Publishable Summary for 15HLT03 Ears II
Metrology for modern hearing assessment and protecting public health from emerging noise sources

Overview

This project concerned two aspects of hearing assessment and conservation; the further development of the next generation of ear simulators that will provide measurement traceability for hearing tests on adults, children and neonates, and improvement in our understanding of human response to infrasound and ultrasound, including novel assessment methods for potential health risks.

Need

Virtually everyone will have their hearing tested at stages throughout their life. It is essential for effective diagnosis that these tests are accurate and quality assured. Measurement devices known as *ear simulators* provide the basis for measurement traceability, but in the past have been designed for adults only. The EMRP HLT01 EARS project made first significant steps at specifying ear simulators for other age groups and produced a prototype neonatal ear simulator. However, the concept of an all-encompassing ear simulator family needed further refinement to cover for all forms of audiometric testing before it can be adopted into clinical practice. Modern audiometric methods now use short-duration test stimuli such as tone bursts and clicks, rather than steady tones that will be familiar to most people. One specific aspect is that new calibration methods for short-duration test stimuli are needed to replace the current, technically flawed methods. The move to the next-generation of ear simulators was the ideal time to introduce improved calibration methods for these stimuli.

Noise exposure from both environmental and industrial sources is another important aspect of hearing conservation. Urbanisation and industrial innovation are often accompanied by undesirable consequences, including the generation of infrasound and airborne ultrasound. These emerging noise hazards present potentially significant new social and occupation health issues. Indeed, the health risks extend beyond hearing damage and into general areas of cardio-vascular and mental health. Effective mitigation first required a better understanding of the human perception mechanisms. Due to the inaudible nature of some of these noise sources, a multi-disciplinary approach to the research was needed, combining neuro-imaging and advanced audiological investigations to fully understand the human response. Then, to supplement this understanding, new measurement methods and instrumentation were needed to assess noise sources in both public and workplace environments.

Objectives

The overall objective of this project was the improvement and further development of strategies for hearing assessment, hearing diagnosis and safety, appropriate for modern society. The specific objectives of the project were:

1. To finalise the universal ear simulator concept to fulfil the whole range of audiological requirements for traceability to sound pressure, including the development of an alternative approach to transient calibration based on impulse response and adaptors for the most common devices, and realisation of demonstrator devices for the novel ear simulators.
2. To generate robust normative reference threshold data (transfer and input impedance), calibrate devices across partners, quantify the degree of equivalence with currently established practices and provide a user guide summarising features, calibration and handling for application of the novel ear simulator in practice.

3. To exploit neuro-imaging and audiology to further develop understanding of perception as well as response and loudness thresholds for ultrasound (16 kHz – 80 kHz), infrasound (4 Hz – 16 Hz), and the influence of infrasound on sound within the normal hearing range; together with the development of instrumentation and measurement methods for the determination of noise and its hazards in those frequency ranges in both public and workplace environments.
4. To determine experimentally the impact of infrasound and ultrasound on hearing, mental health, cognitive abilities and general wellbeing, and their contribution to annoyance and loudness, including the study of individuals with particular sensitivity to noise.
5. To engage and work closely with stakeholders to establish the clinical protocols and international standards proposals for the use of the universal ear simulators in the calibration of audiometric equipment used for hearing assessment and hearing aid fitting for both children and adults; and to create the knowledge for future guidelines and policy framework to enhance the wellbeing of European citizens and protect them from health hazards associated with infrasound and ultrasound.

Progress beyond the state of the art

Having produced and tested a prototype of an ear simulator for neonates in the EMRP EARS project, this project was to develop the concept further to become practically viable for all age ranges. This included a reduction in the number of different designs, in conjunction with alternative criteria for matching the ear simulator to the patient, and an extension to allow the coupling of circumaural and supra-aural headphones.

Separately, the project was to develop an innovative approach to the calibration of audiological transducers for short-duration stimuli, based on the impulse response of the ear simulator. Starting from the selection and characterisation of short-duration stimuli based on properties of the auditory system, novel methods for determining the impulse response of the ear simulator were to be investigated and to form the basis for a new calibration strategy for the transducer under test. Together with newly determined reference hearing threshold levels, these elements would represent a significant departure from established practice and mark the first attempt to improve on the flawed method currently specified in international standards.

