



REPORT

UNDESIRABLE EFFECTS AS A RESULT OF SHORT-TERM EXPOSURE TO AN ULTRASONIC REPELLENT DEVICE

Assignment no. DG5/PB_PP/IVC/13026

By Prof. Dr. Christ Glorieux (part I) and Prof. Dr. Astrid van Wieringen (part II)

Date: 28 July 2014

By order of



Introduction

Since several years, the Directorate-General (DG) Environment of the Federal Public Service (FPS) of Health, Food chain safety and Environment receives complaints about the noise coming from ultrasonic animal repellents. These devices emit high-frequency sound and low-frequency ultrasound, in most cases in a frequency range from 8 kHz to 40 kHz, depending on which animal species should be driven away. There exist no standards for the restriction of the emissions of this type of devices.

There are, however, two authorities who have recommendations on the subject: the International Non-Ionizing Radiation Committee (INIRC/IRPA, 1984) and the Canadian government (1991). For the frequency range from 16 to 20 kHz, both authorities impose a limit value of 75 dB for the SPL for professional exposure. The INIRC/IRPA also gives a value for the exposure of the general public, namely 70 dB at 20 kHz. Respecting these limit values should give protection against symptoms such as nausea, headache, vomiting, pain, disturbance of coordination, dizziness, fatigue, and against possible hearing loss due to prolonged exposure. For ultrasound between 25 kHz and 100 kHz, INIRC/IRPA advises a limit value of 100 dB.

In a preliminary study, the sound pressure level (SPL) of 7 ultrasonic animal repellents was measured (AIB Vinçotte, 2011). In this study, some of the devices produced a sound pressure of more than 70 dB at frequencies between 16 and 20 kHz, and some can produce more than 100 dB at frequencies above 20 kHz at a distance of one meter.

This preliminary study only gives the SPL, and these numbers do not give sufficient information on the undesirable effects that people can experience due to the sound these devices produce. In literature, effects are only reported at high SPLs (more than 100 dB).

In view of the development of a proper policy, DG environment has ordered this study, in which subjects were exposed to SPLs as expected with normal use of an animal repellent device. For this study, we have chosen a device that has been measured in the preliminary study and which gives high SPLs at a broad range of frequencies (settings), and with which an extra loudspeaker can be used.

This report consists of two parts:

Part I: acoustic measurements

In view of accurately knowing the sound pressure during the exposure tests, the tests that were performed earlier by Vinçotte, were repeated for the same settings used in the exposure tests. In addition, the effect of possible reflections of objects in the surroundings and the relative position of the person's head with respect to the position of the ultrasonic device was examined.

Part II: exposure of volunteers

In this part of the study, two groups of volunteers were exposed to the emissions of the device: one group of young subjects aged between 18 and 25 years, and the other group of middle-aged subjects ages between 46 and 58 years.





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PART I - ACOUSTIC MEASUREMENTS

By Prof. Dr. Christ Glorieux, Geert Dierckx (part I) Laboratorium voor Akoestiek en Thermische Fysica Departement Natuurkunde en Sterrenkunde Katholieke Universiteit Leuven Celestijnenlaan 200D 3001 Heverlee, Belgium

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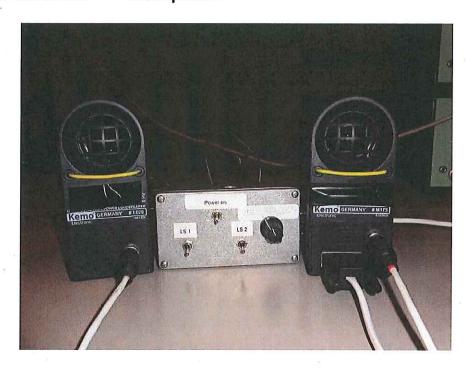
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1. Motivation and methodology

The impact of the exposure to ultrasonic animal repellent devices is determined by the sound pressure spectrum at the person's position, in addition to his or her audiometric profile. The sound field is determined both by the sound emissions (electroacoustic features) of the device and by the transfer of the acoustic waves from the device to the person, which in turn depends on the positioning of the device with respect to the person (distance and direction), possible reflections of objects in the surroundings and the relative position of the person's head with respect to the position of the ultrasonic device. In order to determine the impact of the high frequency sound emission by a device, it is of great importance to have accurate information on the sound pressure level and spectral characteristics of the (ultra)sound at the position of the ears of the persons during exposure tests, and adequate understanding on how the factors above affect the (ultra)sound the person is receiving during the exposure tests, and in real life situations.

In order to achieve this, preliminary measurements were organized to characterize the influence of all possible factors on the sound field generated by the device of interest, for different device settings: the positioning of the measurement device, the position of the test person and the presence and nature of sound reflecting surfaces in the surroundings.

The tests were performed in a semi-anechoic measurement room (residual noise level < Lp = 0 dB), mimicking free-field conditions, which was ideally suited to control and reproduce all environmental factors for all tests and measurements.



NL Extra hoge tonen luidspreker voor

Luidspreker voorLuidspreker (optie) voor Kemo
nen dierenverjager, hiermee 1 u het acoustische gebied
vergroten. Niet mee geleverd is een 2-aderig aansluitsnoer van
max, 50 mtr, > 2 x 0,5 mm². De kuidspreker moet zo
gemonteerd worden, dat water niet in aanraking komt van de
luidspreker bijvoorbeeld onder de dakgoot. Een led is als
indicatie, De kabel wordt via een 2-poljee klem aangesloten
onder de schuifklep van de extra luidsprekers. De extra
luidspreker moet zo gemonteerd worden dat er geen obstakels
voor staan, die beperkt het geluidsgebied.

Voor staan, me bepeare het gegevenst:

Geluids druk: max. 135 db ± 30% | Acoustische reikwijdte: max. 100 mtr | Luidspreker: High-power-ukrasoon-met kunstofmembraan | Afmeting: ca. 140 x 65 x 37 mm

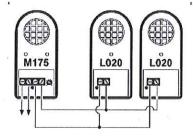


Figure 1. Top: Photo of the slightly modified and the control-box used for inaudibly switching between different device settings. Bottom: extract from the technical specifications of the device type and loudspeaker

The device is constructed in such a way that the emitted frequency range is set by a turning button connected with a potentiometer. The button is provided with an indicator that points to a scale graded from 0 to 10. The product specifications give a rough numerical indication of the corresponding (ultra)sound frequency ranges. Since the button rotation is continuous, its position can be subject to deviations, leading to frequency variations of the order of 1 kHz.

In order to ensure reproducibility of the frequency range during all tests, and to allow switching the device settings by the operator inaudibly and invisibly for the test person, the original potentiometer was replaced by a circuit containing 3 analogous potentiometer,

which could be swiftly selected by making use of a switch with 3 positions. The potentiometers were set in order to reproduce button positions 5 (frequency range 12 kHz – 15 kHz), 8 (frequency range 24 kHz – 29 kHz) and 9 (frequency range 36 kHz – 42 kHz). The sound pressure level of the device was determined for these 3 positions, without and with activation of the additional L020 loudspeaker, resulting in 6 scenarios.

