearing Aid Feature

        - **NOTE**: Compatible audiograms must contain results at 250, 500, 1000, 2000, 4000 and 8000 Hz. Results at 3000 and 6000 Hz are optional.

        - **NOTE:** The Hearing Aid Feature is only intended for users with perceived mild to moderate hearing loss. If you have hearing loss that exceeds the moderate hearing loss category, the Hearing Aid Feature may not provide sufficient amplification.

- **NOTE:** To receive the best experience when using the Hearing Aid Feature, select an audiogram from a reliable source (such as from a hearing healthcare professional) and make sure that the audiogram reflects your current hearing health. If you are unsure about the source or accuracy of your audiogram or would like a more recent audiogram, you may use the Apple Hearing Test Feature to obtain a clinically validated audiogram.

- You may exit on-boarding at any time by tapping "Cancel".

NOTE: It can take time to adjust to the Hearing Aid Feature. Your hearing will need to adjust to the new sound of your AirPods Pro 2. This is normal and typically takes a few days or weeks. Consistent wear is most important.

NOTE: Once you onboard and set-up your Hearing Aid Feature, your hearing profile will be maintained to the AirPods Pro 2 that you used to set up the feature. You will be able to use your Hearing Aid Feature without your iPhone. DO NOT share your AirPods Pro 2 that has Hearing Aid Feature set up with others.

Fine-Tuning

Fine-Tuning is an important step to achieve your optimal Hearing Aid settings. Fine-Tuning should be conducted after Hearing Aid Set-Up/Onboarding to ensure optimal hearing preferences.

There are three types of adjustments (Amplification, Tone and Balance) that you can make to optimise your hearing preferences. Adjusting all three sliders may be required to achieve the desired hearing preference setting. Descriptions of the three fine-tuning sliders can be found below:

1. Amplification - Makes the sounds you hear louder or quieter

2. Tone - Changes the amount of high and low pitch sounds (e.g. modify the 'brightness' of the sound)

3. Balance - Adjusts the ratio of sound level between the left and right AirPods Pro 2 buds

You are able to adjust the fine-tuning settings anytime on your compatible iPhone, iPad, MacBook or Apple Watch.

NOTE: Only the amplification slider is available on the Apple Watch. You will need to use one of the other compatible devices to change the other fine-tuning settings.

Fine tuning can be performed on your iPhone, iPad or MacBook by:

- Open Settings → [Name]'s AirPods Pro 2 → Under Hearing Health, tap Hearing Assistance → Adjustment Settings

- Adjust sliders to your hearing preference

Fine-tuning settings can also be adjusted via Control Centre.

Default Setting

- Open Settings → [Name]'s AirPods Pro 2 → Under Hearing Health, tap Hearing Assistance → Adjustment Settings → Reset All

- Your tuning is returned to original setting (i.e. sliders are returned to middle)

Update Tuning

- Open Settings → [Name]'s AirPods Pro 2 → Under Hearing Health, tap Hearing Assistance→ Update Hearing Test Results

- You will be prompted to choose a new audiogram

- After setting up the Hearing Aid Feature with the new audiogram, it is recommended to perform fine-tuning to find the settings optimal for you

How to enable and disable your Hearing Aid Feature

- Open Settings → [Name]'s AirPods Pro 2 → Under Hearing Health, tap Hearing Assistance

- Toggle Hearing Aid Mode on or off

- The Hearing Aid Mode Toggle is only available after set-up

Using the Noise Control Modes with the Hearing Aid Feature

- In order to make the Hearing Aid Feature active, the Hearing Aid Feature must first be enabled

- Afterwards, the Hearing Aid Feature is only active when the Noise Control Mode has been set to 'Transparency' mode

    - When the Noise Control mode is set to 'Off', 'Adaptive' or 'Noise Cancellation', the Hearing Aid Feature can remain enabled but will not be active. While in 'Adaptive' and 'Noise Cancellation', users will be able to use these modes as expected without HAF active.

