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

Overview

This project concerns 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. The project started in May 2016.

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. Ear simulators provide the basis for measurement traceability, but in the past have been designed for adults only. The EMRP HLT01 EARS project made the first significant steps at specifying ear simulators for other age groups and produced a prototype neonatal ear simulator. However, the concept of a universal ear simulator needs further refinement and extending to cover all forms of audiological testing before it can be adopted into clinical practice. 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 is the ideal time to introduce new improved calibration methods for these stimuli.

Another aspect of hearing conservation concerns environmental and industrial exposure to noise which represents a major public and occupational health issue. With urbanisation and industrial innovation often come undesirable consequences such as new types of noise hazard from infrasound and airborne ultrasound. Greater understanding of the human perception mechanisms is needed in order to tackle the risks posed by this emerging noise. Due to the inaudible nature of some of these noise sources, a multi-disciplinary approach is needed combining neuro-imaging and advanced audiological investigations. Alongside the development of this understanding, new methods and instrumentation are needed to measure and assess noise sources in both public and workplace environments.

Objectives

The overall objective of this project is the improvement and further development of strategies and methods of metrology and calibration for hearing assessment, hearing diagnosis and safety. The specific objectives of the project are:

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. A demonstrator will be realised for the novel ear simulator.
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 will develop the concept further to become practically viable for all age ranges. This includes 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 will 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 will be investigated and form the basis for a new calibration strategy for the transducer under test. Together these elements represent a significant departure from established practice and mark the first attempt to improve on the flawed method currently specified in international standards.

Furthermore, the EARS project developed the first primary measurement standard for airborne ultrasound measurements and made first attempts to develop exposure measurement techniques for use in laboratories. This project will design, assemble and validate practical ultrasound measurement devices and components.

Results of the EARS project showed that infrasound leads to a hearing sensation and indications exist that an emotional response is activated in brain. This project will pursue these findings further with new more comprehensive study designs including other indicator modalities as frequency-following techniques in magnetoencephalography (MEG).

Results

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

Objective 1

A calibration concept has been developed to ensure that the correct stimulus level is used in hearing assessment for example during audiological investigations in clinics. The new EARSII ear simulators provide age-related calibration reference points and are supplemented by an in-test procedure to interpolate between these points resulting in a calibration tailored to the individual test subject. A user consultation has confirmed the proposal for three ear simulators designed for test subjects of 3 months old, 24 months old and adults (actually 7 years old and upwards) respectively. In this way, an optimum arrangement of fewer ear simulators (compared to the number proposed in the first EARS project) and better calibration for individual test subjects is achieved. New specifications were therefore developed for these specific age groups, and associated ear simulator designs produced and verified through modelling. Finally, five sets of the ear simulators (15 devices in total) have been manufactured and are currently undergoing laboratory evaluation in the consortium. The range of earphones used in clinical practise for which the ear simulators can be used, has also been expanded by the use of adapters and couplers, and prototypes have been produced for all of the commonly used earphone types identified through user consultation.

The EARSII ear simulator family is supplemented by a newly developed method of calibration suited particularly to short-duration stimuli typically employed in modern hearing assessment, for example the determination of hearing thresholds. The new calibration method enables the determination of all features related to the loudness of the stimulus. Together the new ear simulator and the novel calibration technique form the basis for a completely new and improved approach to audiometric calibration.

Objective 2

Following manufacturing of the EARSII ear simulators, an intercomparison exercise is underway to verify the key performance characteristics and produce normative data for input into the standardisation process.

As the basis for a test or a calibration of an audiological device, it is necessary to know the sound characteristics produced within the ear simulator by a given type of earphone that corresponds to the typical hearing threshold of potential test subjects. These characteristics define the zero setting on the audiometric equipment used to test hearing and are a function of frequency. In the past it has been common to use the sound level for quantitative definition of the characteristic, but this is deemed inappropriate for short-durations test stimuli. So, a more complex definition has been adopted that accounts not only for the peak sound level produced but also for the time duration and overall energy in the stimulation signal.

An important consideration when proposing major changes to hearing assessment methodology is that the test outcomes should not be altered. Therefore, it is necessary to assess the equivalence of current practices and the new proposals. In order to do this, the terms which will be used to evaluate the level of equivalence have been defined. In a next step they will be applied to ensure a smooth transfer from common practise to the novel methods.

Objective 3

Progress has been made both with the quantitative determination of ultrasound fields in both public spaces and workplaces, and with understanding the human physiological response associated with ultrasound and infrasound.

In the absence of suitable measurement instrumentation of airborne ultrasound, a first key step in the project was to develop its own tools for an application at workplaces and in the public. Development of all devices, setups and calibration techniques are now complete and fully operational and are being used extensively in a number of project tasks. 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 has been developed using the latest miniature microphone technology (MEMS microphones). The device called the 'MEMS array' allows ultrasound sources to be identified and visualised. A number of technical challenges had to be overcome to make the device operate effectively, but it is now ready for field testing where it is intended to supplement single-microphone systems. Initial surveys have been carried out to confirm the presence of ultrasound, as suspected in selected public spaces. Additional candidate sites have been identified and permissions obtained for more detailed study using both the MEMS array and calibrated single-microphone systems to quantify the potential exposure to airborne ultrasound at these sites. This is the basis for a review about the current situation of ultrasound exposure in the public.

For the study of occupational exposure to airborne ultrasound, two reference workplaces have been built simulating typical industrial conditions, which have provided controlled environments necessary for developing new measurement and assessment methods. An industrial collaborator provided a sample welding machine which was used as a test object in the reference workplaces for evaluating different ways of making the measurements, ranging from relatively rapid single-point measurements, to a detailed scanning technique in order to build up a map of the ultrasound field. The key element was the development of a compact scanning technique which can be carried out by a technician by hand at any workplace. Experimentation with the reference workplace setups has also enabled the influence of the machine operator 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. The capabilities and methods that have been developed are now under test in real industrial settings of collaborating companies.

