Canadian Academy of Audiology
Academie Canadienne d'audiologie

Backgrounder for "Canadian Academy of Audiology Position Statement on Over-The-Counter devices and Sound Amplifying Products"

This document is intended to provide background material for a proposed updated CAA Position Paper on OTC devices.

Recently Health Canada approved a Class II medical license for the Apple Air Pod II which includes both hardware and software elements. This device allows for a four-threshold based pure tone test that a consumer can self-administer as well as the capability to upload an audiogram.

It should be noted that many hearing aid manufacturers have an OTC or OTC-like product that are marketed to the consumer market directly but under a different model name or as a different form factor casing shape. Some manufacturers are marketing this technology in conjunction with third party providers such as Bose and Sensheisser.

Our previous Position Paper (November 15, 2022) https://canadianaudiology.ca/professional-resources/guidelines-and-position-statements/ on OTC devices contained a call for increased federal oversite/regulation, while acknowledging that OTC devices may fill in the gaps relating to accessibility for some consumers. This 2022 document pointed out that without Audiology input, the hard of hearing consumer may not have optimal aided hearing, receive inappropriate counselling, and lack verification of the OTC fitting for both safety and sound quality.

While maintaining the important point that the CAA supports the introduction of any new device, or Smartphone app that potentially can improve accessibility for adults with mild to moderate sensorineural hearing loss in Canada, this new proposed Position Paper has two essential differences:

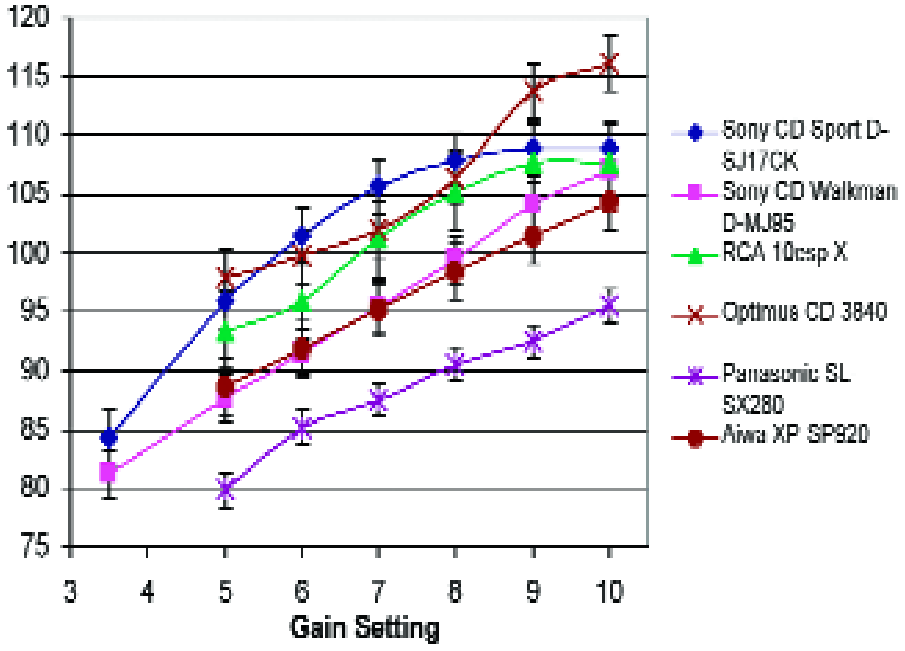
1. **The orientation of this new proposed position paper is much more broadly based and talks about all "sound producing" products**. This would not only include OTC devices, but also Personal Sound Amplification Products (PSAPs), and also earphones that can be connected to speech, noise, and music such as that from our Smartphones or computer systems. These sound producing products, when taken together as used by many Canadians, can contribute to the maximum noise/music

dose. It is not just the availability of OTC devices, but also the added noise exposure of mowing one's lawn, using leaf blowers, the use of recreational vehicles, and the contributions of occupational sources of noise exposure. Each one of these, when taken together, can boost the individual's exposure to over 100% of their dose.

Additional information:

(a) PSAPs are not intended to be marketed to hard of hearing consumers but nevertheless do provide amplification. It is sometimes a marketing decision whether a device should be considered an OTC device or a PSAP but regardless, the amplification is still present. There are voluntary regulations for PSAPs that do specify maximum output levels (ANSI-CTA-2051-2017) and mandatory regulations for OTC devices (: Federal Register :: Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids Published Document: 2022-17230 (87 FR 50698). This however is measured in a 2 cc coupler and the actual gain and output that is generated in a person's occluded ear canal can vary significantly, especially for children.

(b) The research on the potential output of consumer earphones such as those used with Smartphone applications and computers demonstrate that in addition to the volume setting, the selection of the appropriate earphone would significantly alter the sound level that is produced. (see for example, Fligor and Cox, 2004; Fligor, 2006, Portnuff and Fligor, 2009). The following graph from Fligor (2006) shows the output in dB SPL for the same mp3 device, and same music, over a range of volume controls (3-10) but with different earphones. At volume 6 out of 10, one earphone may only generate 85 dB SPL whereas at that same volume 6, another earphone may generate levels in excess of 100 dB SPL.



(c) "Dose" is a much more appropriate term to discuss than just sound level. Hearing loss can occur both as a result to high level sound and the duration of the exposure. Dose (being a value from 0% and up) integrates both of these factors. For example, there is nothing wrong with an exposure to 94 dBA as long as the duration of exposure is less than 5 hours. There are many commercially available dosimeters as well as Smartphone apps such as the NIOSH sound level meter app and dosimeter (but only for iOS at the current time). While portable music may not in itself cause hearing loss, it can contribute to the other noise/music sources such as recreational vehicles, lawn maintenance, and occupational sources of noise exposure, all resulting is an exposure of greater than 100% dose.

