

Self-Fitting Hearing Devices

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Audiology Australia (AudA) supports the provision of hearing devices for all clients that have been diagnosed, through appropriate clinical consultation, as benefiting from the assistance of a hearing device. As the peak body for the health profession of audiology, AudA acknowledges that some clients may be interested in self-fitting hearing devices as a solution to managing their hearing loss or perceived hearing difficulty.

This guide has been developed to assist clients who are interested in self-fitting hearing devices with understanding some of the challenges associated with purchasing, fitting and adjusting a self-fitting hearing device. In all cases, AudA recommends the involvement of an accredited audiologist in the diagnosis of hearing loss or a self-perceived hearing difficulty, and in the support of clients, either face-to-face or through teleaudiology, with the adjustment of their preferred hearing device.

What are Self-Fitting Hearing Devices?

Self-fitting hearing devices are sound amplification devices which are designed to not require the devices to be fitted by a hearing health professional. Self-fitting hearing devices include personal sound amplification products (PSAPs) and hearing aids that allow individuals to 'self fit' the devices to their ears. Individuals with self-fitting hearing devices are generally able to select their own amplification parameters without the assistance of a hearing health professional. Self-fitting hearing devices may also be referred to as over the counter (OTC) hearing devices or direct to consumer hearing devices.

It is important to note that there is a difference between hearing aids and PSAPs. PSAPs, unlike hearing aids, are not intended to be used to compensate for hearing loss. PSAPs are generally intended to be used for people with normal hearing who may want to amplify sounds in certain environments, such as to watch television without disturbing people nearby. PSAPs are not considered to be medical devices and are not regulated by the Therapeutic Goods Administration (TGA).

Hearing aids, on the other hand, are devices that are used to compensate or to help manage the consequences of hearing loss. In Australia, hearing aids are regulated as medical devices by the TGA. Refer to *Hearing Aids are Medical Devices* section below.

Hearing Aids are Medical Devices

Hearing aids are complex medical devices used to help manage the consequences of hearing loss.* Hearing aids are adjusted to suit an individual's unique hearing needs to ensure that the best hearing results are obtained.

In Australia, hearing aids are registered medical devices listed on the Australian Register of Therapeutic Goods (ARTG). These medical devices are assessed by the TGA for quality and performance and must go through an evaluation process to ensure they meet the required standard for a hearing aid prior to being supplied in Australia.

It is important to note that hearing aids imported by individuals for personal use may not necessarily be regulated by the TGA. Overseas purchased hearing devices that are not imported or exported by Australia

*AudA is aware of a new and emerging category of wearable technology known as hearables. Hearables is a broad term used to describe electronic technologies that are incorporated into devices or accessories worn by individuals in or on the ear (Ear Science Institute Australia). Under this definition, hearing aids may potentially be categorised as a hearable. However, it is important to note that unlike hearing aids, not all hearables are designed with the main purpose of addressing hearing loss and/or to custom fit to an individual's hearing needs.

and/or manufactured or supplied within Australia will not be listed on the ARTG and may also not be eligible for service and repair under warranty.

Self-Fitting Hearing Aids

Self-fitting hearing aids are devices intended to be used by people with a self-perceived mild to moderate hearing loss to help them in the management of their perceived hearing loss without direct assistance of a hearing health professional.

As self-fitting hearing aids allow you to 'self-fit' the hearing device to your ears, you will generally rely on your own judgement in regard to estimating your hearing difficulty and in selecting the amplification parameters of the hearing aid. However, for an accurate assessment of your hearing ability, AudA recommends the involvement of an accredited audiologist who can offer a comprehensive hearing assessment and provide advice on whether a self-fitting hearing aid can meet your hearing needs.

An accredited audiologist can also provide expert advice on how you can protect your hearing over the long term. They can identify alternative options that may be more appropriate for your hearing needs, such as assistive listening devices. Audiologists can recommend auditory training exercises and communication strategies to supplement the use of your hearing device.

