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Recommendation ITU-T H.871

Safe listening guidelines for personal sound amplifiers

Summary

Recommendation ITU-T H.871 complements ITU-T H.870 "Guidelines for safe listening devices/systems". Currently there is no international standard for personal sound amplifiers (PSAs). These devices, which are freely available to anyone, require this standard to ensure that these devices are safe for users and do not further damage users' hearing.

PSAs are non-medical devices, intended for people with normal hearing and a) can have a design physically comparable to hearing aids, in which case they are called personal sound amplification products (PSAPs) or b) can also simply be an application on any smartphone or other device, in which case they are called personal sound amplification applications (PSAAs).

As defined in ITU-T H.870, the sound exposure should be limited to an accumulated dose (100 % calculated sound dose (CSD)) over 7 days of in total 1.6 Pa²h which corresponds to 80 dBA for 40 hours to prevent noise-induced hearing loss. When the 100% CSD is reached, the sound level should suddenly drop, and the user will get a suggestion to lower the sound level, since the weekly sound listening dose is exceeded.

When PSAPs and PSAAs do not have the capacity to measure CSD, the output level of the device needs to be permanently limited to 95 dBA, so that a user is unlikely to use the device at a level higher than 80 dBA, since the dynamic range of speech has a crest factor of 12 to 17 dB.

The U.S. Food and Drug Administration has carried out considerable work on these devices and their work is referenced in this Recommendation.

History

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Hearing aid, hearing assistive technology, hearing enhancer, noise induced hearing loss, personal sound amplifier, personal sound amplifier app, personal sound amplifier product, safe listening, safe sound output, wearable personal amplifiers.

* To access the Recommendation, type the URL http://handle.itu.int/ in the address field of your web browser, followed by the Recommendation's unique ID. For example, http://handle.itu.int/11.1002/1000/11830-en.
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The World Telecommunication Standardization Assembly (WTSA), which meets every four years, establishes the topics for study by the ITU-T study groups which, in turn, produce Recommendations on these topics.

The approval of ITU-T Recommendations is covered by the procedure laid down in WTSA Resolution 1.

In some areas of information technology which fall within ITU-T’s purview, the necessary standards are prepared on a collaborative basis with ISO and IEC.

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As of the date of approval of this Recommendation, ITU had not received notice of intellectual property, protected by patents, which may be required to implement this Recommendation. However, implementers are cautioned that this may not represent the latest information and are therefore strongly urged to consult the TSB patent database at http://www.itu.int/ITU-T/ipr/.

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Recommendation ITU-T H.871

Safe listening guidelines for personal sound amplifiers

1 Scope

This Recommendation describes safety requirements for personal sound amplifiers (PSAs), including both personal sound amplification products (PSAPs) and personal sound amplification apps (PSAAs) types, to protect people from further hearing loss.

Currently there is no international standard for PSAs; a standard is needed to ensure that these devices, which are freely available to anyone, are safe for users and do not further damage users' hearing.

[ITU-T H.870] provides safe listening standards but excludes PSAs. Therefore, this Recommendation follows the logic and concept of [ITU-T H.870] but is specifically intended for PSAs.

This Recommendation provides characteristics of PSAs and suggests ways of informing consumers about the potential unacceptable noise levels when using these devices for prolonged periods of time.

2 References

The following ITU-T Recommendations and other references contain provisions which, through reference in this text, constitute provisions of this Recommendation. At the time of publication, the editions indicated were valid. All Recommendations and other references are subject to revision; users of this Recommendation are therefore encouraged to investigate the possibility of applying the most recent edition of the Recommendations and other references listed below. A list of the currently valid ITU-T Recommendations is regularly published. The reference to a document within this Recommendation does not give it, as a stand-alone document, the status of a Recommendation.


3 Definitions

3.1 Terms defined elsewhere

This Recommendation uses the following terms defined elsewhere:

3.1.1 calculated sound dose [b-IEC 62368-1]: One week rolling estimate of sound exposure expressed in percent of the maximum considered safe.

3.1.2 hearing aid – hearing instrument [b-IEC 60601-2-66]: Medical electrical equipment which picks up sound and delivers processed sound to the ear canal through air-conduction. A hearing instrument includes all detachable parts that are essential for the performance of its intended use.

3.1.3 personal audio system (PAS) [ITU-T H.870]: A system of a personal audio device and a listening device.

3.1.4 sound dose [ITU-T H.870]: The total quantity of sound received by the human ear during a specified period. The unit of (sound) dose is Pa²h.
3.2 Terms defined in this Recommendation

This Recommendation defines the following terms:

3.2.1 hearing assistive device: Any wearable instrument or device designed for assisting a person's hearing ability.

3.2.2 personal sound amplifier (PSA): A non-medical electronic device or software amplifying sounds picked up by a microphone, intended for people with normal hearing which can have a design physically comparable to a hearing aid or it can be an app on any smartphone or other device.