The background noise level in the semi-anechoic room in which the device characterization tests were performed was less than Lp = 0 dB. In the semi-anechoic room where the exposure tests were performed, the overall background sound pressure level was 21.5 dBA. In all cases, except for the test episodes with the device switched off, the total sound pressure level in the frequency range covering the (ultra)sound emission band was dominated by the sound field of the device.

The -device and the loudspeaker were placed at 6.5 m from the measurement-device and about 3.8 m apart.

In order to determine absolute sound pressure levels and signal spectra (linear and in 1/3 octave-bands between 20 Hz and 46000 Hz), the following equipment was used:

- Calibrated condenser microphone B&K type 4138 (flatness of 1 dB between 20 Hz and 50000 Hz)
- B&K measurement amplifier type 2606 (bandwidth 200 kHz)
- Roland Studio Capture audio interface (sampling frequency 96 kHz, 24 bits, -90 dBu noise level)
- B&K dual channel real-time frequency analyzer type 2144 for calibration and noiselevel performance of the measurement chain up to 20 kHz)
- DANKA Calibrated B&K pistophone-calibrator as level-reference at 250 Hz.
- B&K 4231 1 kHz, Lp=94 dB calibrator for reference calibration.

For each scenario of interest, a wave file was recorded and the spectrum was calculated by a Fourier transform routine. In order to scale the amplitude of the signals and spectra, a reference wave file was recorded while placing the microphone in 1 kHz, Lp = 94 dB calibrator, using the same settings for the hardware and the data processing. In cases where the (ultra)sound emission was of the same order of magnitude as the broadband electronic background noise, the corresponding (ultra)sound level was determined in the frequency window of the (ultra)sound emission band, thus discarding possible contributions of the background noise to the determined sound pressure level. It should be noted that this electronic background contribution was generated in the measurement chain and therefore of purely electronic reason, and hence not an indication of audible noise. Two approaches were taken to determine the sound pressure level experienced by the test persons during exposure sessions. In the first approach, the signals were acquired for the microphone at 6.5 m from the loudspeaker(s), in order to directly result in the quantity of interest. In the second approach, the sound pressure level was determined at one meter from the source(s). In this scenario, the signal to noise ratio of the data was better than at 6.5 m. Since at 1 meter from the source(s) far-field conditions could be assumed, the sound pressure level at 6.5 m could be calculated from the one at 1 m by applying a geometrical reduction factor

R=2010log(6.5/1)= 16.3dB, and a frequency dependent atmospheric absorption factor, which was taken to be

 $A=0.002(f/1000Hz)2 dB/m \times (6.5m-1m)$, with f the frequency.

Since in reality ultrasound attenuation is strongly temperature and humidity dependent, with a temperature and humidity dependent frequency dependence (ISO 9613-1), the latter equation gives only a very rough approximation of the real value, but can be considered as indicative.

All values are listed in Table 1. Overall, the measured values are between 9±4dB and 17±4dB higher than the theoretically calculated ones. The discrepancy is partly due to inaccuracies of the geometrical attenuation model (ideal point source), of the atmospheric absorption model (simplified frequency dependence, and neglecting humidity and temperature effects), spurious contributions of electronic noise, and contributions of soil reflections. However, the main reason lies in the substantial directivity of the devices, which results in increasing concentration of acoustic energy in the frontal direction, towards the evaluation position, with increasing frequency (see further Section 3).

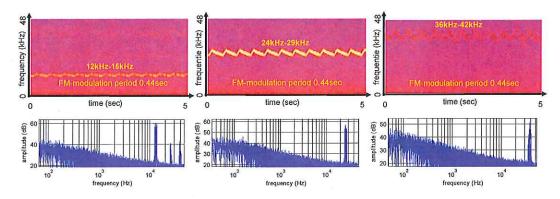
Table 1

		100				
Device setting	7	Lp in dB at 1 meter calibrated with 94 dB 1 kHz reference	Geometrical correction 1→6.5m dB	Air attenuation correction dB	Extrapolated SPL L _p (dB) at 6.5 m including geometrical and attenuation correction	SPL L _p (dB) measured at 6.5 m from the source(s)
5	Source 1	80±2	-16.3	-1.7	62 ± 3	71 ± 2
(12-15 kHz)	Sources 1+2	80±2	-16.3	-1.7	62 ± 3	74 ± 2
8	Source 1	76±2	-16.3	-6.9	53 ± 2	70 ± 2
(24-29 kHz)	Sources 1+2	81±2	-16.3	-6.9	58 ± 2	75 ± 2
9	Source 1	75±2	-16.3	-13.5	46 ± 2	63 ± 1
(36-42 kHz)	Sources 1+2	78±2	-16.3	-13.5	49 ± 2	66 ± 1

As a consequence of the dissipative attenuation increasing with increasing frequency, the sound pressure levels decline with increasing frequency. For an interpretation on the subjective loudness perception, we refer to part 2 of this report.

The sound pressure levels for 2 sources in Table 1 are systematically higher (0 dB to 5 dB) than using only 1 source. For non-coherent sound we expect, for 2 equal sources at the same distance to the receiver, an increase of 3 dB. In our case, the sounds had a narrowband character with a relative slow frequency modulation (see further). Such a situation, with

fairly coherent sources, can lead to very strong location-dependent interferences between the 2 sound waves from the respective sources. The distances at which the interference switches between constructive and destructive are of the order of half the wavelength, and range, for settings 5, 8, 9 respectively, around 1.2 cm, 0.7 cm and 0.5 cm. In case of totally constructive interference between 2 equally strong sound waves, an increase of 6 dB is expected compared to the level of a single source. In the case of perfect destructive interference, a theoretical extinction (up to the level of background noise) could occur. In these measurements, with amplifications between 0 dB and 5 dB (Table 1), there was moderate destructive till substantial constructive interference.



25kHz-10cm (extra-20dbtov94)2LS.wav

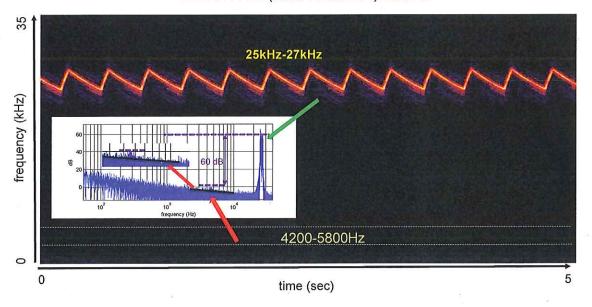


Figure 2. Spectrograms and overall spectra of _____-generated (ultra)sound. Top: from left to right: 13.5 kHz, 26.5 kHz, 39 kHz. Bottom: detailed view of the 26.5 kHz spectrogram and spectrum. Careful inspection of the low frequency range of the spectrogram reveals a faint peak in the audible frequency range between 4.2 kHz and 5.8 kHz.

