AEA: European Association Of Hearing Aid Professionals

EFHOH: European Federation of Hard of Hearing People

Paper on the potential risk of using "Personal Sound Amplification Products" PSAPs

December 2015

I. Introduction

The **European Association of Hearing Aid Professionals (AEA)** was founded in 1970 as the European umbrella organisation for "Hearing Aid Professionals". AEA membership is open to all national associations of hearing aid professionals in Europe that have been officially recognised by their relevant national authorities. We currently represent the interests of more than 8,000 small and medium-sized enterprises (SMEs) and more than 20,000 practitioners in the following 13 European countries: Austria, Belgium, France, Germany, Greece, Italy, the Netherlands, Romania, Poland, Portugal, Spain, Switzerland and the United Kingdom.

The **European Federation of Hard of Hearing People (EFHOH)** is a non-profit European non-governmental organisation consisting of/for hard of hearing and late deafened people, parent organisations and professional organisations. EFHOH has been registered as a charitable organisation and has its registered office in London, UK (Action on Hearing Loss offices). EFHOH's aim is a Europe where hard of hearing people can live without barriers, and have the opportunity to participate on all levels in society. EFHOH realises this vision through a series of actions, contacts and campaigns, involving the EFHOH members and partners.

AEA and EFHOH want to inform all relevant stakeholders on the potential risks of using Personal Sound Amplification Products – PSAPs. This with the aim to prevent such products from resulting in permanent noise induced hearing loss by the user.

II. What are "Personal Sound Amplification Products" or "PSAPs"?

Personal Sound Amplification Products are intended to be introduced in the ear to amplify environmental sounds for people with no hearing impairment. Examples of situations in which PSAPs are typically suggested for use are; 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, performances).

III. Definition of the problem

In February 2014, the UK national association of hard of hearing people "Action on Hearing Loss"[1] , which is a member of EFHOH, used a study commissioned by Danish Hard of Hearing Organisation to analyse a personal sound amplifier product, commercialised in the UK and measured 130.0 dBSPL maximum output level[2], which is much louder than the 85dB than the accepted maximum safety level. Based on this analysis, they were able to convince the distributor of this specific PSAP to withdraw this device form the UK market.

This issue was raised during a joined meeting between EFHOH and AEA and a proposal was made to investigate if comparable products were sold in other European countries and to analyse the performance of these products in order to evaluate the potential risk for noise induced hearing loss.

This kind of products, which are easily confused with hearing aids, are likely to be bought mostly by the most vulnerable group of users, i.e. people having limited financial resources and no or very difficult access to professional hearing care.

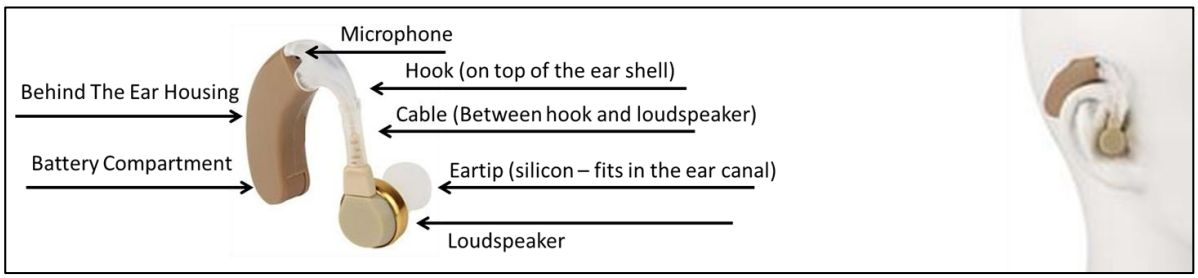
Therefore, in March, 2015, EFHOH and AEA asked their members to buy the most frequently promoted low cost PSAPs in their country and send them to the European Commission for Audiology and Technology (ECAT) – the technical workgroup working for the AEA - for analysis.

[1] www.actiononhearingloss.org.uk
[2] DELTA Test Report, Acoustic Test Report according to IEC 60118-0,1,2,6 on INVISI EAR, 2014 (report available upon request).

