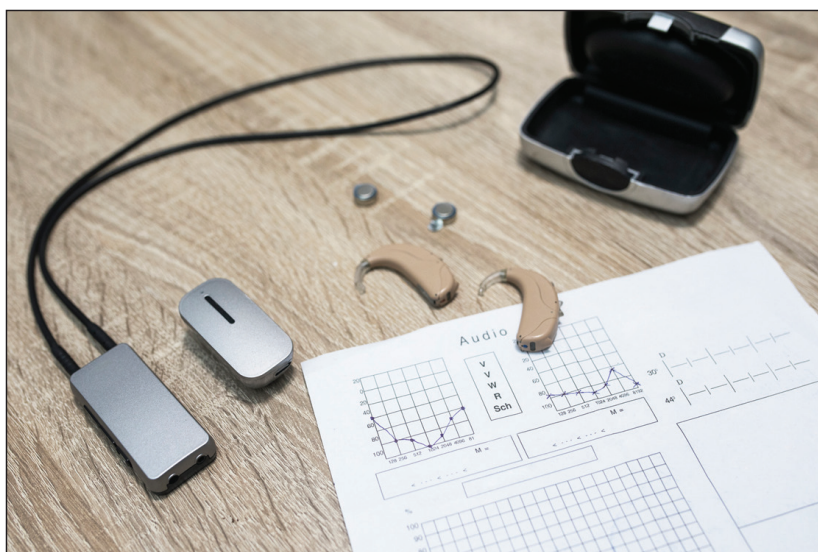


Today's Hearing Technologies: Definitions, Regulations, Overlaps

By Jackie DiFrancesco and Jennifer Tufts, PhD

A hearing aid, a hearing protection device (HPD), and a set of noise-cancelling headphones—it used to be easy to tell the difference between these devices. They looked different from one another, performed distinct functions, and were regulated by different government agencies. Today, the lines between these device types are increasingly blurry. Electronic HPDs incorporate signal-processing features like amplification and compression previously associated with hearing aids only. Hearing aids now offer features often associated with consumer electronics, such as wireless connectivity with smartphones. Other categories of devices have emerged that have features in common with hearing aids and HPDs, including personal sound amplification products (PSAPs) and hearables. Given the growing variety of these devices and the increasing overlap in their designs and capabilities, it can be tricky to distinguish one device from the next.

As such, we propose a new term to encompass all these devices—Personal Auditory Device, or PAD—and disentangle



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some of the terminologies, capabilities, and regulatory requirements for different types of PAD.

WHAT ARE PADs?

PADs are devices that are worn in, on, or over the ear that may amplify or attenuate sound, connect to other devices such as smartphones, and/or monitor the user, in any combination. Common types include:

Hearing Aid: An FDA-cleared medical device that amplifies sound for a hearing-impaired user. Hearing aids come in several styles, most of which are variations of either the behind-the-ear or in-the-ear design.

Over-the-Counter (OTC) Hearing Aid: A hearing aid intended for adults with mild to moderate hearing loss that can be purchased directly by consumers from a retailer. (Not yet available; the FDA is developing regulations for these devices.)

Personal Sound Amplification Product (PSAP): A device that amplifies sound for a user with normal hearing. PSAPs can look and function like a hearing aid but cannot be marketed for people with hearing impairment:

Hearing Protection Device (HPD): A device that attenuates the level of sound that reaches the ear. Most HPDs act as a passive barrier to sound but do not have any signal-processing capability. Common passive HPDs include foam or flange earplugs, and earmuffs.

Electronic (aka Active) HPD: An HPD that requires a power source and has signal-processing capability. Some incorporate communication capability through a wireless signal, making it easier for users to communicate over long distances

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or in high noise levels. Electronic components are usually found in an earmuff design but can also be found in an earbud-style device or a custom plug.

Hearable (aka Smart Headphone/Earbud): A wireless ear-worn device designed for multiple purposes, including communication, noise-cancellation, streaming media, medical monitoring, and fitness tracking (think step-counter that can be worn in your ear instead of on your wrist). Note that a “hearable” is not defined in federal regulations. The term is evolving rapidly and may refer to other types of PADs, especially PSAPs and hearing aids.

WHAT DO PADs DO?

PADs have some of these features and functions:

- **Amplify:** In the case of electronic HPDs, amplification is only active when the noise level in the environment is below a level that would be considered hazardous.
- **Attenuate:** Passive and electronic HPDs and some hearables reduce the level of sound reaching the ear. Sound may be attenuated for safety reasons in occupational or recreational environments, or for comfort such as when traveling on an airplane.
- **Connect:** Many PADs, except for passive HPDs, can connect to other technology such as phones, tablets, computers, radios, or other PADs to stream media or enable two-way communication.
- **Monitor:** Some PADs can collect data on the user. For example, some hearing aids have data-logging features that monitor how the device is used (such as duration of use and type of acoustic environment). Some hearables perform fitness tracking and/or medical monitoring.