Due to the strong frequency dependence of the sensitivity of the human ear, it is of high importance to have information on spectral content of the measured sound, besides the global absolute sound pressure level. By inspecting the spectra and spectrograms (Figure 2),

and by listening to recordings played at a lower sample frequency, we could evaluate a strong tonal character with peaks around 13.5 kHz (setting 5), 26.5 kHz (setting 8) and 39 kHz (setting 9), with smaller peaks around the harmonics (harmonic multiples of the fundamental frequency). Further investigation reveals some faint spectral content at frequencies far below the nominal (ultra)sound frequency (in Figure 2, there is audible spectral content between 4 kHz and 5 kHz). We have verified that this electronically generated sound component was always present, albeit with a fluctuating character and magnitude. For settings 5, 8, 9. the frequency of the main peak is modulated with positive and negative variations between respectively 12 kHz-15 kHz, 24 kHz-29 kHz and 36 kHz-42 kHz with a modulation rate of about 3 Hz. Given the slowness of modulation, the character of the sounds is tonal on a short time scale, with a well-defined spectral peak. The long term averaged spectra contain bands with the ranges listed above. The slow FM (sirenlike) effect could easily be heard, when playing back the sounds at the recording sample rate (12-15 kHz signal – setting 5) or at a sampling rate that was slowed down to transfer the spectrum to the audible range.

3. Experimental evaluation of the parameters influencing the sound pressure levels at the listening position

The exposure tests were performed in the standard scenario, for which the sound levels, determined by the measurements described above and listed in Table 1, were applicable. However, it is also important to know the sound levels for different conditions that can occur in real life circumstances:

• Distance between source(s) and measurement/listening-position. As an effect of the geometrical expansion of the wave front as a function of distance to the source, the sound pressure level decreases as a function of this distance. In the approximation of a point source, the wave fronts are spherical and the sound pressure amplitude decreases inversely proportional with distance, implying a decrease of 6 dB per double distance or 20 dB per tenfold distance. The validity of this approximation is demonstrated by the measurements of Figure 3. Because of additional attenuation of sound waves by air-dissipation, an effect that increases by higher frequencies and thus becomes of substantial relevance for high frequency sound, there is an additional decrease of the sound pressure level with increase of distance, of about 0.002 x (f/1000Hz)2 dB/m. For the frequency ranges 12-15 kHz, 24-29 kHz and 36-42 kHz this means respectively 0.3 dB per meter, 1.3 dB per meter en 2.5 dB per meter, or for the standard-scenario source-measurement position of 6.5 m this leads to 2.0 dB, 8.5 dB and 16.3 dB respectively. The high increase of attenuation with increasing frequency explains the sound level values of Table 1 at 6.5 m distance at the higher frequencies.

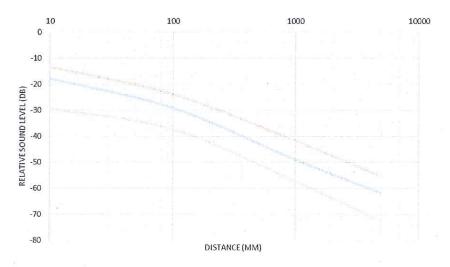


Figure 3. Relative decrease in dB of the sound pressure level produced by the —device as a function of the distance to the device, for 3 discrete frequency settings (top to bottom: device setting 5, 8, 9).

• Since the dimensions of the —device for the used frequencies are higher than the wavelengths for the 3 frequency settings, the radiation pattern is not isotropic. The sound is emitted most efficiently (up to 25 dB stronger) in the direction along the speaker membrane axis. *The directivity of the source* for the 3 discrete frequency settings are shown in Figure 4. The highest part of sound is radiated in an opening angle of 60°-80°. During the exposure tests, the device membrane pointed towards the test person (00 in Figure 4).

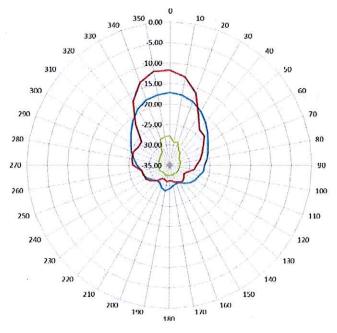


Figure 4. Dependence of the relative sound pressure level in dB on the orientation of the device with respect to the connecting line between the source and the measurement location (0: front of the source pointed to the measurement location, 180: backside of the source pointed to the measurement location), for setting 5 (blue), 8 (red) and 9 (green).

Also the acoustical shadow effect of the human head and the pinna of a person, which is determined by the orientation of the head with respect to the connecting line between the head and the source has an influence on the effective sound level at the level of the inner ear. This is shown in figure 5. The sound pressure level was measured with a sensitive microphone that was connected near one of the inner ears of an artificial head. The orientation of the artificial head was rotated in the horizontal equator plane of the source. There is a clear increase of the level when the microphone at the inner ear is positioned in the direction of the source, compared to the level for the diametrical position, on the other side of the artificial head. As expected there is less diffraction around the head as the frequency increases, and thus more acoustical shadow effect with increasing frequency: the front-back ratio is about 10 dB at setting 5 and 20 dB at setting 8. During the listening-tests, the front head of the test persons was pointed towards the source, corresponding with angles of 90° and 270° for the left- en right ear respectively. Interestingly, although the artificial head is left-right symmetrical, the measured values are not. This is a consequence of the measurement scenario, in which the microphone was placed very close to the artificial head. Due to the coherent, tonal character of the sound, such a situation leads to interference effects, where subtle details in the head orientation and distance between the microphone and the head, determine whether the combination between incoming waves and sound waves reflected off the head-surface leads to full or partially destructive or constructive interference. The interference induced variations amount up to 10 dB.

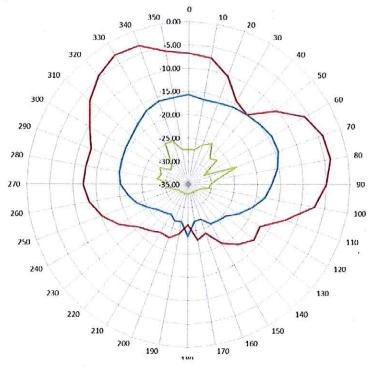


Figure 5. Dependence of the relative sound pressure level in dB for the orientation of the artificial head with the microphone positioned at the right ear, with respect to the connecting line between the source and the measurement location (0°: right ear and microphone point to the source, 180°: left ear points to the source), for 3 frequency settings: 5 (blue), 8 (red) and 9 (green).

