

Hearing Aids and Personal Sound Amplification Products: What to Know

Learn about hearing aids, including OTC hearing aids, and personal sound amplification products.



Español (<https://www.fda.gov/consumers/articulos-en-espanol/los-audifonos-y-los-productos-personales-de-amplificacion-del-sonido-lo-que-debe-saber/>)

简体中文 (<https://www.fda.gov/consumers/consumer-updates/zhutingqiyugerenkuoyinchanpinguanjianxinxi>)

Are you or a loved one having a hard time hearing? Perhaps you considered getting a hearing aid in the past?

Hearing aid technology keeps evolving, which means there's a growing variety of styles and features to consider.

“People who already use a hearing aid know that selecting one is not a simple decision,” says Eric Mann, M.D., Ph.D., Senior Advisor in the U.S. Food and Drug Administration office responsible for hearing aids. “Hearing loss affects people in different ways. So, it's important to choose a hearing aid that's appropriate for your condition and fits your lifestyle.”

The FDA regulates hearing aids to make sure they provide reasonable assurance of safety and effectiveness. If you're considering hearing aids, this article highlights some common technologies and terms you may encounter, including information about the FDA's requirements for hearing aids sold over-the-counter (OTC), which are intended for people 18 years of age and older who have perceived mild to moderate hearing loss.

Hearing Aids and How They Work

People may be born with hearing loss. Or they may develop it later in life — often because the inner ear can wear out as we age or be damaged by years of exposure to loud sounds.

In some cases, hearing loss is temporary and can be restored with medical help. In other cases, it's permanent but can be improved with hearing aids.

[Hearing aids are medical devices \(/medical-devices/consumer-products/hearing-aids\)](#)worn behind or in the ear. They can improve hearing by making sounds louder. However, hearing aids usually won't restore your hearing to normal levels or quality in the way that eyeglasses can often restore vision to 20/20.

Air-conduction vs. bone-conduction hearing aids

Most hearing aids work through air conduction. They bring amplified sound into the ear canal. Sound then moves through the eardrum and three tiny bones in the middle ear to reach the inner ear, where it's processed and sent to the brain.

For people who have problems with their outer or middle ear, those areas can be bypassed with bone-conduction hearing aids. They send sound through the skull to reach the inner ear.

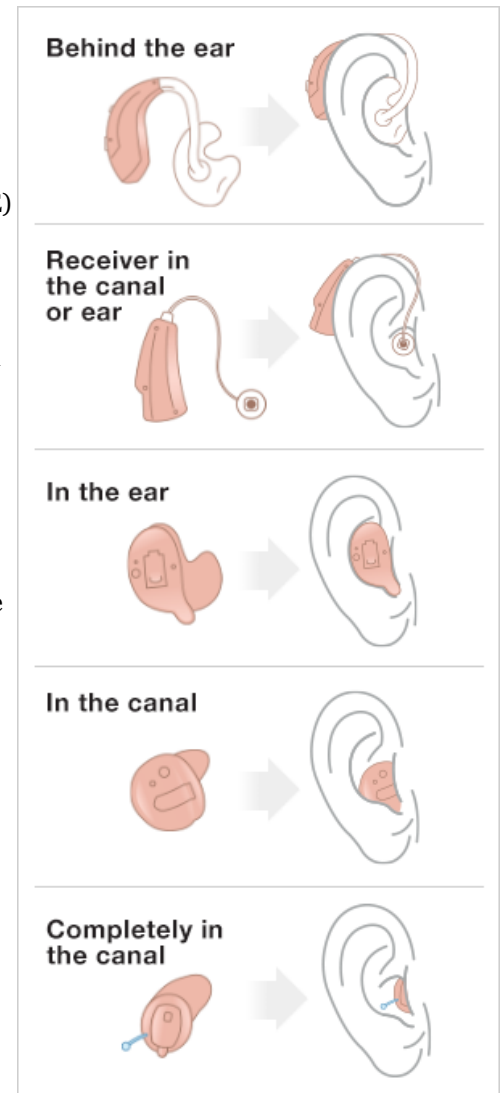
Styles of Hearing Aids

Behind-the-ear (BTE) aids: BTE hearing aids are generally the largest hearing aid style. A plastic case containing most of the electronics sits behind the ear and is connected to an earmold that fits in the ear canal. BTE hearing aids can be used by people of all ages. The style is often chosen for young children because it can be adapted as they grow.

Receiver-in-the-canal (RIC) aids: RIC (or mini receiver-in-the-ear; mini RITE) hearing aids sit behind the ear but are typically smaller than a BTE. The RIC hearing aid is attached to a tube housing a small wire with a dome-shaped tip at the end that rests in the ear canal (in some cases, earmolds are used). The RIC design allows more of the ear canal to remain open and is less visible than the BTE style.

In-the-ear (ITE) aids: This hearing aid sits completely in the outer ear (the “bowl” of the ear). All the hearing aid electronics are housed in a custom-fit shell.

In-the-canal (ITC) aids and completely-in-the-canal (CIC) aids: These are the smallest hearing aids currently available. The electronics are contained in a small custom-fit shell that fits partly or completely into the ear canal. Some people may like them because they are less noticeable while other people may find them harder to handle.