Traditionally, PAD types have been segregated based on their function (e.g., hearing aids amplify, HPDs attenuate). However, the lines of functionality are blurring as devices expand their capabilities.

HOW DO THEY DO IT?

Various signal processing strategies are used in PADs to manipulate sound signals. Table 2 shows the general guidelines

Table 1. Main Functions of Personal Auditory Devices (PADs)

Device Type	Amplify	Attenuate	Connect	Monitor
Hearing Aid	✓	✗	✓	✓
OTC Hearing Aid	✓	✗	✓	✓
PSAP	✓	✓	✓	✗
Passive HPD	✗	✓	✗	✗
Electronic HPD	✓	✓	✓	✗
Hearable	✓	✓	✓	✓

on how different PADs incorporate various features, but there are many gray areas.

Most PADs use some of the same basic processing features (Table 2). Compression reduces the dynamic range of the incoming sound signal. Wide dynamic range compression (WDRC) adjusts gain so the entire dynamic range of speech is audible, while maintaining the intensity relationships of individual sounds (e.g., soft sounds still sound soft; loud sounds still sound loud). Expansion is the opposite of compression, but its main use is for minimizing low-level noise, such as the processing noise of the device itself.

Noise Reduction

Many strategies have evolved to reduce noise in sound signals, but some terms related to noise reduction are rather straightforward:

- **Compression** can also be used to reduce noise by lessening the gain in low frequencies, under the assumption that noise has greater low-frequency energy than speech. Any speech information that may be lost in those low frequencies tends to be of little consequence to communication (*J Acoust Soc Am.* 1947;19:90).
- **Directionality** uses directional microphones to create polar patterns that increase gain only from the direction of the target speech signal, while noise from other directions is reduced.
- **Digital Noise Reduction (DNR)** refers to signal-processing algorithms used in PADs to enhance speech by reducing noise in the signal. DNR may incorporate various strategies, including the noise reduction methods below (ANC or ANR).

Table 2. Processing Features Used by Personal Auditory Devices

Device Type	Active Noise Cancellation	Digital Noise Reduction	Compression	Expansion	Directionality	Feedback Reduction	Frequency Lowering
Hearing Aid	✗	✓	✓	✓	✓	✓	✓
OTC Hearing Aid	✗	✓	✓	✓	✓	✓	✓
PSAP	✓	✓	✓	✓	✓	✓	✗
Electronic HPD	✓	✗	✓	✓	✗	✓	✗
Hearable	✓	✓	✓	✓	✓	✓	✗

Table 3. The Role of Government Agencies in PAD Regulations

U.S. Government Agency	Role in PAD Regulation
Environmental Protection Agency (EPA)	HPD efficacy, labeling, verification
Federal Communications Commission (FCC)	Hearing aid/telephone compatibility and certification of wireless technology
Food & Drug Administration (FDA)	Hearing aid safety, sale, manufacture, labeling, verification
Federal Trade Commission (FTC)	Consumer protection against deceptive or fraudulent marketing and sales practices
Occupational Safety & Health Administration (OSHA)	Occupational use of HPDs
Mine Safety and Health Administration (MSHA)	Occupational use of HPDs for miners
Federal Railroad Administration (FRA)	Occupational use of HPDs for railroad workers
Department of Defense (DOD)	Occupational use of HPDs for the military

- **Feedback reduction** helps control a specific type of noise: feedback. Techniques tend to fall into two categories: gain reduction for the problem frequencies or phase-inversion to cancel out the feedback.

The real confusion arises when the acronyms “ANC” or “ANR” are used. ANC may refer to Active Noise Control, Active Noise Cancellation, or Adaptive Noise Cancellation, while ANR may refer to Adaptive Noise Reduction or Active Noise Reduction. In most instances, “active” refers to true noise-cancelling by phase reversal, while “adaptive” refers to the device’s ability to detect and respond to changes in the signal.

- **Active Noise Cancellation, Active Noise Control, Active Noise Reduction, and Electronic Noise Cancellation** all refer to the process of creating a signal identical to the incoming noise but with opposite phase so that it cancels out the noise. This method is most effective for low-frequency, steady-state noise.
- **Adaptive Noise Cancellation** is a form of digital noise reduction requiring two microphones. Ideally, one picks up both signal and noise, while the other picks up noise alone. These two signals are then subtracted so that only speech remains.
- **Adaptive Noise Reduction** is another form of digital noise reduction in which gain is reduced in specific frequency bands. ANR algorithms find frequency bands and/or moments in time with poor signal-to-noise ratio (SNR) and provide less amplification for those conditions.