If you are considering how to self-identify mild to moderate hearing loss, the American Academy of Audiology has provided the following questions which you can ask yourself to help determine whether you might have a mild to moderate hearing loss condition:

1. *Are you able to hear easily in quiet, one-to-one situations?*
2. *Are there are few difficult listening situations where you think you would want to wear hearing aids as opposed to feeling like you would need it in most communication situations?*
3. *Does turning up the volume on the phone or TV just slightly help you hear better (this level might be considered a little loud by others but not extremely loud as opposed to needing to turn these devices up quite a bit to a level that bothers others)?*

If you answered yes to the above questions, you may have mild to moderate hearing loss which a self-fitting hearing aid might be able to address. However, as not all hearing loss is the same, AudA recommends that the best way to know whether a self-fitting hearing aid is suitable for your hearing needs will be to see an accredited audiologist for an accurate diagnosis of your hearing loss condition.

Self-fitting hearing aids are not an effective and appropriate management option for individuals with moderate to severe hearing loss. AudA strongly recommends that you consult with an audiologist or medical practitioner before purchasing a self-fitting hearing aid if you have any of the following conditions, including:

- deformity of the ear
- vertigo or severe dizziness
- sudden loss or rapid deterioration of hearing
- hearing loss with additional symptoms or signs (i.e., altered sensation, facial droop etc.,)
- persistent pain or discomfort in the ear
- tinnitus (ringing) that occurs in one ear only and/or has significantly changed in nature
- fluid, pus or blood coming from the ear

It is important to note that the use of a self-fitting hearing aid when it is not necessarily the most effective and appropriate management option for you may make your long-term hearing health outcomes worse. It can result in additional noise injury through improper amplification and in the delay in seeking an accurate diagnosis to ascertain the underlying cause of a hearing loss condition. As such, AudA recommends the involvement of an accredited audiologist for an accurate diagnosis of a hearing loss condition.

How Are Self-Fitting Hearing Aids Supplied in Australia?

Self-fitting hearing aids are a new category of hearing aids emerging on the market. In the US, recent regulatory changes regarding the supply of over the counter (OTC) hearing aids have been introduced, which will likely influence how self-fitting hearing aids will be supplied in Australia.

In August 2022, the US Food and Drug Administration (FDA) approved for certain OTC hearing aids to be made available to American consumers for direct purchase in-store or at online retailers, without the need for a medical exam, prescription, or a fitting appointment by an accredited audiologist. This new category of OTC hearing aids is intended for people 18 years and over who have a self-perceived mild to moderate hearing impairment. Under these new changes, it is anticipated that the new category of OTC hearing aids will become available for direct consumer purchase at US retailers and online by mid October 2022.

The FDA's decision to approve a new category of OTC hearing aids for direct purchase by consumers without the involvement of an accredited audiologist aims to lower the cost barrier of purchasing hearing aids and improve their accessibility to people with a self-perceived mild to moderate hearing loss. It also aims to foster innovation and competition in the hearing aid technology market and recognises the substantial technology gains that have been made over the years which supports the safe use of hearing aids without the involvement of a hearing health professional. Further information on the recent FDA approval of the new category of OTC hearing aids can be viewed [here](#) and [here](#).

In Australia, the TGA regulates the sale of hearing aids for safety, quality and performance. In light of the new regulatory class of OTC hearing aids in the US, it is likely that the TGA will be reviewing its current hearing aid regulations to decide if a similar regulatory approach will be taken in the supply of self-fitting hearing aids in Australia.

If the TGA decides to approve for the regulation of a separate category of hearing aids that can be purchased over the counter without the involvement of a hearing health professional, the OTC hearing aids will be subject to TGA regulatory requirements for safety, quality and performance, and listed on the ARTG as medical devices. The listing of OTC hearing aids on the ARTG will help individuals to ascertain which OTC hearing devices are specifically designed for hearing loss and separate these products from PSAPs, which are not regulated by the TGA and generally not intended for hearing loss.