On the topic of airborne ultrasound, the first primary measurement standards were established in the original EARS project and the first attempts were made to develop measurement techniques for exposure, for use in laboratories. This project aimed to design, assemble and validate practical ultrasound measurement devices and components for assessments at workplaces, and in public spaces, thereby contributing new knowledge on sources, levels of occurrence and the validity of concerns about ultrasound as a risk to public health. In parallel, the project also aimed to improve on the measurement capability for determining human hearing threshold for ultrasound and studied the influences of airborne ultrasound on cognitive abilities.

Results of the original EARS project showed that, contrary to popular belief, infrasound can lead to a hearing sensation and indications were seen that an emotional response is activated in brain. This project was to pursue these findings further with new and more comprehensive study designs extending to other indicator modalities such as frequency-following techniques in encephalographic experiments, studies outside of laboratory settings and investigations of longer-term impact of infrasound on humans.

Results

The key technical achievements against each of the project objectives described above are:

Objective 1

Three new ear simulator designs have been produced for use in the calibration of audiometric equipment to ensure that the correct stimulus level is used in hearing assessment, regardless of the age of the test subject and even accounting for individual ear characteristics. Known as the ‘EARS family occluded-ear simulators’ they provide age-related calibration reference points and are to be supplemented by a proposed in-test procedure for interpolating between these points resulting in a calibration tailored to the individual test subject.

During development, key decisions such as the number of different age-points necessary and which ages to choose as reference points, were decided by user consultation. This indicated the need for three ear simulators designed for test subjects of 3 months, 24 months and adults (actually 7 years and upwards) respectively. In this way, an optimum arrangement of fewer ear simulators (compared to the five proposed in the first EARS project) and better calibration for individual test subjects is achieved. New specifications were therefore developed, and the three associated ear simulator designs produced and verified through modelling. However, it should be noted that due to limitations in the available anatomical data used to specify the ear simulators, especially for small children, further research is necessary before the specifications can be considered definitive. Nevertheless, the concept for a universally applicable calibration approach has been established. As a demonstration of the concept, five sets of EARS family occluded-ear simulators (15 devices in total) were professionally manufactured for further use in the project and are now available on request to other users for evaluation.

The ear simulators are intrinsically suited to earphone types that are inserted directly into the ear canal. However, through the use of adapters that have also been designed and produced, other types of on-ear earphones can also be measured, so that the full range of earphones commonly used in clinical practise is covered.

The EARS family occluded-ear simulators are supplemented by a newly developed method of calibration suited particularly to short-duration stimuli typically employed in modern hearing assessment. Indeed, the calibration method is not restricted to the new EARS family occluded-ear simulators in its application and can be readily applied to conventional devices. The new calibration method takes better account of the features related to the loudness of the stimulus.

Together, the ear simulators and the novel calibration technique form the basis for a completely new and improved approach to audiometric calibration, and fully meet the objective.

Objective 2

Following the manufacture of the EARS family occluded-ear simulators, an intercomparison exercise was carried out to verify their key performance characteristics and produce normative data for input into the standardisation process. Independent measurements at four laboratories showed excellent reproducibility in the measured performance characteristics indicating that the manufacturing process is highly reliable, that the devices can be calibrated consistently, and that their characteristics can be standardised. All these factors are essential qualities for reference devices.

When conducting a hearing test or calibrating an audiometric device, it is necessary to know the magnitude of the sound produced by a given type of earphone within the ear simulator, that corresponds to the typical hearing threshold of potential test subjects. These characteristics define the zero setting on the audiometric equipment which in-turn corresponds to normal hearing. For steady signals the magnitude of the sound is relatively easy to quantify, but for short-duration stimuli there are different ways this can be specified. At present a very basic approach based only on the peak sound level produced is used, but the resulting levels do not correlate well with perceived loudness of different forms of stimuli. So, an alternative approach has been derived which takes account of the time duration and overall energy of the stimulus. These additional features also seem implicated in our judgement of the stimulus level.