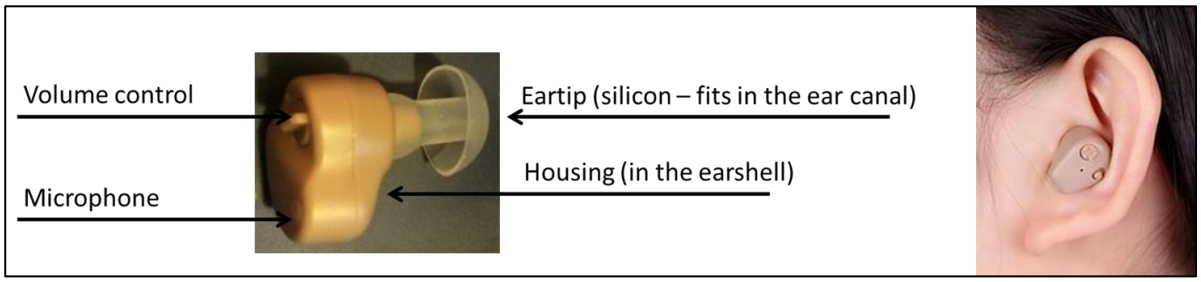
IV. Results of the analysis

In total 27 products were purchased and analysed. The products were purchased in 7 different countries (Austria, Belgium, Germany, Greece, Italy, Romania and UK).

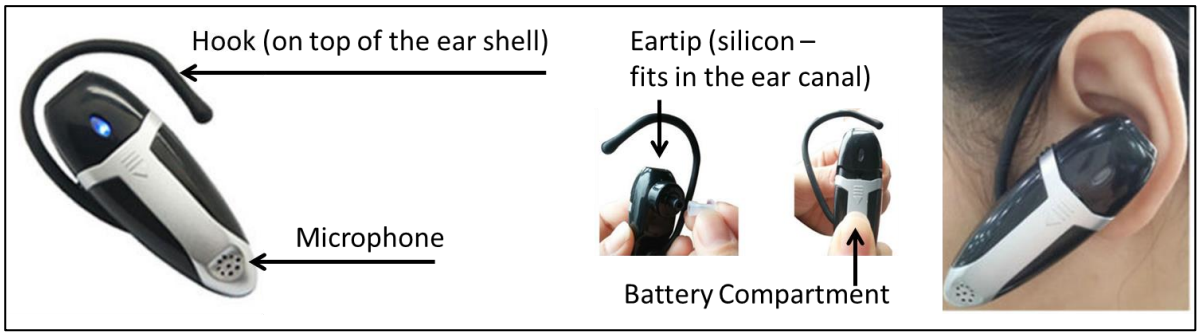
17 products had a BTE (Behind The Ear) design, where the housing is behind the ear and a loudspeaker is fit into the ear canal with a silicon tip.



6 product had a ITE (In The Ear) design, where the housing is inserted in the earshell and the tip is inserted in the ear canal with a silicone tip.



And 4 devices had a Headset design, where the device looks like a hands-free wireless headset with even a blue light ... but is in fact a personal sound amplifier.



All 27 devices were analysed according to the IEC 60118-7 test-standard and had a maximum power level (OSPL 90) of more than 120 dBSPL (significantly higher than the 85dBSPL maximum safety level), 23 had a maximum power level of 125 dBSPL or more and 8 devices had a maximum power level of 130 dBSPL or more. None of the products had a limiter of the maximum power.