• In a real life situation, besides reaching a person via the shortest possible, direct way, the sound of a source can also reach the person through reflections by objects in the surroundings. In a closed space with strongly reflecting surfaces, this can lead to many echoes with strong reverberant level enhancement as a consequence. In case the

device is placed outdoors, also the reflection of the ground is of importance. In case of a concrete soil, the reflection approaches 100%. In order to assess the effect of reflections in a garden, we have also determined the high frequency sound reflection coefficient of a grass soil. A setup was built in which broadband sound (5-50kHz) was generated by a spark source, reaching the microphone directly and via reflection off a slab of grass soil (Figure 6). The measurement (Figure 7) shows the arrival of the direct (via the air) sound wave excited by a spark, and, somewhat later due to the longer pathway, the arrival of the wave reaching the microphone after reflection by the grass surface. The second wave packet has a much smaller amplitude, which can be attributed to a small reflection coefficient of grass. By taking the spectrum of the reflected and direct wave packet and by taking into account the travelled distance, the reflection coefficient of the grass-soil was determined. Although, as a consequence of the small amplitude of the reflected wave and of not flat source spectrum, the calculated reflection coefficient (Figure 8) shows quite some irregularity, the reflection coefficient can be roughly estimated at 0.25, or -6 dB. The possible increase in sound pressure level due to reflection of a grass surface therefore will always be limited to maximum (constructive interference, neglecting the path length difference between the direct wave and the reflected wave) 2010log(1+0.25) = 2 dB. In the case of a hard concrete soil, the ultimate increase would be $2010\log(1+1) = 6$ dB.



Figure 6. Experimental setup to determine the acoustical reflection coefficient of a slab of grass soil till high frequencies by means of a spark source (near to the red dot) and a high frequency microphone.

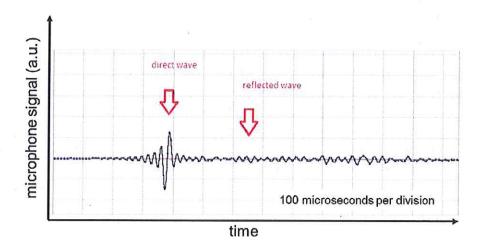


Figure 7. Arrival of the direct wave packet, excited by the spark, and the wave packet that reaches the microphone after reflection from a slab of grass soil.

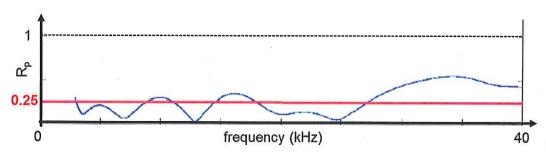


Figure 8. Spectrum of the acoustic reflection coefficient (for pressure)

4. Summary

The sound levels at the test person reception point, at 6.5 meter from the device, for the 3 investigated device settings (5, 8, 9), listed in Table 1, ranged from Lp = 45 to Lp = 67dB. Addition of a second loudspeaker led to an increase between 0 dB and 5 dB. The level differences between the different device settings can be explained by the increasing attenuation at higher frequencies, which is substantial at 6.5 meter distance. Also the influence of determining factors in real life situations were tackled and quantified: the distance between the source and the person, the directivity of the source, the shadowing effect of the human head, the contribution of the reflection by a concrete or grass soil to the total sound pressure level. The measurement and test protocols were set to assess with maximum reliability the conditions during the exposure tests.





REPORT

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Assignment no. DG5/PB_PP/IVC/13026

Part II - EXPOSURE OF VOLUNTEERS

By Prof. Dr. Astrid van Wieringen (part II) KU Leuven-University of Leuven Dept Neurosciences, Experimental Oto-rhino-laryngologie Herestraat 49 (box 721) 3000 Leuven Belgium

28 July 2014

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Abstract

Aim: The objective of the present study is to investigate undesirable effects after exposure to an ultrasonic repellent. This is done for 25 young and 25 middle-aged persons, all with normal hearing thresholds in a quiet room.

Methodology: the subject was exposed to 8 experimental conditions at random order: 3 frequencies/settings x 2 loudspeaker settings + 2 dummy conditions (= no signal). Each condition lasted 20 minutes. In addition to objective measurements (high frequency audiometry and otoacoustic emissions) possible undesirable effects were investigated by means of a 15-item survey presented before and immediately after each condition.

Result: The main conclusions are that relatively short exposure (20 min) to the 3 frequencies and 2 sources under test does not lead to significant undesirable effects (eg. headache, tinnitus, nausea). However, the frequencies and levels are considered disturbing by those who can perceive them.

Remark: Some settings of the ultrasonic repellent were not investigated in this study. One of the reasons was that their respective emissions were considered so loud and annoying that it was agreed that prolonged continuous exposure would not be possible.

1. Introduction and aim of study

The aim of the present study is to investigate possible undesirable effects caused by short-term exposure to an ultrasonic repellent. These devices are designed to repel birds, rodents and insects by emitting high-pitched sounds (almost) inaudible to the human ear. Although the airborne ultrasounds are often above the upper level of human hearing they can still cause undesirable effects (fatigue, headache, tinnitus, nausea,...). These effects have mainly been reported for high exposure levels, i.e. higher than 100 dB SPL (eg. Acton and Carson, 1967; Ahmadi et al., 2012). As a result of industrial applications using airborne ultrasound several recommendations on exposure limits and guidelines for safe use are reported in the literature (Guidelines for safe use, 1991; Howard et al., 2005; Leighton, 2007). In the current study exposure to airborne ultrasound will be investigated for levels of exposure lower than 100 dB.

The human ear is very sensitive: a healthy young person hears all sound frequencies from approximately 20 to 20 kHz. The upper level of hearing becomes lower with age, but can still be relatively high, as is recently reported by Rodriguez et al. (2014). Young persons (19-29 yrs) can perceive a 20-kHz tone if it is presented at 100 dB SPL, while middle-aged persons (50-60 yrs) perceive a 16 or 18 kHz-tone at the same sound pressure level. For more 'normal' sound pressure levels, i.e. between 60-70 dB SPL, healthy middle-aged persons perceive up to about 14 kHz.

The objective of the present study is to investigate undesirable effects after exposure to an ultrasonic repellent. This is done for young and middle-aged persons, all with normal hearing thresholds between 125 Hz and 8 kHz. Testing is done in a quiet (semi-anechoic) room. It is expected that any undesirable effects would appear more prominently for persons with normal hearing than for those with (high frequency) hearing impairment, and also more pronounced in a quiet environment than in an environment where the ultrasonic tone is masked by noise. Moreover, it is expected that younger persons would experience more undesirable effects than middle-aged persons as a result of the decreasing range of hearing with increasing age.