If the TGA does not decide to approve for the regulation of OTC hearing aids, individuals in Australia will still be able to purchase and/or import the OTC hearing aids developed for the US market for personal use, either online or through a local supplier. However, without TGA approval, OTC hearing aids will not be marketed in Australia as medical devices specifically designed for hearing loss. This will likely make it harder for individuals to ascertain on their own which are safe and effective OTC products for hearing loss.

➤ Refer to: [Changes in US hearing aid regulations: possible benefits and risks to Australia](#)

Self-Fitting Personal Sound Amplification Products

PSAPs are small lower cost electronic sound amplifiers which can look similar to hearing aids. They contain a microphone, receiver and amplifier to provide amplification of sounds, and can vary greatly in their quality and effectiveness. However, unlike hearing aids, most PSAPs amplify all sounds in the environment and generally cannot be programmed to amplify or mute certain sounds. PSAPs are intended to be used by people with normal hearing who may want to amplify sounds that are at low volume or at a distance. They are not generally intended to be used for the management of hearing loss.

PSAPs are typically a one-size-fits-all standard device that are not custom programmed by a hearing health professional to be tailored to your hearing needs. However, more advanced PSAP devices may be available on the market that allows an individual to 'self-fit' a PSAP device to their ears through the selection of amplification parameters without requiring the involvement of a hearing health professional.

The Australian Government advises that PSAPs should only be purchased if an individual has been assessed by a hearing health professional as not having a hearing loss condition. PSAPs can potentially make a hearing loss condition worse due to the overamplification of sounds. A delay in the diagnosis of hearing loss can also potentially worsen the long-term hearing health outcomes of an individual due to the delay in receiving appropriate treatment addressing the underlying cause of the hearing loss condition.

How Are Self-Fitting Personal Sound Amplification Products Supplied in Australia?

In Australia, PSAPs are not considered to be medical devices specifically designed for the purpose of hearing loss. They are therefore not regulated by the TGA. The Australian Government notes that it does not appear that PSAPs are generally being supplied in Australia, however, the products may be commonly advertised for purchase via online retailers and overseas suppliers.

Online retailers and overseas suppliers that conduct business within Australia must comply with the Australian Consumer Law (ACL). Under the ACL, businesses are required to provide consumer guarantees for most consumer goods and services they sell. Learn more about your consumer rights [here](#) and the requirements that online businesses selling goods and services must meet [here](#).

It is important to note that the ACL does not apply to overseas retailers and suppliers that do not sell goods or services to Australia. Individuals who purchase consumer goods overseas from a seller that does not conduct business in Australia will not be protected under the ACL. However, you may be able to engage with the consumer protection agency in the country that the seller is based to resolve any issues that arise.

- Refer to: Australian Government Hearing Services Program, [Hearing aids and personal sound amplifiers: what is the difference?](#)
- Refer to: Australian Competition and Consumer Commission, [Shopping online](#)

Role of the Audiologist in Protecting Hearing Health

Audiologists are tertiary educated hearing health professionals with specialised knowledge and skills in ear and hearing health care. Audiologists work with clients across the lifespan to help them to preserve, manage and improve their hearing, their ability to process and understand sounds, and their balance.

Audiologists are highly skilled and must complete at least five years of study at university. This includes completing the equivalent of an Australian University Master-level degree in Clinical Audiology. Audiologists who are certified as an Audiology Australia Accredited Audiologist must also complete a full-time, one-year clinical internship program after their university studies.

Audiologists are trained to deliver a wide range of hearing services and supports. They can perform advanced diagnostic audiology tests and provide tailored counselling and communication strategies to ensure that you are able to achieve the best hearing for most listening situations. This counselling may involve assisting you to get the most from your hearing device and ensuring that you obtain the amplification outcomes which best suit your circumstances. Quality sound amplification can be best achieved through a hearing device that is professionally fitted to your ear by a trained and accredited audiologist.