A series of measurements on selected test subjects were then carried out to determine their individual hearing thresholds using a new type of earphone. The tests were made with steady tones, tone bursts and clicks. For the latter two, being short-duration stimuli, the magnitude of the sound was calculated using the currently established peak-level approach and the proposed new approach. Measurements were also made in the EARS occluded-ear simulator for adults and the corresponding conventional ear simulator. The results of this study have been presented to the standardisation bodies responsible for specifying hearing assessment methodology for further consideration by the international audiometric community.

An important consideration when proposing major changes to hearing assessment methodology is that the test outcomes should not be altered. Therefore, the terms used to evaluate the level of equivalence were defined at the outset and measurements carried out to quantify those terms. While the EARS family occluded-ear simulators provide traceability for all test subjects regardless of age, current practices only cover adult test subjects. Therefore, the demonstration of equivalence was necessarily restricted to the adult group, where results from the study noted above showed levels of agreement significantly below normal test margins. Thus, a smooth transfer from current practise to the proposed new methods is assured.

With the calibration capability, data sets and documentation noted above, this objective has been fully achieved and the key research achievements are summarised in a guidance document.

Objective 3

In the absence of suitable measurement instrumentation of airborne ultrasound, a first key step was for the project to develop its own tools for assessments at workplaces and in the public. A special portable microphone system operating in the ultrasound range was established and calibrated using capability developed in the project. However, a particular difficulty with ultrasound measurement in public spaces is that the location of sources, and therefore the best place to make the measurement, is not always obvious. To help with this, a multi-microphone device was conceived and developed using the latest miniature microphone technology that allows ultrasound sources to be identified and visualised. Unfortunately, due to significant technical challenges the device was not ready in time for the field surveys, but is part of the capability now available for future studies. Nevertheless, field surveys were carried with the portable ultrasound microphone system, building on a citizen science project to identify suspected sources of ultrasound in public locations. The locations selected for further investigation included railway stations and museums with significant public traffic. Sources included pest deterrents, proximity detectors for automatic door and public address systems. Measurements of noise levels and frequency content were made and contributed to the first authoritative review on the current situation of ultrasound exposure in the public areas.

For the study of occupational exposure to airborne ultrasound, two reference workplaces were built simulating typical industrial conditions, which provided the controlled environments necessary for developing new noise assessment methods. An industrial collaborator provided an ultrasonic welding machine for use as a test object in the reference workplaces. Different ways of making the measurements on the machine were then be evaluated, ranging from relatively rapid single-point measurements, to a detailed scanning technique in order to build up a map of the ultrasound field. Scanning of the field was found to be essential so the development of a practical technique which could be carried out by a technician by hand in the workplace was key. Experimentation with the reference workplace setups has also enabled the influence of the machine operator on the measurement levels to be evaluated, which would have been almost impossible in a real industrial situation. The presence of a person can easily distort the ultrasound field, leading to errors when trying to characterise the noise produced by the machine itself. Finally, the methods were tested at real workplace settings, on the production lines in three industrial enterprises. The capabilities and methods developed with the reference workplace have enabled new recommendations to be established on the assessment of airborne ultrasound in the workplace, which are being disseminated through regular training on the general topic of industrial noise assessment conducted in Germany.

In parallel, the physiological responses to infrasound and to airborne ultrasound were studied using imaging of brain activity following sound exposure, using well-established techniques; functional magnetic resonance imaging (fMRI), magnetoencephalography (MEG) and electroencephalography (EEG). When EEG produces a response to regularly repeating stimulus it is termed a frequency-following response. This method is well suited to infrasound stimuli, but it was nevertheless a surprising result that significant brain synchronisation was detected with infrasound tones at barely perceptible levels. This contrasts with the normal hearing range, which requires sound significantly above the hearing threshold to elicit a response.

For the MEG response to ultrasound, the project has pioneered the use of novel optical sensors (optically pumped magnetometers) that were shown to be completely immune to magnetic fields above 1 kHz, and therefore not impacted by the ultrasound sound source. The compact size of the optical sensors enabled fifteen of them to be mounted into a 3D-printed helmet specifically fitted to the test subject. Given the experimental nature of the new sensors, technical problems in their use were inevitable. However, the first acoustically evoked magnetic-potentials were successfully elicited. The prospects opened by the successes so far are exciting. The system that has been developed is extraordinary in making it possible to link acoustic perception to quantitative electrophysiology.