2. Characteristics of the ultrasonic repellent

In this study the ultrasonic repellent from type is tested. It produces a (frequency modulated) high-frequency sound and ultrasound (> 20 kHz) in 10 different settings between 8 kHz and 43 kHz. See part I for more details on the signals. In order to achieve the best results the frequency range should be between 10-12 kHz for birds, between 20-30 kHz for rodents, and between 30-40 kHz for insects. Based on this information the following 3 frequencies were chosen for evaluation, one for each species, nl. 12.5 kHz, 25 kHz and 35 kHz. These frequencies correspond to settings 5, 8, 9 of the device, respectively. Lower settings, from 1 to 4, were not investigated for two reasons: 1) they emit lower frequencies than advised for repelling birds, and 2) in a pilot test, exposure to their respective frequencies was considered so loud and annoying that it was agreed that prolonged continuous exposure would not be possible.

The device is tested for two different loudspeaker settings, 1) using the internal loudspeaker (source 1), and 2) also together with an external loudspeaker (source 1+2). The ranges of effective sound pressure levels, measured at the position of the subject seated behind the table, are listed in table 1. On average, adding the 2nd source results in an increase of 3 dB.

Table 1. Effective sound level pressure values for the 3 tested frequencies and for 1 and 2 sources. The range indicates the lowest and highest of 4 values, measured at 4 locations (= chairs) behind the table. Measurements were done by G. Dierckx at Acoustics and Thermal Physics, Campus Heverlee.

Frequency, (setting)	Source	SPL		
12.5 kHz, (5)	Source 1	65 - 68.2 dB		
	Source 1+2	69.3 - 71 dB		
25 kHz, (8)	Source 1	55.6 - 58.4 dB		
	Source 1+2	60.3 - 64.6 dB		
35 kHz, (9)	Source 1	44.6 - 46.2 dB		
	Source 1+2	47.4 - 50.0 dB		

3. Montage

Testing took place in a semi-anechoic room on the 4th floor of the research team Acoustics and Thermal Physics on the Science Campus in Heverlee (Leuven). The room size is $6.8 \times 2.1 \times 13.1$ m. Because of the directive radiation emitted by the repellent the two sources were mounted at a height of 2.40m on two pillars in the corners of the room (cf circles in figure 1). The distance between the two pillars was 4.6m. The two sources were positioned at 6.5m from the subject, according to the specifications of the manual. The subjects were seated behind the table (front of figure 1). Eight different conditions (see further) were controlled at random order by a custom-made cable linked to a computer placed outside of the testing room.

The room itself was shielded (see figure 1) and very quiet. However, a soft high-pitched sound, presumably originating from the floor above, was sometimes audible. Prior to testing subjects were informed that this tone had nothing to do with the experimental conditions and had to be ignored as much as possible. After exposure to an experimental condition and before filling out the survey the subject was reminded of the 'extra tone' as not being part of the survey.

The test room itself was occupied for 2½ hours (8 x 20 minutes) by at least two persons at a time for safety reasons (test leader cannot hear from the outside if something is wrong inside the room).



Figure 1. Montage of ultrasonic device and position of the subjects re exposure. Location: 4th floor Acoustics and Thermal Physics on the Science Campus in Heverlee.

4. Quantifying undesirable effects

In addition to the objective measurements (high frequency audiometry and otoacoustic emissions) possible undesirable effects were investigated by means of a 15-item survey presented immediately after each condition. The survey was custom-made, and designed on the basis of the most likely complaints reported by persons and/or in the literature. Subjects were required to respond to yes/no or open questions and rate their level of agreement or disagreement on a symmetric 5-point agree/disagree scale for a series of statements (1=absolutely not to 5= very severe). This Likert-type rating method is one of the most widely used approaches to scale responses (Burn and Burns, 2008). The survey contained two parts. Part I, which was filled out before the experiment, consisted of a few general questions (gender, date of birth, medical history with regard to hearing and vestibular function). Do you have experience with ultrasonic repellents (yes/no)?, and do you wear ear plugs (yes/no)? This was followed by the 15 item survey in order to have a baseline.

15 items of the survey, scored on a Likert scale between 1 (absolutely not) to 5 (very severe)

- 1) I am sensitive to loud sounds
- 2) I am sensitive to high sounds
- 3) I am sensitive to low sounds
- 4) I feel nauseous
- 5) I have a headache
- 6) I am dizzy
- 7) I have a pressing feeling in my ears
- 8) I have pain in my ears
- 9) I have tinnitus
- 10) I feel tense

- 11) I feel tired
- 12) I feel warm
- 13) I feel uneasy
- 14) I feel frightened
- 15) I feel... (open comment)

After exposure to each of the 8 conditions (see 6.2), part II of the survey was filled out. It consisted of a few general questions: Did you hear a sound in addition to the sound that is always present in the room? (yes/no) If so, 'how did you experience the sound?' (nice, neutral, unpleasant, very unpleasant), and 'did you get used to the sound?' (yes - I don't know- no), and 'Please describe the sound'. Subsequently, the subject had to respond to 12 items, the 11 ones indicated in bold above and also included in part 1 (questions 4-14), as well as one additional question "During the test I could not concentrate on what I was doing". This was done on a visual-analogue scale (1-5) on paper.

5. Subjects

Two groups of 25 normal hearing subjects voluntarily took part in the listening experiments. The young adults, between 18 and 25 yrs, and the middle-aged persons (between 46 and 58 yrs) were recruited through personal contacts, flyers, the FPS Health intranet and Facebook page). The distribution male/female was 12/13 in the young group and 11/14 in the middle-aged group. Prior to being included in the listening experiment their hearing thresholds were determined by means of pure tone audiometry to ensure audibility in the 'normal range' (octave frequencies between 125 Hz – 8000 Hz, cf 6.1.1 for audiometric procedure). This screening was usually done at their homes. Approximately double of the screened middle-aged persons were not included as subjects. After subject selection the hearing thresholds in the *high frequency region* were determined of all subjects prior to commencing the experiment (see 6.1.1).

The study is approved by the Medical ethical committee of the University Hospital Leuven (B322201318943). Subjects were informed by means of a letter and signed an informed consent. They were paid 30€ for approximately 4 hours in total. Data were analyzed anonymously. The conditions were administered by four students as part of their Master thesis of Speech pathology and Audiology sciences 2015.

6. Protocol

The protocol consisted of objective tests (high frequency audiometry and otoacoustic emissions) to measure hearing sensitivity to the high tones and a survey to quantify possible undesirable effects. The audiometric tests were carried in the room next door to the test room (with ultrasonic repellent).

6.1. Pre exposure

6.1.1. High frequency audiometry

Before testing the hearing thresholds of the left and right ear were determined in the high-frequency region, between 1kHz and 16kHz, the frequency range of the high-frequency audiometer. Pure tone thresholds for these frequencies were determined using a portable audiometer (Orbiter

922 version 2, Madsen Electronics) with a HDA200 Sennheiser circumaural headphone. The equipment was calibrated according to the manufacturer's recommendations and ISO 389-5 (International Organization for Standardization 2006). Thresholds (=minimal audible tone) were determined using the Hughson-Westlake 1 down-1 up method. In this procedure the subject is presented with a tone of a certain frequency and level. If the tone is audible the level is decreased by 5 dB (example figure 2). This is done until the tone is inaudible. Subsequently, the level of the tone is increased (and decreased) until the clinician is convinced of the minimal audible tone. This is procedure is done for several frequencies (see x-axis figures 3 and 4) and for the left and right ear separately.