3.2.3 personal sound amplification app (PSAA): A non-medical software amplifying sounds picked up by a microphone, intended for people with normal hearing designed as an app on any smartphone or other device.

3.2.4 personal sound amplification product (PSAP): A non-medical electronic device amplifying sounds picked up by a microphone, intended for people with normal hearing with a design physically comparable to a hearing aid.

4 Abbreviations and acronyms

This Recommendation uses the following abbreviations and acronyms:

ALD Assistive Listening Device
App Application
BTE Behind the Ear
CSD Calculated Sound Dose
DAC Digital to Analogue Conversion
dBA A-Weighted Decibels
dBSPL Decibel Sound Pressure Level
FDA U.S. Food and Drug Administration
HA Hearing Aid
HAD Hearing Assistive Device
ITE In the Ear
PSA Personal Sound Amplifier
PSAA Personal Sound Amplification Application
PSAP Personal Sound Amplification Product
RMS Root Mean Square

5 Conventions

None.

6 Introduction

At the World Health Assembly held on 30 May 2017, delegates of World Health Organization agreed to intensify action to prevent deafness and hearing loss. Some 360 million people across the world live with disabling hearing loss, a total that includes 32 million children and nearly 180 million older adults. Nearly 90% of people with hearing loss live in low- and middle-income countries which often lack resources and strategies to address hearing loss [b-WHA].
Personal sound amplifiers are non-medical devices which amplify sounds picked up by a microphone. This device is intended for people with normal hearing and can: a) have a design physically comparable to a hearing aid, in which case it is called personal sound amplification product (PSAP) or b) simply be an application (app) on any smartphone or other device, in which case it is called a personal sound amplification application (PSAA). In practice, it is frequently seen that people with (mild) hearing loss buy and use these devices as an alternative to hearing aids.

Personal sound amplifiers are intended to be introduced in the ear to amplify environmental sounds for people with no hearing impairment. Examples of situations in which personal sound amplifiers are typically suggested for use include bird watching, listening to lectures, listening to a distant speaker or listening to soft sounds that would be difficult for normal hearing individuals to hear (e.g., distant conversations, conversations in noisy environments, theatre performances).

Until recently, these devices consisted of portable amplifying systems, but with the advent of downloadable amplifying software, this category has broadened to include mobile and body-worn devices with amplifier apps.

NOTE – As the original definition by the U.S. Food and Drug Administration (FDA) does not specify software as a PSAP, the definition in clause 3.2.4 is adopted in this Recommendation.

The latest developments of these products, coupled with personal music players, are used to listen to sounds without any safety levels. For further information see Appendix I.

6.1 Characteristics of personal sound amplifiers

A PSA is typically a device with two transducers, one for audio input (microphone) and the other for audio output (loudspeaker), and which typically modifies, e.g., amplifies, the input sound.

The main difference between personal audio systems, the topic of [ITU-T H.870], and PSAs, as illustrated in Figures 1 and 2, is that for the latter the input is not a pre-recorded audio file, but rather any live input signal in the environment that is picked up by the microphone(s) of the PSAs. Further, the majority of the currently available PSAs do not have the capacity to measure the weekly sound exposure dose. In Figure 2, the interface (IF) between the PSA device and the listening device may be within the same hardware.

![Figure 1 – Graphic presentation of a personal audio system](image)
6.2 Physical characteristics of personal sound amplifiers

PSAPs are typically worn around the ear, the organ for hearing. While there are other possible designs, two typical types include the behind the ear (BTE) type or the in the ear (ITE) type, as illustrated in Figures 3 and 4, respectively.

A PSAA is typically an app stored on a smart device, such as a smartphone, which provides sound amplification. Figure 5 illustrates a typical setup of a PSAA.
7 Requirements for safe listening for personal sound amplifiers

It is recommended that PSAs follow the requirements listed below:

R1: It is required that weekly maximum sound dose needs to be less than 1.6 Pa\(^2\)h, which corresponds to 80 dBA for 40 hours. For example, at 89 dBA, the exposure time shall be limited to 5 hours/week. For other exposure levels, a linear intrapolation and extrapolation applies. Measurements taken of the dynamic range of sound should be accounted for and the reasonably foreseeable use of the products. [ITU-T H.870].

R2: When these devices do not have the capacity to measure weekly sound dose, the maximum output of the device needs to be permanently limited to 95 dBA; a user then is unlikely to use the device at a level higher than 80 dBA since the dynamic range of speech has a crest factor of 12 to 17 dB.

R3: personal sound amplifiers need to provide adequate warnings in advertisements, user guides and packaging detailing the risks of further damaging the user's hearing as a result of using the device, and provide information to users showing how to avoid these risks.

[EN 50332-3] defines 1.6 Pa\(^2\)h (equivalent to 80 dBA L\(_{eq,40}\)) as the weekly sound allowance, i.e., a 100% calculated sound dose (CSD) acquired over a period of 7 days.