Hearing Aid Features

Today’s hearing aids come with a variety of features. Here are some of the more common ones.

Directional microphones focus on sound from a specific direction. They could help you hear someone in a face-to-face conversation over the noise around you, for example.

Telecoils enable the hearing aid to pick up sound directly from compatible phones or compatible sound systems in public places, such as theaters and houses of worship.

Wireless connectivity such as Bluetooth allows hearing aids to interact with televisions, cellphones, computers or tablets, for example.

Getting Hearing Aids

Medical evaluation for children (younger than 18 years of age)

While hearing loss in adults is often caused by aging or noise exposure, the reasons for hearing loss in children are more varied and may be associated with other medical conditions that should be medically evaluated prior to prescribing hearing aids. OTC hearing aids are not intended for and must not be sold to people younger than 18 years of age. Hearing aids intended for people younger than 18 years of age are prescription hearing aids.

Prescription hearing aids are sold by audiologists; ear, nose, and throat doctors; or sellers licensed to dispense hearing aids, such as instrument specialists.

Over-the-counter (OTC) hearing aids

To broaden access to hearing aids, the FDA established a new category of OTC hearing aids so you will be able to buy one in the store or online without seeing a physician for an exam or an audiologist for help with fitting. The new FDA regulation, which implements a [law from Congress \(/regulatory-information/selected-amendments-fdc-act/fda-reauthorization-act-2017-fdara\)](#), also aims to stimulate competition, providing consumers with improved access to devices that meet their needs and are less expensive than current options.

The OTC final rule applies to certain air-conduction hearing aids intended for people 18 years of age and older who have perceived **mild to moderate hearing loss** (<https://www.cdc.gov/ncbddd/hearingloss/types.html>). A person with mild hearing loss may have difficulty hearing some speech sounds but not others. A person with moderate hearing loss may have increased difficulty hearing some speech sounds, even in a quiet room with someone talking at a normal level.

“We want hearing aids to be more readily available and accessible, especially as our population ages,” Mann explains. “It’s also important for people to recognize that hearing loss could be a sign of an easily treatable problem like built-up earwax or a more serious problem like a benign tumor on the hearing nerve. See a doctor when things don’t feel right, when your hearing loss is progressing, or if you are having associated symptoms like dizziness, ear pain, or drainage from the ear canal.”

Hearing aids vs. personal sound amplification products

You may have seen products in stores or online that are known as personal sound amplification products (PSAPs). These are not alternatives to hearing aids.

While hearing aids and PSAPs both amplify sound for the user, the products have different intended uses. Hearing aids are intended to make up for impaired hearing. PSAPs, in contrast, are intended for people with normal hearing to amplify sounds in certain situations, such as recreational activities like birdwatching or hunting.

Because such PSAPs are regulated as consumer electronics and not medical devices, they may be more variable in terms of product quality compared to hearing aids.

	Over-the-Counter (OTC) Hearing Aids	Prescription Hearing Aids (Any hearing aids that do not meet OTC requirements)	Personal Sound Amplification Products
Type of Product	Medical device Electronic product	Medical device Electronic product	Electronic product
Intended Users	<ul style="list-style-type: none"> • People 18 years and older • For those with perceived mild to moderate hearing loss 	<ul style="list-style-type: none"> • People of any age, including those younger than 18 years • For people with any degree of hearing loss, including severe 	<ul style="list-style-type: none"> • People of any age with normal hearing to amplify sounds in certain environments

Conditions for Sale	<ul style="list-style-type: none"> • Purchaser must be 18 years or older • No medical exam • No prescription • No fitting by audiologist • No need for licensed seller 	<ul style="list-style-type: none"> • Prescription needed • Must purchase from licensed seller in some states 	No applicable FDA requirements regarding conditions for sale
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Additional Resources

- FDA webpage, [Hearing Aids \(/medical-devices/consumer-products/hearing-aids\)](/medical-devices/consumer-products/hearing-aids).
- FDA Consumer Update, [Cochlear Implants: A Different Kind of 'Hearing' \(/consumers/consumer-updates/cochlear-implants-different-kind-hearing\)](/consumers/consumer-updates/cochlear-implants-different-kind-hearing).
- National Institute on Deafness and Other Communications Disorders, [Hearing, Ear Infections and Deafness \(https://www.nidcd.nih.gov/health/hearing-ear-infections-deafness\)](https://www.nidcd.nih.gov/health/hearing-ear-infections-deafness).
- [Establishing Over-the-Counter Hearing Aids - Final Rule \(https://www.federalregister.gov/public-inspection/2022-17230/medical-devices-ear-nose-and-throat-devices-establishing-over-the-counter-hearing-aids\)](https://www.federalregister.gov/public-inspection/2022-17230/medical-devices-ear-nose-and-throat-devices-establishing-over-the-counter-hearing-aids).
- [Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products - Final Guidance for Industry and Food and Drug Administration Staff \(/regulatory-information/search-fda-guidance-documents/regulatory-requirements-hearing-aid-devices-and-personal-sound-amplification-products\)](/regulatory-information/search-fda-guidance-documents/regulatory-requirements-hearing-aid-devices-and-personal-sound-amplification-products).