(d) Hearing damage is difficult to measure clinically and may not always be apparent as "hearing loss" as measured in an audiogram. The work of Kujawa and Liberman (see for example, Kujawa SG, Liberman MC. Acceleration of age-related hearing loss by early noise exposure: evidence of a misspent youth. J Neurosci. 2006;26(7):2115–2123.)

shows that if juvenile mice are subjected to higher sound levels when young, there is a greater than predicted hearing loss when older.

Another example is from Vasilkov, V., et al. (2023). ("Evidence of cochlear neural degeneration in normal-hearing subjects with tinnitus", Nature. https://www.nature.com/articles/s41598-023-46741-5.pdf) shows that neural degeneration in the auditory system precedes any measure of cochlear reduction in sensitivity.

2. **A call for "labelling or warnings" of these products either on the packaging or in the associated consumer information- printed or online- regarding the potential contribution towards the consumer's noise exposure dose.** Simply calling for "more government regulation" (as in our November 15, 2022 Position Paper) is an amorphous policy unless we can specify exactly what it is that we are calling for. Labelling or the use of warnings is a more specific call-out.

   Additional Information:

   (a) Boyle's Law specifies that the smaller the residual volume, the greater the pressure. With respect to occluding hearing aids or other sound producing products such as OTC devices or earphones, the smaller the residual volume, the higher the sound pressure that is generated. This is especially the case with children and other small-eared individuals. This is one of the important elements of real ear verification.

   (b) Note that in this document, this would not apply to hearing aids since those are provided only through the professional route where Best-Practices dictate the use of real ear verification to ensure that sound levels are not excessively high (and that targets are available with respect to sound quality).

   (c) Some manufacturers such as Apple and some Android applications already have voluntary warnings regarding the potential of excessive high sound levels and that the market be adults age 18 years and older, and the Canadian Academy of Audiology applauds these endeavors.

(d) Part of the labelling requirements for any Class II approved device (other than name, instructions for use, and warning/precaution statements) is the "intended use". Since a consumer would have no way of knowing whether they have a mild to moderate hearing loss, it is still incumbent upon the consumer to seek out an assessment of an audiologist to determine the degree and nature of the hearing loss. The built-in four threshold measuring software of the Apple Air Pod II (based on CTA-2118, 2023) still may provide results where other factors such as wax occlusion, collapsing ear canals, untreated middle ear disorders or even asymmetries in cochlear function would not be apparent. And other (future) devices that may obtain medical Class II license approval may, or may not have a built-in threshold estimating method.

Health Canada Medical Device Class II License:

An application for a Medical Class II License from Health Canada (FRM-0292) does not require information on safety and optimal sound quality- merely quality control in the manufacturing process (ISO 13485 Certification), and if manufactured outside of Canada, another associated application will be required (Medical Device Establishment License) which allows non-Canadian products to be distributed in Canada. Issues surrounding safety and effectiveness are required for Class III and Class IV Medical Devices in Canada, but not Class II (which includes hearing aids and new OTC devices that are aimed at the consumer market.) The Health Canada Medical Device Class II license only requires that such information exist in a pre-market condition, but there is no requirement to supply it. This License does require certain labelling requirements: name, intended use, instructions for use, and warnings and precautions. It is not clear that specification of "mild to moderate" hearing loss is something that a consumer would know without an assessment by a hearing health care professional.

Conclusion:

With this "more broadly-based" interpretation of the data and the effects of noise/music exposure, the time is right to talk (not just about OTC devices) but all sound producing products.

This as an opportunity for the CAA and its members to better educate the consuming public about the potential for further hearing deterioration. Education should be provided regarding the "dose" where a single "sound producing" device may only be one contributing factor

towards the dose. The CAA has an associated information sheet for the consumer and physician with information about "dose" rather than just SPL as described in this "backgrounder" along with some peer reviewed literature.

It may be that "labelling" or the inclusion of warnings in the consumer literature for these products will never be approved, but this call-out for better information and caution (especially for children with small volume ear canals) and its rationale could be very useful for media consumption. Many Apple and Android products currently do have some warning materials, but what about a future submission from Company X hoping to market a device? It is not that a sound producing device in itself is problematic, but the use of that device along with other forms of sound exposure (e.g. mowing the lawn, air blowers, portable music, recreational vehicles, etc.) could generate sound levels and durations that could exceed 100% of the dose.

Summary:

(1) This new CAA Position Paper sufficiently addresses OTC devices and maintains that CAA welcomes things such as devices and Smartphone apps that could potentially improve accessibility.

(2) This new CAA Position Paper places OTC devices in the correct context that they are only one of a number of consumer devices that need oversight, and that the CAA is calling for product labelling/warnings.

(3) This new CAA Position Paper makes it clear that something as "everyday" as consumer earphones can also contribute to their patients' noise/music exposure.

(4) This new CAA Position Paper is backed by peer reviewed research that potential recreational noise/music damage may not show up immediately on an audiogram, and when it does, it may not be until years later.

(5) This new CAA Position Paper does not apply to hearing aids that are fit through the professional Audiology route since Best-Practices ensure optimal sound quality as well as prevention of excessive sound levels.

Contributors: Marshall Chasin. AuD., Steve Aiken, PhD., Steve Armstong, B. Eng Elec., Calvin Staples, M.Sc