It was suggested that infrasound might affect sound perception in the normal hearing range. This is evidently true for high-level infrasound, but no evidence was found for such effects for sub-threshold infrasound. By contrast, a surprising result was that sound in the normal hearing range can increase the sensation threshold to infrasound. It was also considered that low-frequency sound above 20 Hz can be mistaken as infrasound if it fluctuates at lower rates than this. This was indeed found to be the case under certain experimental conditions, and several studies showed that infrasound can be effectively suppressed and masked by higher frequency sound. This masking could be explained by modelling the mechanical response of the cochlea, the inner ear organ that turns sound into nerve impulses sent to the brain. Although all these findings do not exclude the possibility that at higher intensities other modalities contribute to its sensation, the masking and suppression results, in line with the fMRI observation of auditory cortex activation by infrasound, are hard evidence that the auditory nerve is the most sensitive pathway to perceive infrasound. This was further supported by a study which investigated the vestibular-evoked myogenic potentials which represent an acoustically stimulated response from the vestibular system. In all experiments no vestibular activation by infrasound could objectively be measured.

Objective 4

A number of studies have been carried out to characterise annoyance from infrasound and ultrasound, including attempts to quantify annoyance thresholds. The studies combined techniques from psychophysics, audiology and brain imaging sciences.

Experiments investigating the impact of infrasound on humans used different experimental approaches. A multi-language questionnaire enabled a comprehensive lifestyle and sound exposure profile to be evaluated, and annoyance rating and psychological personality to be assessed. More than 200 participants from the adult population assessed high-frequency and low-frequency noise sensitivity. From this it was found that low-frequency and high-frequency sensitivity only correlate to a moderate extent with one another, and slightly less so with audible noise sensitivity. This suggests that low-frequency and high-frequency sensitivity might indeed reflect different aspects of sound sensitivity. In addition, both types of sensitivity are associated with different symptoms, (psychiatric and somatic; self-report), pointing towards their potential role in the emergence of adverse reactions to high- and low-frequency emissions.

A test group with 19 participants then underwent fMRI investigation to identify brain activation induced by infrasound stimulation and to verify annoyance and subjective perception statements. Using a test stimulus with 8 Hz frequency a significant activation of the auditory cortex was found and the comparison with an activation via a 32 Hz sound showed no significant difference. In addition, correlation analysis revealed that unpleasantness is a better predictor of activation than loudness which is in turn better than sound pressure level. Most striking is that infrasound seems to behave like audible sound which supports its assessment using similar strategies with audible sound.

Before this project, most studies made use of short-term exposures, with maximum durations of several minutes. To extend the investigations to long-term impact, specially developed infrasound and airborne ultrasound sources were designed for installation into the normal living environment of the test subject(s), closely resembling ‘real-life’ exposure to sound. The preliminary results were based on a sample of 42 healthy individuals who were exposed to either 6Hz inaudible infrasound, 22.4 kHz inaudible ultrasound or a placebo for 28 nights (8 hours per night) or received a placebo exposure (sham sound source). Overall, there was a tendency for no observable effect on assessments of cognitive performance, reported psychiatric and somatic symptoms taken before and after the exposure. Hence, inaudible infrasound or ultrasound does not seem to have a significant impact on typical healthy subjects. However, descriptively there were single effects on specific variables both for infrasound and ultrasound, that should be investigated in future studies.

Impact

The objectives and outputs outlined above have been formulated to meet the declared needs. Therefore, delivery of these outputs will enable a significant impact in key areas to be created.

Impact on industrial and other user communities

The consortium worked with industry and clinicians directly, to enable early adoption ahead of the research outputs becoming mainstream. Clinical users have been consulted about the practicalities in using the ear simulators, and their feedback was incorporated in the final specifications. They were given access to the ear simulators in order to assess their impact alongside established protocols. There is close contact with companies involved in calibration and testing of audiological equipment as the main users of the new ear simulators and calibration procedures.

The research on objectives 1 and 2 covered many measurement-related aspects of hearing assessment, that have an impact across a wide range of stakeholders, from health service policy makers, and hearing assessment practitioners, to instrumentation manufacturers and calibration service providers. A guidance document has been produced summarising the key research achievements and future recommendations, for dissemination to the above stakeholders.