NOTE: Apple's Hearing Protection feature is compatible with the Hearing Aid Feature in 'Transparency' mode and is on by default. You will not receive the Hearing Protection feature benefits if the Hearing Protection feature is off or if the battery is not charged. See support.apple.com/120850 for total attenuation and more information regarding the Hearing Protection feature.

BATTERIES AND CHARGING AIRPODS PRO 2

The Hearing Aid Feature is compatible with AirPods Pro 2, which have rechargeable batteries. AirPods Pro 2 are designed to have a battery life of approximately 6 hours on a single charge for the Hearing Aid Feature. AirPods Pro 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 Pro completely. Battery life depends on device settings, environment, usage and many other factors.

- **NOTE:** It is recommended that you fully charge your AirPods Pro 2 before extended use. Short periods of quick charge can help keep the Hearing Aid Feature available to you when you need it throughout the day. For example, placing AirPods Pro 2 in the case when showering, when sleeping, or during parts of the day when you are not using AirPods Pro 2.

AirPods Pro 2 will provide an audible sign when the battery is getting low and requires charging.

For more instructions on charging your AirPods Pro 2 and AirPods Pro 2 case, please visit https://support.apple.com/guide/airpods/charge-airpods-pro-dev65b83ea7b/web.

SAFETY AND PERFORMANCE

The Hearing Aid Feature (HAF) was validated in a clinical study with 118 subjects aged 18 years or older, with perceived mild to moderate hearing impairment, over a 31-day period. The study measured the user-perceived benefit, per the International Outcome Inventory for Hearing Aids (IOI-HA) survey, between subjects who were Self-Fit (SF) using the HAF fitting strategy against participants Professionally-Fit (PF) by an audiologist following the National Acoustic Laboratories Non-Linear 2nd edition (NAL-NL2) fitting procedures. The study enrolled subjects across the spectrum of hearing loss classifications, based upon the four-frequency pure tone average (4PTA), which is the average of the hearing thresholds at 0.5, 1, 2 and 4 kHz. The enrolled subjects contained a representative distribution across each of the following categories: No Impairment/Perceived Hearing Loss (4PTA: 15-25 dB HL), Mild Hearing Loss (4PTA: 26-40 dB HL), and Moderate Hearing Loss (4PTA: 41-60 dB HL). Subjects were also enrolled based on specific age and sex targets, representative of the intended patient population.

The results from the clinical study demonstrate that users who self-tuned the HAF were able to achieve the same perceived benefit compared with users who had their settings tuned by a professional audiologist. The mean IOI-HA total scores for the SF and PF cohorts were 25.5 (SD=3.03) and 26.6 (SD=3.63), respectively. The mean difference (defined as PF – SF) between the two cohorts was 1.17 (SD=3.343), with the 95% confidence interval of the mean difference being (-0.05, 2.39) and the p-value for the non-inferiority test being 0.0036. Thus, the null hypothesis was rejected, and the SF group was found to be non-inferior to the PF group. Subgroup analyses indicated that the IOI-HA scores were consistent for both the SF and PF groups across hearing

classification, age, sex and race. Additional objective measures (Speech-in-Noise (QuickSIN) and Real Ear Measures (REM)) were also collected to assess objective changes in amplification between the SF and PF groups. The QuickSIN results demonstrated that there was no difference in speech intelligibility performance between the SF and PF group. In line with the finding of non-inferior IOI-HA scores between groups, REM results demonstrated no substantive differences in gain trends across the 3 conditions measured (speech at 50, 65 and 80 dB SPL).

No device-related adverse events were reported in the study. Only 1 subject (1/118, 0.8% of total subjects) in the PF group experienced two non-device related adverse events that were evaluated to be unrelated to the study or device. Both events were considered serious adverse events (SAEs) as the subject experienced chest pain and pain in the extremity, which resulted in hospitalisation. However, the SAEs were determined to not be related to the study procedures or the device.

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 HAF.