Frequency-Lowering

Frequency-lowering is exactly what it sounds like. Some listeners are unable to make use of high-frequency information in speech due to lack of audibility, distortion, or discomfort. This high-frequency speech information is shifted to a lower frequency range that is audible.

- **Frequency transposition** is a technique that lowers high-frequency information by a constant number of Hertz.
- **Frequency compression** lowers high-frequency information by a constant fraction of the input frequency.

FEDERAL REGULATION OF PADs

The proliferation of PADs and the demand for greater consumer access to hearing assistance technology have spurred changes in some of the existing federal regulations and the creation of new regulations. In the United States, PADs are regulated by various government agencies according to their function, intended use, and associated risks (Tables 3 and 4). For a brief history of selected milestones in federal PAD regulation, see Fig. 1.

Regulation of Hearing Aids

Hearing aids have been federally regulated as medical devices since 1938. The FDA defines a medical device as one that is “intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or

Table 4. Government Agencies and the PADs They Regulate

Device Type	EPA	FCC	FDA	FTC	OSHA	MSHA	FRA	DOD
Hearing Aid	×	✓	✓	✓	×	×	×	×
OTC Hearing Aid	×	✓	✓	✓	×	×	×	×
PSAP	×	✓*	×	✓	×	×	×	×
Hearable	×	✓*	×	✓	×	×	×	×
Passive HPD	✓	×	×	✓	✓	✓	✓	✓
Electronic HPD	✓	✓*	×	✓	✓	✓	✓	✓

*The FCC regulates these devices if they include wireless technology.

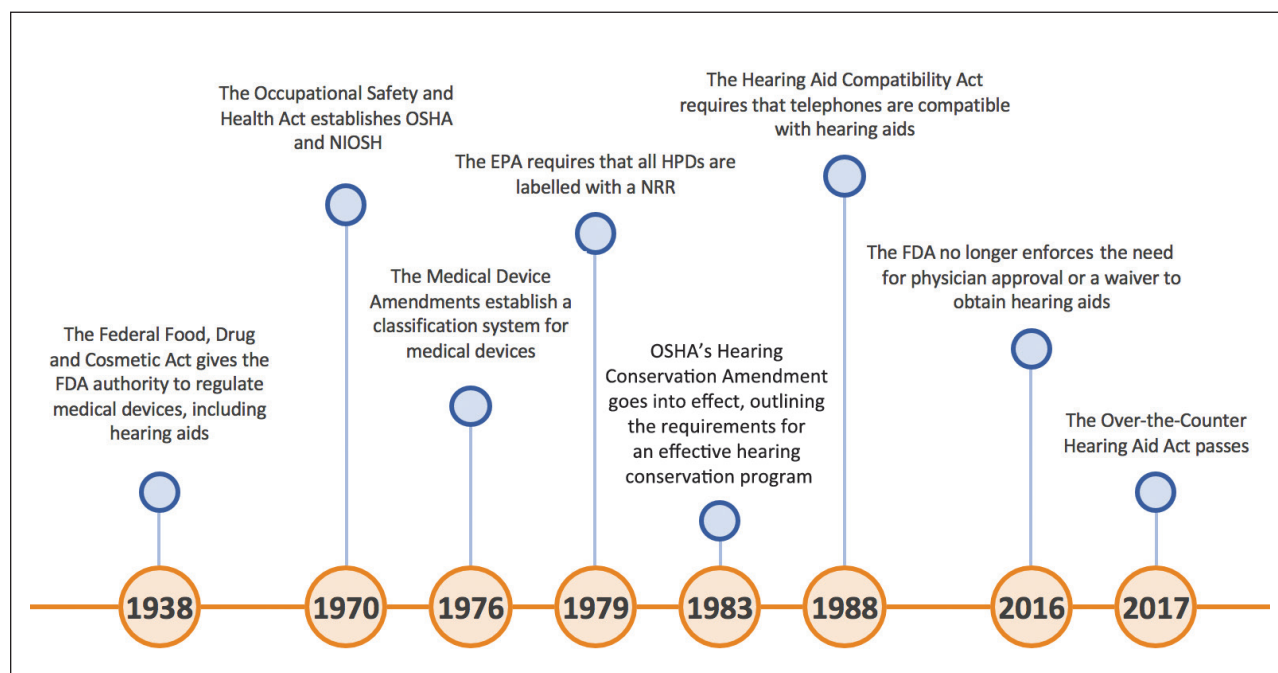


Figure 1. Milestones in PAD regulation.

prevention of disease.” This includes hearing aids, which are “wearable sound-amplifying device[s] that [are] intended to compensate for impaired hearing” (21 CFR § 874.3300, 2017).