New measurement techniques for infrasound and ultrasound have also been demonstrated within the project and now form the basis of new measurement capability and services. In case of airborne ultrasound at workplaces, new measurement methodologies were developed and successfully tested in three German companies with ultrasound technology. These new methods now form the basis of a significantly improved assessment methodology of noise at ultrasound work places leading to a higher level of occupational safety in this field.

New understanding of human factors such as perception and annoyance will also assist industry and local authorities in mitigation of noise hazards in a systematic way with scientifically robust approaches. Regular training and awareness raising of noise in the workplace now includes the topic of ultrasound as a direct result of this work. This is the basis for an appropriate and sustainable noise protection at workplaces, ensuring safety for machine operators and avoids unnecessary, bulky, and expensive noise isolation equipment and setups.

Impact on the metrology and scientific communities

A virtual centre of excellence in metrology and measurement capability for infrasound and airborne ultrasound has emerged from the project activities, providing an open resource for the metrology and scientific communities across Europe, and making duplication in this highly specialised area unnecessary. The project consortium is already in contact with other NMIs with an interest in these activities.

The newly developed psychometric questionnaire provided a new tool for evaluating an individual's susceptibility to annoyance and other impacts from infrasound and ultrasound with respect to acoustic, psychoacoustic and psychological factors. This has the potential to identify sub-populations of individuals who are particularly responsive to high- or low frequency sound and for more fine-grained analyses of potential adverse health- or other effects in environmental, experimental, audiological, psycho-acoustic or other types of studies.

The research on infrasound perception produced various interesting results. There is no apparent difference in infrasound sensitivity per-se while many properties and issues are not that strictly different to audible noise. The new finding of masking will give future research, into the infrasound problem, a completely new direction, such as whether the efficiency of the discovered masking effects is individually different.

The use of novel optical sensors in MEG studies has been successfully demonstrated, paving the way for further studies on human behavior and perception, not just for auditory studies but with the full range of stimulus types.

Impact on relevant standards

Many project outputs have directly or indirectly targeted the standardisation activities of the International Standardisation Organisation (ISO) and the International Electrotechnical Commission (IEC).

For ear simulator standardisation, it is essential for the new technology to gain recognition and ultimately be taken up in clinical practice to yield quality assurance and reliability improvements in hearing assessment, particularly for children and neonates. Members of the project team are also involved in the IEC working group that prepares the standards so there has been regular contact between the groups. An early draft document was presented to the working group around the mid-point of the project but concerns about the robustness of the anatomical data and the tentative nature of the specifications stalled the standardisation project. However, feedback from the dissemination workshops led to the preparation of a Publicly Available Specification that has been submitted to the working group. This will allow others to pursue their own ear simulator developments building on the project outputs.

A communication has been sent to another IEC working group dealing with audiometric equipment. This concerns the use of the new metric for specifying the level of short-duration test stimuli, and its relationship with existing metrics.

Another communication has been sent to the ISO working group dealing with the specification of hearing thresholds, on the measured data for the new earphone type used in the hearing threshold studies. This is the first data of its kind and was measured in full compliance with the requirements necessary for it to be adopted as normative data. This will increase the reliability and consistency of clinical measurements made with the new earphone type.

At the national level, contributions have been made to the German standardisation body on the new model of how infrasound is detected by the inner ear, which will ultimately contribute to international standards on loudness and perception.

Likewise, contributions have been made on the new recommendations and protocols for measuring airborne ultrasound in the context of general assessment of industrial noise exposure. These are expected to feed-forward to the corresponding international working group under the auspices of ISO in due course, fostering widespread recognition and take-up of research outputs from the project.

Longer-term economic, social and environmental impacts

The project will have long-term effects since many of the initiated changes, technology and methodology will take time to evolve. The transition to the new arrangements for hearing assessment involving the EARS family occluded-ear simulators will take many years before standards are finalised and health policy is changed. Individualised calibration ultimately reduces cases where test results are neither a certain pass or a certain fail, leading to improved confidence and reduced false-positive results. In neonatal and infant screening, unnecessary referrals for further testing and the associated parental anxiety from false-positive results are also reduced.