CLINICAL BENEFIT (EU)

The Hearing Aid Feature's intended clinical benefits includes amplification of sound for perceived mild to moderate hearing impairment for individuals 18 years of age or older.

TROUBLESHOOTING

If you experience difficulties in operating your Hearing Aid Feature, refer to the troubleshooting guide below.

Problem: I cannot hear well even with the Hearing Aid Feature turned on.

Solution:

- Make sure that you are using the AirPods Pro 2 that you used to set up the Hearing Aid Feature
- Make sure the Noise Control Mode is set to 'Transparency'
- Adjust Hearing Aid Feature settings using Fine-Tune adjustments. Please see Fine-Tuning section above for instructions for how to access the Fine-Tuning settings
- Make sure you use the best ear tip size. Your ear tips should make a good seal with your ear canal. When the fit is right, you experience better sound. For instructions on choosing the best ear tips, please visit https://support.apple.com/HT210633

- Ensure you are not experiencing any of the symptoms listed in the “Precautions and Warnings” section

- Ensure that the hearing test result you use to set up the Hearing Aid Feature reflects your latest hearing ability. It is recommended that you use a hearing test result from within the last 12 months to set up the Hearing Aid Feature

- Ensure that your audiogram is from a reliable source (e.g. obtained from an audiologist or the Apple Hearing Test Feature)

- If you uploaded an audiogram manually, ensure that you have entered the values correctly. The correct audiogram values are necessary to ensure that the Hearing Aid Feature is set up to meet your specific hearing needs

- Your ear will need to adjust to the new hearing profile of your AirPods Pro 2. This is normal and typically takes a a few weeks of consistent wear

- If the problem does not resolve after a few weeks of consistent wear, seek consultation from an ENT specialist. You may have hearing loss that cannot be adequately treated by this feature

Problem: The sound is too loud and it hurts my ears.

Solution:

- Adjust Hearing Aid Feature settings using Fine-Tuning Adjustments

- If sound continues to be too loud after adjustments, consider turning off the Hearing Aid Feature. The Hearing Aid Feature is intended for individuals with perceived mild to moderate hearing loss. You may not have hearing loss and may not benefit from this feature

Problem: I hear whistling or squealing when I use the Hearing Aid Feature

Solution:

- Try repositioning the AirPods so that the AirPods are seated comfortably and securely

- Make sure you use the best ear tip size. Your ear tips should make a good seal with your ear canal. When the fit is right, you experience better sound. For instructions on choosing the best ear tips, please visit https://support.apple.com/HT210633

- Adjust Hearing Aid Feature settings using Fine-Tune adjustments. Please see Fine-Tuning section above for instructions for how to access the Fine-Tuning settings

TECHNICAL SPECIFICATION

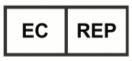
The Hearing Aid Feature was shown to perform at or better than the following technical specifications associated with Over-the-Counter Hearing Aids (21 CFR 800.30).

Device Compatibility Requirement	AirPods Pro 2, excluding AirPods iPhone Xs or later 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)
	Availability to Adjust Settings MacBook Air (2020 and later), MacBook Pro (2018 and later), iMac (2019 and later), iMac Pro (2017 and later), Mac mini (2018 and later), Mac Studio (2022 and later) and Mac Pro (2019 and later) Apple Watch Series 6 and later, all Apple Watch Ultra models, Apple Watch SE (2nd generation)
Maximum Output Limit Value (Output Sound Pressure Level 90 (OSPL90))	106 dB SPL
Full-On Gain (FOG50)	27 dB
Total Harmonic Distortion Value (500 Hz, 800 Hz, 1600 Hz)	<1%
Self-Generated Noise Value	28 dBA
Latency Value	3.15 ms
Frequency Response Bandwidth	100 - 10,000 Hz

EQUIPMENT SYMBOLS

Manufacturer

Read instructions before use



European Authorised Representative

Medical Device

_____

099-42809 Revision E, October 2024, en_AU