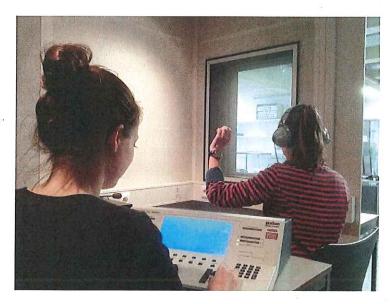


Figure 2. Example of audiometry through headphones

6.1.2. Distortion product otoacoustic emissions (DPOAE)

Otoacoustic emissions are sounds produced either spontaneously or evoked by the cochlea, specifically the outer hair cells, and measured in the outer ear canal. They are generated in the cochlea in response to two tones of a given frequency and a certain sound pressure level presented in the ear canal. The probe assembly in the ear canal contains a loudspeaker that generates the acoustic stimulus and a microphone that measures the resulting OAEs that are produced within the cochlea and then transmitted back through the middle ear into the outer ear canal. DPOAEs are an objective indicator of normally functioning cochlea outer hair cells. The resulting emission is picked up by the microphone, analyzed, digitized and processed by the specially designed OAE hardware and software. The recorded OAEs, which are very low-level, are differentiated from the ambient background noise by the software provided within the equipment. If there is damage to the outer hair cells, which produce hearing loss, then the OAEs will not be present. DPOAEs were determined in a quiet room on location with a portable system (Otodynamics OAE IL Ov6).

6.2. Exposure

Prior to exposure the subject was asked to fill out part I of the survey. Subsequently, the subject was exposed to 8 experimental conditions at random order: 3 frequencies x 2 loudspeaker settings. + 2 dummy conditions (= no-signal). Each condition lasted 20 minutes. During exposure the subject was allowed to read, play with tablet, however not type on a keyboard, talk, or make specific noises. After each 20-minute exposure the subject was required to fill out a 15-item questionnaire.

6.3 Post exposure

Pure tone thresholds were only determined before exposure, as it is quite a time consuming task, and because the step size/error is in the order of 5dB. Moreover, a pilot test with 3 subjects showed no significant pre-post difference. DPOAEs were measured before and at the end of the testing session. Although all subjects were normal hearing (a criterion to be included) and therefore the OAEs are expected to be present, the comparison pre-post exposure may yield first signs of 'damage' as a result of exposure which do not show up in the pure tone audiometry.

7. Results

We will first discuss the audibility of sounds for the normal and high frequency ranges, separately, and then the distortion product otoacoustic emissions and possible undesirable effects.

7.1 Audibility of high frequency sounds

Threshold values in the normal frequency range, averaged across the two ears, are shown for young and middle-aged subjects separately in Figure 3. They are illustrated in terms of hearing loss: 0 dB HL is the norm value for young subjects, and the higher the value the poorer the hearing. Although the threshold values are significantly lower for the middle-age subjects than for the younger ones (t-test, p < 0.001), most values are lower than 20 dB HL (0 dB HL is the norm). All subjects are normal hearing, and the somewhat lower thresholds values at 8 kHz mark the onset of presbycusis in the middle-age range.

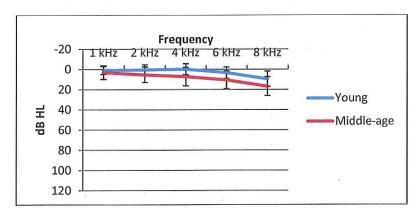


Figure 3. Average threshold values of the young and middle-age subjects in the normal/speech frequency range between 1 and 8 kHz.

Threshold values in the high frequency region (> 10 kHz) are plotted in figure 4 in terms of dB SPL (not dB HL). This is done for the sake of comparison with the sound pressure levels listed in table 1 and in order to compare with the recently reported norm data of Rodriguez et al. (2014). Our high-frequency threshold data are similar to the ones reported by Rodriguez and colleagues. At 16 kHz the younger subjects can perceive the tone clearly (60 dB SPL). However, the middle-aged subjects require at least 100 dB SPL to 'just' perceive this frequency. The standard deviation of this value is somewhat smaller than of the younger group as it only includes values of 15/25 persons. Ten subjects could not perceive this frequency at all.

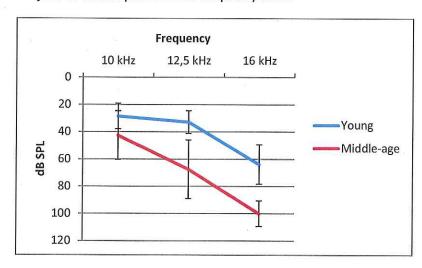


Figure 4. Average hearing thresholds of the younger and middle-aged participants for 10 kHz, 12.5 kHz, and 16 kHz. Data are given in terms of dB SPL.

Table 2. Percentage of subjects who reported that they had heard a signal after exposure for 20 minutes.

	Youngsters	Youngsters	Middle-aged	Middle-aged		
	Source 1 in %	Source 1 + 2 in %	Source 1 in %	Source 1 + 2 in %		
12.5 kHz (setting 5)	100	100	100	92		
25 kHz (setting 8)	24	100	36	63		
35 kHz (setting 9)	8	48	12	48		
No signal/dummy	4	4	0	20		

7.1.1 Discrepancy between threshold values and self-report

Given these threshold data (figure 4) it is rather surprising that all subjects reported in their survey that they could hear the 12.5 kHz signal (Table 2) while the sound pressure levels (Table 1) are lower than the just perceivable sound pressure levels of middle-aged persons at this frequency. Although it was not possible to measure hearing thresholds at even higher frequencies it is expected that even higher sound pressure levels are needed to just detect the (higher) frequency (if the subject can detect it at all). In view of this it is strange that the 25 kHz tone was perceived by all the young persons and 63% of the middle-aged subjects when 2 sources were administered (approximately 65 dB SPL, Table 1). With only 1 source approximately 30% of the young and middle-aged subjects

reported that they heard a signal. At the highest frequency nearly 50% of both age groups report that they perceive a signal when two sound sources are on.