Considerations for Purchasing a Self-Fitting Hearing Device

Self-fitting hearing devices may be an attractive solution for the management of your hearing loss or self-perceived hearing difficulty, or to amplify environmental sounds in certain situations. In particular, self-fitting hearing aids can be a cost-effective solution to treating mild to moderate hearing loss and increase the accessibility of hearing health care for individuals. However, it is important to be aware of a couple of things when considering the purchase of a self-fitting hearing device.

Has an audiologist been involved in your decision to purchase the self-fitting hearing device?

To safeguard your long-term hearing health, it is important that an audiologist is involved in the assessment of your hearing ability prior to the purchase of a self-fitting hearing device. It is important to know that a hearing loss condition may be caused by a variety of factors, and – based on medical advice – may be better treated through surgery. If that is the case, purchasing a self-fitting hearing aid might not be the best solution for your particular clinical needs. Trained and accredited audiologists possess the skills necessary to evaluate your hearing ability, accurately diagnose the cause of a hearing loss condition and make the most suitable recommendations for treatment. This includes identifying alternative options that may be more appropriate for your hearing needs.

Additionally, the use of a self-fitting hearing device when it is not necessarily required may result in additional noise injury through improper amplification. In these circumstances, the use of a self-fitting hearing device may actually make your long-term hearing health worse.

Are you comfortable with the process of fitting and adjusting your self-fitting hearing device?

Self-fitting hearing devices require a certain level of comfort following unfamiliar instructions and may require access to hardware such as a proprietary interface, computer, smartphone or tablet. Most people have never self-administered a hearing test before and the process of fitting and adjusting a hearing device can require some fine tuning. It is important that you feel comfortable with the instructions for selecting and fitting your chosen device. If you do not feel comfortable, it is advised that you seek the assistance of an audiologist to help measure your hearing and guide you through the process of fitting your preferred hearing device. This assistance can be provided either face-to-face or through a teleaudiology consultation, depending on your chosen hearing health care provider.

While some clients may successfully measure their own hearing and adjust their devices, research suggests that some participants using a self-fitting hearing device will struggle to adjust their device appropriately (Humes et al. 2017).

Research further suggests that clients are likely to require support with some aspect of the self-fitting task but an untrained person, such as the spouse of a hearing device user, may not have the skills to support the required tasks, reducing the chances of a successfully fitted hearing device. If you are not confident with how to use a smart phone application or have any kind of cognitive impairment or dexterity difficulties, we recommend that you seek the advice of a trained and accredited audiologist to ensure the best performance outcomes for your hearing device.

Have you researched your self-fitting hearing device?

Self-fitting hearing devices may be a less expensive option, but it is important that you research the intended purpose and use of your self-fitting hearing device and understand whether the device is best suited to your hearing health needs. In regard to hearing aids, the TGA considers the intended purpose or use of a hearing loss product as it is determined by the manufacturer when deciding whether a product should be regulated as a medical device for supply in Australia. Self-fitting hearing aids which are sold without any information regarding their status with the TGA may not comply with Australian regulations.

An audiologist can advise you on whether a self-fitting hearing device can meet your hearing needs and help you to consider the hearing management option that is most suitable for you. An accurate evaluation of your hearing ability is key to an effective hearing management plan and the best way you can safeguard your long-term hearing health.

Conclusion

AudA understands that self-fitting hearing devices may assist some clients with the self-management of milder hearing loss or with the amplification of sounds in certain situations. The use of self-fitting hearing devices may also represent convenience, autonomy and a financial saving.

However, AudA recommends that anyone seeking to purchase a self-fitting hearing device considers their requirements carefully and ensures that, where they may need support for the fitting and adjustment of their hearing device, they seek the involvement of a qualified hearing health practitioner. To safeguard long term hearing health, AudA strongly recommends that an audiologist is involved in the assessment of hearing ability prior to the purchase of a hearing device, which include self-fitting hearing devices.

AudA further encourages clients to take action to ensure that the products they are purchasing are done so through a reputable supplier after they have sought appropriate advice and diagnosis from an accredited audiologist to ascertain that a hearing device is the best support for their individual circumstances.

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