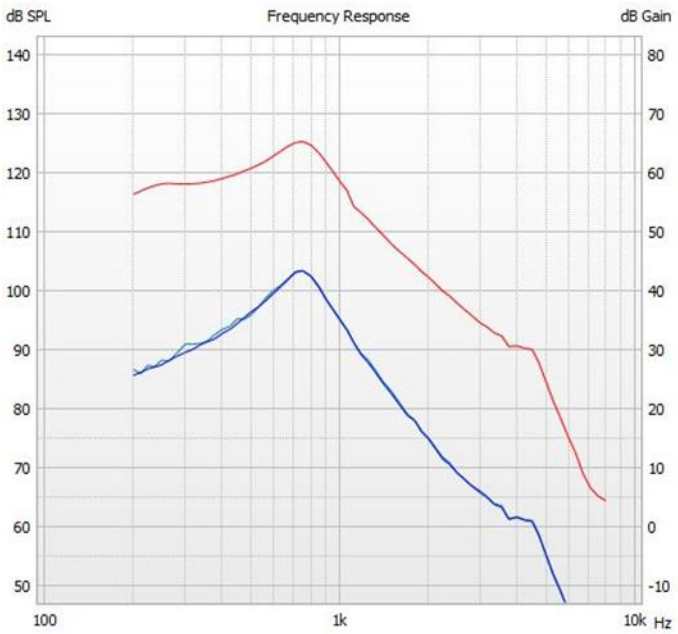
Product Name	Max Output	Max Gain	Analysed by	Country of purchase
LoudNClear (Headset)	135,1 dBSPL	48,5 dB	THOMAS MORE	Romania
Melody Acustica (BTE)	135,0 dBSPL	52,0 dB	DHI (G)	Italy
Mini Sound Amplifier (BTE)	134,8 dBSPL	63,0 dB	THOMAS MORE	Greece
Sanitas (Lidl) SHA 15 (BTE)	134,0 dBSPL	49,0 dB	DHI (G)	UK
TOPSOUND (Headset)	131,9 dBSPL	48,8 dB	THOMAS MORE	Italy
Earzoom (Headset)	130,1 dBSPL	40,7 dB	THOMAS MORE	Belgium
Invisi Ear (BTE)	130,0 dBSPL	47,0 dB	DELTA (DK)	UK
Powertone F-138 (BTE)	130,0 dBSPL	47,0 dB	DHI (G)	Greece
Acustika Melody (BTE)	129,1 dBSPL	47,9 dB	THOMAS MORE	Italy
INFACTORY (Headset)	129,0 dBSPL	40,4 dB	THOMAS MORE	Italy
Sanitas (Lidl) (BTE)	129,0 dBSPL	42,4 dB	THOMAS MORE	UK
Vitalcontrol (Lidl) (BTE)	129,0 dBSPL	42,4 dB	THOMAS MORE	Spain
WELLYS MINI 7720 (ITE)	129,0 dBSPL	42,8 dB	THOMAS MORE	Italy
WELLYS 8511 (BTE)	127,1 dBSPL	52,9 dB	THOMAS MORE	Italy
Axon X-168 (BTE)	126,0 dBSPL	43,3 dB	THOMAS MORE	Italy
Axon X-168 (BTE)	126,0 dBSPL	43,3 dB	THOMAS MORE	Romania
Axon X-168 (BTE)	126,0 dBSPL	43,3 dB	THOMAS MORE	Greece
HAPI-090D (ITE)	126,0 dBSPL	38,0 dB	DHI (G)	Germany
Sokio X-168 (BTE)	126,0 dBSPL	43,3 dB	THOMAS MORE	Germany
Zinbest (BTE)	125,5 dBSPL	45,6 dB	THOMAS MORE	Austria
BTE K202S (BTE)	125,5 dBSPL	45,7 dB	U Castilla La Mancha	Spain
HAPPY SHEEP HP680 (ITE)	125,3 dBSPL	43,3 dB	THOMAS MORE	Italy
WELLYS RECH 8515B (BTE)	125,2 dBSPL	46,4 dB	THOMAS MORE	Italy
Zinbest HAP-20 (BTE)	125,0 dBSPL	40,0 dB	DHI (G)	Greece
AXON K80 (ITE)	123,4 dBSPL	40,8 dB	THOMAS MORE	Greece
Acutrue (ITE)	120,9 dBSPL	30,4 dB	THOMAS MORE	Romania
AB 900 (ITE)	120,7 dBSPL	36,2 dB	U Castilla La Mancha	Spain

The devices have been analysed in four different labs;

- 19 devices were analysed by the Audiology Department of Thomas More University College – Antwerp – Belgium
- 5 devices were analysed by the Deutche Hörgeräte Institut - Lübeck – Germany
- 2 devices were analysed by the Instituto de Investigación en Discapacidades Neurológicas - Universidad de Castilla La Mancha – Spain
- 1 device was analysed by Delta – Hørsholm – Denmark.

One device was purchased 3 times and one was purchased twice so in total we have 24 unique devices (with different product name).
The devices were mostly sold at department stores, television sales and web shops.
Nearly all of the devices cost less than 50 Euro.

Nearly all devices give their highest gain and output at frequencies lower than 1000 Hz, which increases voice loudness and bass signal, but does not result in improving speech intelligibility in a quiet environment, and certainly not in a noisy environment. The risk is, therefore, very high that the user will increase the gain to be able to understand something, which can result in very dangerous maximum power levels.



V. Conclusion

Analysis of the PSAPs demonstrates that they can reach very high power levels that can result in noise induced hearing loss

The permissible time for safe listening logically decreases as sound levels increase. The image below, taken from the latest WHO "Make Listening Safe" campaign, helps to visualise permissible daily noise exposures at different decibel (dB) levels. It provides examples of various sound levels produced by different objects, and highlights the maximum safe listening duration in hours, minutes and seconds for each dB level. The daily recommended safe volume level of any sound is below 85 dB for a maximum duration of eight hours.

