



Update on the availability of Over-The-Counter devices in Canada

Several years ago the United States approved a new type of sound amplifier called an Over-The-Counter device, also known as an OTC device. This is intended only for adults with a relatively minor degree of hearing loss and does not require an assessment with an audiologist. The idea was to improve access for those adults that just need a bit of assistance in one-to-one communication. More sophisticated hearing aids would be more useful in noisier places and this is where a referral to an audiologist would be quite useful.

A new position paper called “Canadian Academy of Audiology Position Statement on Over-The-Counter devices and Sound Amplifying Products” outlines some of the benefits and some of the challenges of OTC devices. Here are the highlights:

- The Canadian Academy of Audiology supports any new service, app, or product that improves a hard of hearing person’s ability to hear and communicate effectively. This includes over the counter sound amplifiers such as OTC devices.
- To date, Health Canada has only approved one OTC device but there will undoubtedly be more approvals in the years to come. This device is the Apple AirPods Pro II and has received a Medical Device Class II license to be distributed in Canada. This OTC device has the capability of performing a rudimentary hearing test for the consumer.
- A Medical Device Class II license does not ensure safety or that such a device will not cause additional hearing loss for a person. Class II level approvals ensure that devices meet certain manufacturing criteria and that manufacturers maintain records of any complaints or issues resulting from use.
- While there are standards governing the loudest sound that the device can generate, the actual level may be much higher in someone’s ear, which can increase the potential for hearing loss.
- There are a range of other “sound amplifying” devices sold in Canada (such as consumer earphones) which do not require any licensing, and these, along with other approved devices such as OTCs, can generate sound exposures that, over time, can exacerbate hearing loss.
- Regular assessments with an audiologist to both ensure that personal amplification is not excessive, but also to optimize the sound quality of speech and music, are recommended, especially for those over the age of 50. This is a clear recommendation of the Canadian Academy of Audiology.





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- Audiologists are regulated hearing health care professionals who have university level training at the masters and doctorate levels. They are the most appropriate hearing health care professionals to assess, counsel, and provide information on hearing and hearing loss prevention.

Copies of the Position Statement from the Canadian Academy of Audiology can be found [here](#)