The term “hearable” is not defined in federal regulations. It is often used to refer to a variety of ear-worn devices designed for any of multiple purposes, including communication, noise-cancellation, streaming media, medical monitoring, and fitness tracking.

The FDA publishes specific requirements for hearing aid safety, sale, manufacture, labeling, and verification of function. Recently these regulations have been loosening in favor of easier access for consumers. In 2016, the FDA announced that it would no longer enforce the “required conditions for sale” that required written medical clearance from a physician, or a signed waiver, before adults could obtain a hearing aid (21 CFR § 801.421, 2016).

Hearing aids are also regulated by the Federal Trade Commission (FTC) as consumer products. “The FTC enforces regulations that prohibit the use of misleading sales and advertising practices, including making inaccurate claims about hearing loss, hearing aid performance, refund policies, or warranty coverage” (FTC, 2017). The Federal Communications

Commission (FCC) enforces laws that ensure that landline telephones are compatible with hearing aids and that cell phone manufacturers offer hearing aid-compatible device options. In addition, any hearing aid that incorporates wireless technology must be certified by the FCC, ensuring that devices are safe for the public and will not interfere with other products.

Regulation of OTC Hearing Aids

The OTC Hearing Aid Act was passed in 2017, but OTC hearing aids are not yet available to consumers. These devices will be purchased directly by consumers from a retailer (whether brick-and-mortar or online) and will only be intended for the treatment of mild to moderate hearing loss. Like traditional hearing aids, OTC hearing aids will be regulated by the FDA in terms of their use, safety, labeling, and verification. As consumer products, OTC hearing aids will also be covered by the FTC, need wireless technology to be certified by the FCC, and likely follow FCC regulations on telephone compatibility.

Regulation of PSAPs

Functionally, PSAPs may be the same as hearing aids, but it is a device’s “intended use” that determines how it is regulated. PSAPs are not intended to compensate for hearing loss. Therefore, they are not classified as medical devices and are not regulated by the FDA. Instead, they “are intended to amplify environmental sound for non-hearing-impaired consumers” primarily in specific listening situations, such as hunting or bird watching (Guidance, 2009). As consumer products, PSAPs are overseen by the FTC. The FTC warns consumers not to substitute a PSAP for a hearing aid (FTC Hearing Aids). If PSAPs include wireless

technology, it must be certified by the FCC prior to marketing.

Regulation of Hearables

The term “hearable” is not defined in federal regulations. It is often used to refer to a variety of ear-worn devices designed for multiple purposes, including communication, noise cancellation, streaming media, medical monitoring, and fitness tracking. These devices are like PSAPs in that they are not medical devices and thus are not regulated by the FDA. They are not intended to compensate for hearing loss, and any noise control they provide can only be for comfort, not protection. They are still controlled as consumer products by the FTC, and their wireless technology needs to be certified by the FCC. Note, however, that “hearable” is sometimes used to refer to other types of PADs, especially PSAPs and hearing aids, which are subject to additional regulations as described above.

Regulation of HPDs

HPDs are primarily regulated by the Environmental Protection Agency (EPA), which enforces requirements on testing and labeling of HPDs. Since 1979, the EPA has required HPDs to be labeled with the Noise Reduction Rating (NRR), a single-number descriptor of the attenuation provided by the HPD in laboratory tests. Unfortunately, the NRR has several shortcomings. The NRR is unable to capture the noise-attenuating capabilities of electronic HPDs, which were not available when the EPA regulation went into effect. To address this and other concerns, changes have been proposed over the years in the way the NRR is derived and in HPD labeling requirements. To date, however, none of the proposed changes are enforceable.

The use of HPDs in the workplace is regulated by several government agencies, including the Occupational Safety and Health Administration (OSHA), the Mine Safety and Health Administration (MSHA), the Federal Railroad Administration (FRA), and the Department of Defense (DOD). They stipulate when hearing protection must be worn and how much attenuation is required.

LOOKING FORWARD

While PADs continue to evolve in versatility and sophistication, changes in federal regulations are favoring greater consumer access to hearing assistance technology.

Together, these trends will open opportunities (and challenges) for businesses, consumers, and audiologists. Some PAD types will continue to be subject to stricter regulations than others based on their intended use, even though they may have essentially the same capabilities. For example, a PSAP may function like a hearing aid, but cannot be labeled as such without proper FDA clearance, or a hearable may attenuate noise but cannot be labeled as an HPD without meeting EPA standards. To navigate this potentially confusing technological terrain, hearing health care professionals will need to stay abreast of new regulations and developments in PAD technology. 