Analyses of the characteristics of the signal reveal, apart from the frequency which should be emitted according to the manufacturer, smaller peaks around the harmonics (see part I). Further investigation reveals some faint spectral content at frequencies far below the nominal (ultra)sound frequency (in Figure 1 in part I, there is audible spectral content between 4 kHz and 5 kHz). If the signal (or harmonic) is perceived it is often considered disturbing: in the lowest frequency region. Most persons described this signal as a high frequency varying chirp ('cricket'), more faint with 1 source than with 2 sources, but still 'distressing' or 'very distressing'. In the middle-frequency range the sound was described as a faint intermittent chirp sound, more neutral and only disturbing for four young subjects and five middle-aged subjects with two sources. With 1 source the sound was described as neutral. In the high frequency region those who reported hearing the signal (= mostly with 2 sources) described the sound as a neutral soft buzzing sound, only disturbing to 1 person in the middle-aged group.

Irrespective of whether exposure causes undesirable effect or not it is clear that the lowest settings are audible to the young and middle-aged persons and that these audible signals are considered disturbing. These results imply that even lower frequencies (settings) would be perceived as even more disturbing, especially with two sources (or with one source at a shorter distance from the subject).

7.2 Distortion product otoacoustic emissions (DPOAE)

DPOAES were determined for the purpose of screening, not diagnostics. If exposure to an ultrasonic repellent produces damage to the cochlea the values post exposure should be lower than those determined pre exposure. An OAE response is present if it is 6 dB above the noise floor of the recording. If it is absent this *may* indicate hearing loss, but some caution is warranted and additional testing is recommended. Recall that all subjects in the present study have (clinically) normal hearing thresholds and that therefore OAEs should be present in most subjects¹. DPOAE values are somewhat lower for middle-aged subjects than for younger ones, as is shown in figure 5 and also reported by Konomi et al. (2014). However, more relevant for the present study is the comparison of pre- and post-exposure for average DPOAEs as a function of frequency (comparison of red and blue lines in figure 5) for the left and right ear separately. Although some values in the low and high frequencies are below 6 dB most values are far higher, indicating that hearing is normal in all subjects in the range between 1-8 kHz. More importantly, the values pre and post exposure are not significantly different from each other, as was also corroborated by a paired t-test.

¹ DPOAEs of approximately 20% of subjects could not be determined, either because the probe was occluded with ear wax or because they are absent in the pre- and post recordings.

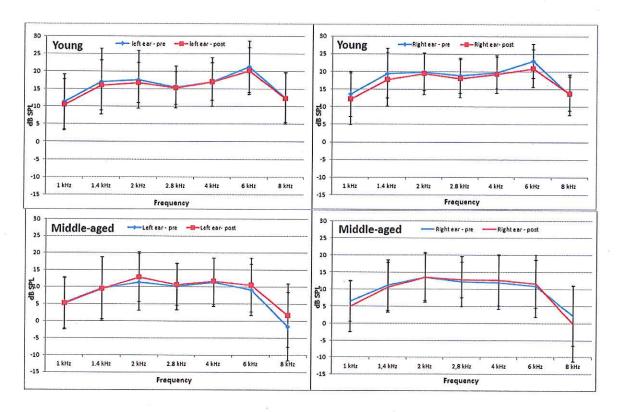


Figure 5. Average DPOAEs (and standard deviations) pre- and post-exposure for the young and middle-aged subjects and for left and right ear separately.

7.3 Undesirable effects

The main aim of the study was to determine possible undesirable effects after exposure to highfrequency (ultra) sound produced by the product under investigation. This was investigated by means of a short survey of 12 items. Tables 3 and 4 present the average Likert score for the 12 items for 25 young and middle-aged subjects, respectively. Values are listed separately for the preexposure condition, the 3 frequencies x 1 or 2 sources and 2 dummy conditions. Standard deviations are given below the average values. Since most values are below 2 it can be concluded that, on average, very little to no undesirable effect is experienced in the different conditions, despite very good hearing. Paired t-tests were performed between the pre- and post scores for 11 out of 14 items for each of the 8 testing conditions separately, and for the young and middle-aged persons separately. With the young subjects 16 out of 88 items were significant (p< 0.05). These are marked by an asterisk in tables 3 and 4, and occur for item 5 ('I have a headache'), item 7 ('I have pain in my ears'), and item 8 'I have tinnitus' for setting 5 (12.5 kHz) with one and two sources. This is a trend. The young subjects reported also feeling significantly more tense before testing than after exposure in 7 out of 8 conditions (item 10). Note that all scores are low (< 2 on the Likert score); significances should be interpreted with some caution, also due to limited sample size. With the middle-aged subjects 2 out of 88 items were significant (p< 0.05). They felt significantly more uneasy after exposure to setting 5 (12.5 kHz), with one and two loudspeakers. However, no other effects were significant.

Note that younger subjects felt that they could not concentrate as well as the older ones during exposure of the lowest frequency, with 1 and 2 sources. This may be related to the self-report data mentioned under 7.1.1.

Table 3: Average Likert score of 25 <u>young</u> subjects, per item in bold, with standard deviation below it. This is for the pre exposure condition (PRE), 3 frequencies, with either 1 or 2 sources (src(s)), and the two dummy (DUM) conditions. The Likert score varies between 1 (= absolutely not) and 5 (very severe).

	PRE	12.5	25 kHz	35 kHz	12.5 kHz	25 kHz	35 kHz	DUM	DUM
	100	kHz	1 src	1 src	2 srcs	2 srcs	2 srcs		
		1 src			13)				
I feel nauseous	1.0	1.2	1.1	1.0	1.1	1.0	1.0	1.1	1.1
	0.2	0.5	0.3	0	0.3	0.2	0.2	0.3	0.3
I have a	1.2	1.7 *	1.3	1.3	1.5 *	1.3	1.2	1.3	1.4
headache	0.5	1.0	0.7	0.7	0.8	0.7	0.5	0.7	0.8
I am dizzy	1.0	1.1	1.0	1.0	1.0	1	1	1	1
	0	0.3	0.2	0.2	0	0	0	0	0
I have a pressing	1.2	1.4	1.2	1.1	1.4	1.2	1.2	1.1	1.2
feeling in my ears	0.4	0.6	0.4	0.3	0.8	0.4	0.5	0.3	0.6
I have pain in my	1.0	1.4 *	1.2	1.1	1.5 *	1.1	1.1	1.2	1.2
ears	0.2	1.0	0.5	0.4	0.8	0.6	0.4	0.5	0.6
I have tinnitus	1.0	1.5 *	1.0	1.1	1.4 *	1.0	1.0	1.0	1.1
	0	0.8	0.2	0.3	0.8	0.2	0.2	0.2	0.3
I feel tense	1.4 *	1.1	1.0	1.0	1.3	1.0	1.0	1.0	1.1
	0.6	0.3	0	0	0.7	0.2	0	0	0.3
I feel tired	1.8	1.8 *	1.8 *	1.7 *	1.7	1.7 *	1.9 *	1.8 *	1.9 *
	0.8	0.7	0.8	0.7	0.8	0.7	0.7	0.6	0.7
I feel warm.	1.6	1.4	1.4*	1.3	1.4	1.4	1.5	1.4*	1.4
	0.8	0.8	0.6	0.6	0.8	0.7	0.8	0.7	0.7
I feel uneasy	1.1	1.3	1.0	1.0	1.4	1.0	1.0	1.0	1.0
	0.2	0.8	0	0	0.8	0	0	0	0.2
I feel frightened	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
	0.2	0	0	0	0.2	0	0	0	0
During the test I		2.3	1.2	1.1	2.5	1.4	1.4	1.2	1.4
could not concentrate on	14	1.1	0.4	0.3	1.3	0.8	0.7	0.5	8.0
what I was doing									