Although the methods are already in use, for example at the measurement groups of the German insurance companies, the development of measurement methods for ultrasound at workplaces will continue because of the large variety in source types, usage and external environment. The core findings of this research will help build a greater wealth of experience necessary to formulate widely applicable methods. This will finally bring the level of occupational safety at ultrasound frequencies to that in the audible frequency range.

The significant progress made in our understanding of the perception of infrasound now enables new mitigation strategies to be suggested, especially for those known to be very sensitive. The masking effects that have been discovered in the auditory sensing mechanism, now indicates how the external acoustic environment can be changed to reduce the impact of the infrasound itself.

The consortium has been active in many dissemination activities to complement the research work. 14 journal papers and conference proceedings have been published, 57 presentations have been made to 20 different organisations or groups at conferences, events or meetings, and 1 article has appeared in the popular press. In addition, the project website will be retained for the foreseeable future.

List of publications

1. Dolder, C. et al. *Measurements of ultrasonic deterrents and an acoustically branded hairdryer: Ambiguities in guideline compliance*. J. Acoust. Soc. Am. 144 (4), pp. 2565-2574, 2018, https://doi.org/10.1121/1.5064279
2. Fletcher, M. et al. *Effects of very high-frequency sound and ultrasound on humans. Part I: Adverse symptoms after exposure to audible very-high frequency sound*. J. Acoust. Soc. Am. 144 (4), pp. 2511-2520, 2018, https://doi.org/10.1121/1.5063819
3. Fletcher, M. et al. *Effects of very high-frequency sound and ultrasound on humans. Part II: A double-blind randomized provocation study of inaudible 20-kHz ultrasound*. J. Acoust. Soc. Am. 144 (4), pp. 2521-2531, 2018, https://doi.org/10.1121/1.5063818
4. Fletcher, M. et al*. Public exposure to ultrasound and very high-frequency sound in air*. J. Acoust. Soc. Am. 144 (4), pp. 2554-2564, 2018, https://doi.org/10.1121/1.5063817
5. Jurado, C., Marquardt, T. *On the Effectiveness of airborne infrasound in eliciting vestibular-evoked myogenic responses*. Journal of Low Frequency Noise, Vibration and Active Control, 2019, https://doi.org/10.1177/1461348419833868
6. Knappe, S., Sander-Thömmes, T., Trahms, L. *Optically Pumped Magnetometers for MEG*. In: Supek S., Aine C. (eds) Magnetoencephalography. Springer, pp. 1-12, 2019, https://doi.org/10.1007/978-3-319-62657-4
7. Leighton, T. *Ultrasound in air—Guidelines, applications, public exposures, and claims of attacks in Cuba and China*. J. Acoust. Soc. Am. 144 (4), pp. 2575-2583, 2018, https://doi.org/10.1121/1.5063351
8. Marquardt, T., Jurado, C. *Amplitude modulation may be confused with infrasound*. Acta Acust united Ac Vol. 104, No. 5, pp. 825–829, 2018, https://doi.org/10.3813/AAA.919232

9. Ullisch-Nelken, C., Kusserow, H., Wolff, A. *Analysis of the noise exposure and the distribution of machine types at ultrasound-related industrial workplaces in Germany*. Acta Acust united Ac Vol. 105 No. 5., p. 733, 2018, https://doi.org/10.3813/AAA.919212
10. Weichenberger, M., Bauer, M., Kühler, R., Hensel, J., Forlim, C., Ihlenfeld, A., Ittermann, B., Gallinat, J., Koch, C., Kühn, S. *Altered cortical and subcortical connectivity due to infrasound administered near the hearing threshold - evidence from fMRI*. PLoS one 12(4), 2017, https://doi.org/10.1371/journal.pone.0174420

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Internal Funded Partners: 1 PTB, Germany 2 BKSV, Denmark 3 DFM, Denmark 4 NPL, United Kingdom (withdrawn from Sep-2016) 5 TUBITAK, Turkey	External Funded Partners: 6 DGUV, Germany 7 UCL, United Kingdom 8 UKE, Germany 9 UL, Slovenia 10 Uni-Oldenburg, Germany 11 UoS, United Kingdom	Unfunded Partners: 12 METAS, Switzerland
RMG: -		