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Ultrasound-in-Air: New applications need improved measurement methods and procedures, and appreciation of any adverse effects on humans

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ABSTRACT

In the growing topic of ultrasound in air, innovations in powerful sources and digital signal processing have produced a wealth of proposed devices and applications. However if we are to realize the benefits of these for companies and consumers, the introduction of these new technologies must come in an environment where we can properly conduct standardized field and source measurements with appropriate processes and calibrations, and set exposure limits based on knowledge of the potential for adverse effects on humans: these are difficult areas in which the research base is scarce. This paper covers new devices and applications, the difficulties with measurements and calibrations, and discoveries regarding the potential for adverse effects.

Keywords: Ultrasound, Ultrasonic, Human effects

1. INTRODUCTION

A review of the field in 2016 showed that, whilst there was over 50 years of anecdotal reports of the adverse effects of ultrasound on humans (supplemented by limited laboratory testing), the state of knowledge was insufficient to meet regulatory needs [1]. Although concern throughout the second half of the 20th Century had been sufficient to generate dozens of national and international guidelines that appeared to show broad agreement, the review [1] identified that any consensus was illusory: it did not derive from independent research, but rather by standards-setting bodies (when faced with this difficult problem) assessing the same sparse set of papers in full knowledge of the conclusions reach by previous standard setting bodies. The publicity following this finding led to some physics-based arguments that ultrasound-in-air could not affect humans. The counter-arguments to these were presented in a rebuttal in 2017 [2].

Several areas in measuring ultrasonic sources and fields in air, and on taking appropriate data to set suitable Maximum Permissible Levels (MPLs) for human exposure, were identified as problematic and likely to lead to misconceptions [1,2]. These included:

- reliance on MPLs based on inadequate data to protect a particular individual who had not been measured, given the huge variability in the responses between people, even within the same age cohort [1];
- application of sparse data taken on one age group and gender (adult men) to the broader population (e.g. children) that could be exposed in a public setting [1];
- reliance, when considering public exposures, on MPLs set for occupational exposures (the context of such known exposures would be worker protection against occupational exposure enshrined in law, subject to monitoring, with known and recorded durations for the exposure and 'quiet' times for recovery. Furthermore, the worker would be made aware of the exposure and might (within reason) be required to wear protective equipment) [1];
- use of trends in hearing thresholds as proxies for trends in thresholds for adverse effects [1];
- concentration on adverse effects which are quantifiable by standard audiological means (e.g. temporary and permanent hearing threshold shifts) whilst neglecting adverse effects that may appear at lower exposure levels (annoyance, inability to work and concentrate,



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headaches etc.) [1];

- use of a third octave band categorization of exposures, and MPLs for signals, that are increasingly found to be narrowband [1];
- reliance on sound level meters (and the interpretation of historical data in papers that were taken with such instruments) that meet the specifications of a standard that allows for sound level meters in general usage to underestimate the level of the signal (measured in the 20 kHz third-octave band) to an unlimited degree and still meet the standard [1];
- use of standard physical measurement techniques in place for 'audio'-frequency signals (such as measurement in an anechoic chamber certified as being anechoic for the frequency in question; or mapping sound pressure levels over a 5 cm grid to assess inhomogeneity of the field) that become increasingly impractical or ineffective as the frequency increases into the ultrasonic band [1];
- use of standard audiological measurement techniques in place for 'audio'-frequency signals (such as use of the Reference Equivalent Threshold Sound Pressure Level etc.) that become increasingly impractical or ineffective as the frequency increases into the ultrasonic band [1];
- reliance on the unproven assumption that an acoustic signal that is too high for an individual to perceive, cannot cause an adverse effect [1].

This led to a number of speculative proposals requiring research, such as:

- the hypothesis that the usable dynamic range between the threshold for detection of a sound, and the threshold for adverse effects, will decrease rapidly as the frequency increases towards and into the ultrasonic band [2];
- whilst some manufacturers publish no source levels, and some provide data of dubious quality, those manufacturers who wish to provide accurate information on the levels emitted by their products are poorly served, in that it is not easy for them to access measurement equipment and utilize procedures traceable back to national standards, or use standardized procedures for conducting and reporting such measurements, because the systems that support them in doing so are not fully developed [1];
- the ability to counter claims that no mechanism can be proposed by which a human could suffer adverse effects from acoustic signals they could not perceive [1, 2].