Table 4: Average Likert score of 25 middle-aged subjects, per item in bold, with standard deviation below it. This is for the pre exposure condition (PRE), 3 frequencies, with either 1 or 2 sources (src(s)), and the two dummy (DUM) conditions. The Likert score varies between 1 (= absolutely not) and 5 (very

severe).

severe).									
	PRE	12.5 kHz	25 kHz	35 kHz	12.5 kHz	25 kHz	35 kHz	DUM	DUM
2		1 src	1 src	1 src	2 srcs	2 srcs	2 srcs		
I feel nauseous.	1.0	1.2	1.0	1.1	1.1	1.0	1.0	1.0	1.0
	0.2	0.4	0.2	0.4	0.4	0	0	0	0.2
I have a	1.2	1.3	1.1	1.1	1.3	1.1	1.1	1.2	1.0
headache	0.5	0.6	0.5	0.4	0.7	0.3	0.3	0,51	0.2
I am dizzy	1.0	1.0	1.0	1	1.1	1.0	1.0	1.0	1.0
12	0.2	0	0,20	0	0.3	0	0	0	0
I have a pressing	1.2	1.3	1.1	1.2	1.4	1.3	1.2	1.2	1.0
feeling in my	0.5	0.6	0.3	0.6	0.6	0.6	0.5	0.4	0
ears		52							
I have pain in my	1.0	1.2	1.0	1.0	1.0	1.0	1.0	1.0	1.0
ears	0.2	0.5	0.2	0.2	0	0.2	0.2	0.2	0
I have tinnitus	1.2	1.5	1.2	1.2	1.4	1.2	1.2	1.1	1.1
	0.4	8.0	0.4	0.5	0.6	0.5	0.4	0.3	0.3
I feel tense	1.2	1.2	1.0	1,1	1.2	1.1	1.1	1.0	1.0
	0.5	0,53	0.2	0.4	0.4	0.4	0.3	0.2	0
I feel tired	1.3	1.2	1.2	1.3	1.4	1.4	1.2	1.3	1.3
	0.7	0.5	0.4	0.5	0.6	0.7	0.4	0.4	0.5
I feel warm	1.1	1	1	1.1	1.0	1.0	1.0	1.1	1.0
	0.3	0	0	0.3	0	0.2	0	0,28	0
I feel uneasy	1.1	1.4 *	1	1.2	1.4 *	1.1	1.0	1.0	1.0
# I	0.4	0.6	0	0.6	0.6	0.4	0	0	0
I feel frightened	1.0	1.0	1	1.0	1.0	1.0	1.0	1.0	1.0
	0.2	0.2	0	0	0.2	0	0	0	0
During the test I		1.5	1.1	1.2	1.6	1.2	1.2	1.0	1.1
could not		0.9	0.3	0.5	1.0	0.5	0.6	0.2	0.4
concentrate on									
what I was doing									

7.4 Individual complaints

Three middle-aged subjects specifically volunteered to participate because of undesirable effects during exposure of an ultrasonic repellent in their home environment (neighbor). Individual analyses of objective and subjective responses did not differ from the average data. While their audibility was good and while they reported that they could perceive the signal in most conditions they did not report any negative effects from exposure to the frequencies used and at the SPL in this study.

8. Conclusion and discussion

The main conclusions are that relatively short exposure (20 min) to the investigated settings does not lead to significant undesirable effects (eg. headache, tinnitus, nausea). However, the frequencies and levels under test are considered disturbing by those who can perceive them.

Only three settings of the specific ultrasonic repellent were investigated: those producing a signal with a sound pressure level between 45 and 70 dB at the frequency 12 kHz (setting 5), 25 kHz (setting 8) and 35 kHz (setting 9). At lower settings, from 1 to 4, the product produces significant audible emissions between 6.3 kHz to 12.5 kHz (AIB-Vinçotte, 2011). Possible undesirable effects of the sound emissions at these settings were not evaluated because of our focus on ultrasound emissions of the product, i.e. those recommended for repelling birds, rodents and insects.

While continuous high-frequency sounds (> 12.5 kHz) are usually inaudible, the subjects in the present study clearly report hearing a signal at 12.5 kHz (setting 5). At the higher frequencies tested, there were fewer subjects who reported hearing a signal, but consistently more subjects could perceive it with two sources compared to one source (table 2). It could be that at the higher frequency settings some audible spectral content could be heard (part I). When the signal is perceived – and this occurs more frequently with the two lower frequencies and with 2 sources – it is considered disturbing (cf 7.1.1.) and affects the ability to concentrate (tables 3 & 4).

The survey does not reveal that short term exposure to the frequencies and sources under test lead to disturbing effects such as headaches, tinnitus or nausea in our participants. However, it is known that less pleasant sonic environments may affect health on the long-term (Andringa and Lanser, 2013). Our study does suggest that the used settings of this specific ultrasonic repellent may be more audible to humans than suggested on the basis of hearing thresholds with sinusoidal tones and advertised by the manufacturer. It is also important to note that subjects participated voluntarily and those who dislike high pitched sounds probably will likely not volunteer to participate.

It is clear that the lowest settings are audible to the young and middle-aged persons and that these audible signals are considered disturbing. These results imply that even lower frequencies (settings) would be perceived as even more disturbing, especially with two sources (or with one source at a shorter distance of the subject). These effects may explain the complaints put forward by some citizens.

It is also important to remember that hearing varies from person to person. Undesirable effects are not easily predictable from the hearing thresholds. Some persons with excellent hearing (audibility) endure a large range of sounds, while others with excellent audibility are highly sensitive to minor changes in sound pressure. Hearing thresholds only reflect audibility to sounds, while several other more central auditory mechanisms are responsible for processing sound up to the auditory cortex in the brain.

It is also possible that differences between devices and differences in montage account for the undesirable effects reported by others. In our study the repellent was secured according to the guidelines described in the manual, this may not always be the case in a home situation. Some subjects claimed that the sound they perceive at the neighbor's home to repel rodents is much clearer and much louder than the sound they perceive during the study. It is possible that other

devices to which they are exposed at home emit lower frequencies and/or higher sound pressure levels to repel cats and stone martens than the device in the present study and/or that persons perceive (sub) harmonics of these frequencies, even at normal intensity levels (cf part I).

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