In line with [ITU-T H.870], a PSA shall provide the user with warnings and cues for action when the user exceeds 100% of the weekly allowance. The requirements are provided in [ITU-T H.870] clause 11.2.1.2:

- The user shall receive first a "warning" expressed through text, visuals, or other means indicating that a threshold has been reached and that from this point on, further listening at the same volume will pose a risk to their hearing.

- The warning shall be followed by a "cue for action" in which the user is offered the choice to either accept the risk of continued listening or protect their hearing. The "cue for action" should be linked to active options on the device such as:
  - automatic safe volume option, by which the device automatically changes the volume to a safe volume level;
  - direct access to volume settings;
  - setup of default volume limits;
  - remind later option;
• ignore and continue option.
  – If the user fails to take any action, the volume will automatically be reduced to below the standard level (80 or 75 dBA as selected).

The details are for further study.

8 Consumer information

All personal sound amplifiers advertising, user guides and packaging shall carry consumer information. The information is required to contain:
  – a description of the product as a PSA;
  – a list and description of the safety features are built into the product;
  – consumer advice related to hearing loss prevention;
  – all of the information on packaging indicated in [ITU-T H.870].

The details are for further study.
Appendix I

Further information from practical testing

(This appendix does not form an integral part of this Recommendation.)

The position paper issued jointly by the European Association of Hearing Aid Professionals (AEA) and the European Federation of Hard of Hearing People (EFHOH) in 2015 \(b\)-AEA/EFHOH PSAP\] raises the question of safety levels for PSAP products that were tested; some that were tested presented 130.0 dB SPL maximum output level. This level is much louder than the 80 dBA at which the exposure time shall be limited to 40 hours/week according to the European Commission Decision (EC) No 490/2009 \(b\)-EC/490/2009].

A total of the 27 devices were analysed according to the test specification in \(b\)-IEC 60118-7. They were measured to have a maximum power level (OSPL 90) of more than 120 dB SPL (significantly higher than the 85 dB SPL maximum safety level), with 23 of them showing a maximum power level of 125 dB SPL or more (8 devices had a maximum power level of 130 dB SPL or more).

None of the products tested had a limitation on the maximum power output or the capacity to measure weekly sound exposure dose.
Appendix II

Maximum Sound Output Level for Personal Sound Amplifiers

(This appendix does not form an integral part of this Recommendation.)

Personal sound amplifiers include both PSAAs and PSAPs.

PSAPs are defined by the FDA as "wearable electronic products that are intended to amplify sounds for people who are not hearing impaired" [b-FDA-PSAP].

For PSAs, there is no known available international recommendation at this time.

According to this Recommendation, the maximum output of PSAs should be set to 95 dBA, when these devices do not have the capacity to measure weekly sound dose.

Hearing aids are typically limited in maximum output level, which is done by the hearing aid professional after a full assessment of a user's hearing functionality, to prevent further hearing loss [b-Safe Max Output].

As seen in Figure II.1, Johnson [b-Safe Max Output] recommends that the maximum sound output be limited to 90 dBSPL root mean square (RMS) level for persons with normal hearing.

An algebraic restatement of the regression equations holding expected PTS constant at 3.5 dB HL to show safe output SPL as a function of hearing loss. (source: Johnson 2017, table 1)

<table>
<thead>
<tr>
<th>4FAdB HL threshold</th>
<th>Safe Output SPL (overall dB)</th>
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</tr>
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<td>5</td>
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<td>99</td>
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The relationship between 4FA dB HL threshold and the safe output SPL output expected from hearing aids fit to prescriptive settings alongside safe output SPL. (source: Johnson 2017, table 2)

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<th>4FAdB HL threshold</th>
<th>Output SPL (RMS level) * prescription</th>
<th>Safe Output SPL (RMS level) **</th>
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* for an 80 dB input level for compressive hearing aid amplification at prescription recommendations
** for 3.5 dB HL Permanent Treshold Shift for an exposure of at least 8 hours

Figure II.1 – Tables presenting maximum sound output limit

Since personal sound amplifiers, when not used for recreation use, will mostly be used to understand speech in quiet and in background noise, the dynamic range or crest factor (the difference in dB between the instantaneous peak of a signal and its RMS value) of speech is essential. According to Chasin [b-CREST FACTOR 12], the crest factor for speech is 12 dB. [b-Safe Max Output], [b-IEC 60118-0]

In section 7.4.3 of [b-IEC 60118-0], the reference test gain is set to 17 dB under the average maximum output of the hearing aid, to ensure that speech will not be distorted, which is also based on the dynamic range (or crest factor) of speech.

Based on these findings, for PSAs that do not have the capacity to measure weekly sound dose, the maximum output of the device needs to be limited to 95 dBA.
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