The increasing interest in this field was seen in several countries, with field measurements showing members of the public were being exposed to high levels by pest scarers (e.g. in a restaurant setting, with reports of adverse effects) [3, 4], and audiological tests showing huge variation in the hearing thresholds at high frequency [5]. At the same time, there was increasing awareness in several countries [1, 2, 6-8] that the extraordinarily permissive MPLs set by the US Occupational Health and Safety Administration (OSHA) appeared to rely on the mistaken argument that MPLs set by other countries were based on measurements of adverse effects in which no air gap existed between the ultrasound source and the skin, so allowing OSHA to make its MPLs 30 dB higher than those in other countries. In the most recent version of the OSHA Technical Manual appendix on ultrasound published in 2015, the exception for a 30 dB increase is no longer mentioned [9, 10].

In response to this increasing interest, the Journal of the Acoustical Society published a special issue on ultrasound in air [11], containing:

- three papers that cover human effects [12-14];
- six papers on the measured outputs of commercial devices [10, 12, 15-18];
- one paper that covers ways of categorizing the ultrasonic regimes [19], written in response to the citation by manufacturers of inappropriate guidelines to imply the outputs of their devices are safe [20];
- two papers on calibration [21, 22]; and
- three papers [23-25] on novel applications.

2. NOVEL APPLICATIONS

It is notable that measurements of commercial sources tend to focus on pest deterrents [10, 12, 18] (because they are inexpensive and produce high levels) and Public Address Voice Alarm (PAVA) systems [16-18] (because they recently came to light as inadvertent sources of ultrasound and are relatively common and accessible [1]).

The introduction of inexpensive sources and amplifiers, and digital systems to control and process

signals and array technology, has caused a rapid increase in the number of devices advertised (though some are more practicable than other).

Leighton [1, 26] defined three categories of exposure of humans to ultrasound in air. Category 1 is labelled 'Ultrasonic by-product noise exposure'. This occurs when some process or device (e.g. a jet engine) generates ultrasound as a by-product of its operation. Category 2 is labelled 'Unintended ultrasonic exposure'. This occurs when some process (such as an ultrasonic cleaning bath) requires the generation of a specific ultrasonic signal as key to completing its task, but in addition to insonifying its inanimate target, it also unintentionally exposes a human or animal to ultrasound. Category 3 is labelled 'Deliberate ultrasonic exposure'. This occurs when devices (such as pest deterrents) are designed to expose humans and/or animals to ultrasound in air in order to elicit some subjective response (whether or not the target is the intended species or demographic).

Category 1 (ultrasonic by-product noise) exposures by jet engines led to the first concerns about 'ultrasonic sickness', dating from the 1940s. However all the data were corrupted by the simultaneous exposure of the workers in question to high levels of lower frequency noise [1]. The recent observation of ultrasound from PAVA systems is a newer form of category 1 exposure [1,16-18].

Category 2 (unintended ultrasonic) exposures formed the basis of much of the interest in the second half of the 20th century, but suffered from the same problem as Category 1 exposures, in that the environments in which the humans were exposed usually contained high levels of lower frequency sound. Measurements on subjects tended to focus on the so-called 'objective' symptoms of temporary and permanent hearing threshold shifts. This is in contrast to the earlier researchers who had looked into in Category 1 exposures, and who had included substantial interest in a range of symptoms that the literature refers to as 'subjective' (headache, nausea, tinnitus, a feeling of 'pressure in the ears'). It should be noted that the term 'subjective' refers, not so much to the symptoms themselves, as to the experimenters' abilities to quantify the effect, compared to measuring the 'objective' symptoms of temporary and permanent hearing threshold shift. One notable researcher of category 2 exposures, who included both 'subjective' and 'objective' symptoms in his assessments, was Acton [27-30]. Maccà et al. [31] made an important contribution in 2015 when they attempted to separate out cohorts who had reeived ultrasonic plus lower frequency exposures, from those who had received similar levels of the lower-frequency exposure. They describe their test as follows:

'The [ultrasound-exposed] group comprised 14 subjects recruited in a spectacle frames factory where there were four welding machines (three Branson welders, operating frequency 30 kHz, and one Schoeller, operating frequency 25 kHz); subjects worked continuously at a distance of 30–40 cm from the machines and non-continuously in front of the cleaning tanks. The other 10 subjects were employed in a textile factory; subjects worked at a distance of 30–40 cm from all the machines. They all had ear protectors, but used them minimally; the shift was 6 h and 30min in a day. The intensity levels measured near the ears of subjects exceeded the TLV-C (threshold limit value-ceiling) proposed by ACGIH [American Conference of Governmental Industrial Hygienists] in all sample cutters and label-trimmers at nominal frequencies of 20, 31.5 and 40 kHz, and in two of the cleaning tanks at frequencies of 20 and 25 kHz. All ultrasound emissions were accompanied by subharmonics produced in the audible high-frequency range as by-products of industrial ultrasonic processes'.

They looked at both 'objective' and 'subjective' symptoms. The statistical analysis of their data was revisited by Leighton [1].

Whilst ultrasonic welders, cutters and cleaning bath are clearly category 2 exposures, the involvement of both patient and device operator in the use of dental ultrasonics means that it falls into two categories, depending on which person is under consideration [1]. All the category 2 exposures discussed above (welders, cutters, cleaners and dental instrumentation) have been in use for many decades. In modern times, there have also been significant sums raised to develop the wireless power delivery systems using ultrasound in air, but there is also scepticism in some quarters as to the practicability of an eventual product, and any exposure of humans by these would be category 2.

Category 3 (deliberate ultrasonic) exposures range from the long-standing use of pest deterrents (which, although designed to deter only pests such as rodents and birds, also expose humans to probably the highest levels the public experiences) to more modern technologies, such as the acoustic spotlight (an in-air version of the older parametric sonar), and the use of ultrasonic haptics to give an impression of touch in air using high intensity ultrasound. It is critically important that the development of any device to generate a category 3 exposure is accompanied by appropriate safety

testing. This is not a simple task for manufacturers, given that:

- half a century of measurements have provided us with guidelines that are not sufficiently supported by appropriate data for us to have faith in them [1]; and
- there is significant variation between people of even the same age in their high frequency hearing thresholds (and the use of this as a proxy for adverse effects is questionable) [1].

It is not an enviable situation for a commercial sector of manufacturers and users, to have, on top of this level of uncertainty, a lack of access to measurement equipment, facilities and expertise. This is especially so given that it would be difficult to overstate the importance of critical and rigorous assessments of the safety of established and new devices that generate public exposures (especially of infants and children).

The category 3 exposure that has generated most interest for its potential to produce adverse effects is that of ultrasonic weapons and deterrents aimed at humans. 'Mosquito'-like devices can be purchased to deter teenagers from locations such as shops, although the unlicensed use of such devices is creating concern in the UK Parliament [32], which is exploring licencing to allow the use of such deterrents to keep teenagers from sites where they should not be (such as railway lines), but restrict their use to deter teenagers from shops etc.

Recently there have also been claims of ultrasonic attacks on US Embassy staff in Cuba and China. These reports lack rigorous acoustical data, and in some ways reflect the state of investigation that began interest in 'ultrasonic sickness' in the 1940s [1]. The narrative has undoubtedly been influenced more by political agents and the mass media, than by the scientists (for whom access to any data is very limited). In the case of these claims regarding Cuba, it is particularly regrettable that these attacks have been associated with claims of 'brain injury', when the statistical basis on which to make those claims in the data released to date is flawed [11].

3. CONCLUSIONS

Realization of the benefits to companies and consumers of new devices cannot be based on extension to the ultrasonic range of our audio-frequency measurement protocols (both physical and audiological) [1, 2, 11]. It requires improved measurements, and must be done in the context of filling our current knowledge gap on what signals cause what adverse effects in what subsets of the human population [1, 2, 11]. Whilst technological developments are allowing long-established principles to be realized as practical devices and intriguing prototypes, the priority must be on ensuring that these devices are safe for any of the humans they could expose. It is not possible to do this with the current data on the adverse effects on humans without setting such cautious MPLs as to severely limit innovation.

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