The levels measured in the above mentioned PSAPs have a very high risk of immediate damage to hearing, even if exposure is very short. According to the WHO "Make Listening Safe" scale, such sound levels can only be sustained for less than 2 seconds/day!

Scientific literature[3] also indicates that prolonged exposure to loud sounds (+/- 80-85 dBA[4]) may possibly result in:

- TTS: Temporary (hearing) threshold shift
- PTS: Permanent (hearing) threshold shift
- Tinnitus: Ringing in the Ears
- Poor Speech Communication in Noisy Conditions

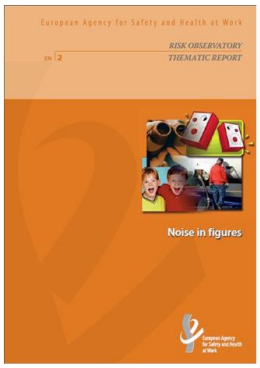
EU institutions previously recognised the need to protect consumers from dangerous sound levels

Directive 2003/10/EC of the European Parliament and of the Council of 6 February 2003 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise) was adopted to ensure that workers use hearing protection when they are exposed to high sound levels.

level	Noise source	Health effects
140dB	Jet plane take off, firecracker, gun shot	Sudden damage to hearing
130dB	Pain threshold exceeded	
120dB	Ambulance siren, pneumatic drill, rock concert	
110dB	Night clubs, disco	
100dB	Motor cycle at 50km/h	
90dB	Heavy goods vehicle at 50km/h	
85dB	Hearing protection recommended in industry	Hearing loss, tinnitus
75dB		Cardiovascular effects
70dB		Sleep disturbances
65dB		Stress effects
60dB		Annoyance
55dB	Desirable outdoor level	
50dB	Normal conversation level	
40dB	Quiet suburb	
30dB	Shoft whisper	
20dB	Normal conversation level	

Source: Nopher, a European Commission concerted action to reduce the health effects of noise pollution. http://www.ucl.ac.uk/noiseandhealth/EC%20Brochure1.pdf

The 27 Personal Sound Amplifier Products – PSAP's!



[3] "Noise in Figures", Risk Obesrvatory Thematic Report, European Agency for Safety and Health at Work, 2005.

[4] Typically, for noise level evaluation in the industry, dBA or A-weighting is used (where the energy at very low frequencies (under 100 Hz) and the very high frequencies (above 5000 Hz) is reduced). For evaluation of hearing aids and personal amplifiers, dBSPL is used (where no weighting is applied). Since these devices provide very little or no gain for very low and very high frequencies (under 100 Hz and above 5000 Hz), there is no real difference between dBA and dBSPL for the purpose of this document.

For the same safety reasons, the European Commission adopted in June 2009 a Decision (2009/490/EC) on the safety requirements to be met by European standards for personal music players pursuant to the General Product Safety Directive (Directive 2001/95/EC). In this Decision, the European Commission set out the following safety requirements for personal music players:

- Exposure to sound levels shall be time limited to avoid hearing damage. At 80 dB(A) exposure, time shall be limited to 40 hours/week, whereas at 89 dB(A), exposure time shall be limited to 5 hours/week. For other exposure levels, a linear intra- and extrapolation applies. Account shall be taken of the dynamic range of sound and the reasonably foreseeable use of the products.
- Personal music players shall provide adequate warnings on the risks involved in using the device and how to avoid those risks, while also providing information to users in cases where exposure poses a risk of hearing damage.

The difference between PSAPs and Hearing Aids is not clear for the consumer

Finally, as demonstrated by the below images, for the end-user it is very hard to see the difference between “hearing aids” (produced with a medical purpose) and “personal amplifiers”.

In short:

- PSAPs have no medical purpose (they are only intended for normal hearing people) and can provide very high and dangerous sound levels;
- Such products are readily available on the EU market;
- For the general public the difference between a “personal amplifier” and a “hearing aid” (a medical device class IIa) is decidedly unclear.

Therefore, the EFHOH and the AEA are calling on all relevant stakeholders to ensure that PSAPs are not used when they exceed unsafe maximum power levels.

A maximum level of 80 dBA – comparable to the personal music systems – can be considered reasonable as long as this level is only used for a maximum of 40 hours per week whereas at 89 dB(A), exposure time shall be limited to 5 hours/week.