The physiological responses to infrasound and to airborne ultrasound are being studied using the imaging of brain activity following exposure, using two well-established techniques, functional magnetic resonance imaging (fMRI) and magnetoencephalography (MEG). Both methods require special infrasound and ultrasound sources to be produced. Improved versions of the infrasound source have been produced for use at different facilities and a new high-power ultrasound source combined with in-ear monitoring has also been developed. This allows a known level of ultrasound to be presented to the test subject and is capable of producing levels thought to be necessary to elicit brain responses. The sources are designed for use in fMRI and MEG facilities and are the first of their kind.

MEG is a sophisticated imaging technology that detects minute magnetic activity associated with activity in the brain, typically using sophisticated sensors called SQUIDs (superconducting quantum interference devices). However, the need for cryogenic cooling makes setups with these sensors extremely bulky and creates an imposing environment for the test subject. However, the project is attempting to use new optical sensors that operate at room temperature and offer a significantly more compact testing arrangement, that is less likely to influence the response of the test subject. The sensors need to be built into a 3D-printed helmet specifically fitted to the test subject. Experiments to verify the performance of the new test arrangement are underway. It is still too early for results to be available, but indications are that the ultrasound source does not interfere with the sensors, which is a valuable first step.

Experiments have been designed to investigate the perception of combined infrasound and audible sound using subjective ratings of unpleasantness. New sound sources have been designed allowing modulation signals and audible sounds to be mixed with infrasound, ready for new experiments on the infrasound detection threshold when audible sounds are also present. In a study with 15 test persons the interaction of infrasound with audible sound (and vice versa) was investigated by determination of hearing thresholds and it could be shown that the audible sound changes the infrasound thresholds, but the infrasound does not influence the threshold of audible sound. This was quite unexpected and confirmation is now being sought from another set of experiments showing that low-frequency audible sound can suppress infrasound perception.

Objective 4

A number of studies are being pursued to characterise annoyance thresholds for infrasound and ultrasound, combining techniques from psychophysics, audiology and brain imaging sciences.

Experiments investigating the impact of infrasound on humans have been carried out with different research approaches. A newly developed questionnaire allows a comprehensive life-style investigation including potential sound exposure, annoyance rating and psychological personality assessment. A test group with 30 participants was then investigated objectively with functional magnetic resonance imaging (fMRI) in order to identify brain activation induced by infrasound stimulation and to verify annoyance and subjective perception statements. While it was a bonus to have such a large test group this has meant that the large volumes of data are still under analysis.

One basic line of research in the project is the application of objective brain imaging methods to investigate the perception and typical human reaction to infrasound and airborne ultrasound. Typically, and out of necessity, studies make 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 have been designed, constructed and tested and are now being installed in the normal living environment and surroundings of the selected test persons. Objective parameters were measured and will be determined after complete exposure in order to identify potential changes in physiology parameters induced by the sound exposure. In case of airborne ultrasound, the results will also be compared to another study which deals with the impact of airborne ultrasound on cognitive abilities.

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 works with industry and clinicians directly, to enable early adoption ahead of the standards being established. Clinical users have been consulted about the practicalities in using the ear simulators, and their feedback was incorporated in the final specifications. As the project proceeds they will be given access to the ear simulators, to assess their impact alongside established protocols. A first clinical study will test the practicability of the novel devices, methods and calibration procedures. In addition, the consortium is in close contact with companies involved in calibration and testing companies of audiological equipment. They are, finally, the main users of the new ear simulators and calibration procedures.

New measurement techniques for infrasound and ultrasound are also being demonstrated within the project and potentially lead to new measurement services. In case of airborne ultrasound at workplaces new measurement methodologies were developed and successfully tested at working places in three German companies with ultrasound technology running.

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. In case of airborne ultrasound occupational health will be improved and currently the technical measurement services of the health insurances and safety bodies start to implement the new measurement methods for a testing in practise.

A Stakeholder Advisory Group has been formed to extend the reach of dissemination from the project, and a process has been developed to pro-actively manage dissemination in such a way that the intended impact of the project is fully realised.

Impact on the metrology and scientific communities

A virtual centre of excellence in metrology and measurement capability for infrasound and airborne ultrasound will emerge 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.

Impact on relevant standards

In standardisation, several new proposals have been initiated that, in the case of the ear simulator, will enable 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. Project results are being communicated to the relevant working groups and the ensuing development of standards is appearing in the agenda for these working groups. In noise control applications, vital new information, for example on human response and measurement capability will enable problems such as airborne ultrasound to be quantified and tackled for the first time.

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 much more time to evolve. The complete transition to the novel ear simulator will take many years including the completed construction of the simulators, bringing them to market and combining them with the new calibration strategies. Here standardisation plays a key role to establish the novel technique and to convince about the potential it has for an improvement of audiological calibration and traceability and finally for an improvement of hearing assessment and diagnostic correctness.

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 of applications. A much larger treasure of experience will be necessary to make the methods versatilely applicable and new adoptions have to be developed. This will finally bring the level of occupational safety at ultrasound frequencies to that in the audible frequency range.

The consortium has been active in many dissemination activities to complement the research work. 15 journal and conference proceedings papers have been published, 45 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 maintains a website and has so far published 3 Newsletters.

List of publications

1. Kühler, R., Weichenberger, M., Bauer, M., Kühn, S., Sander-Thömmes, T., Ihlenfeld, A., Ittermann, B., Hensel, J., Koch, C. *Investigation of hearing perception at ultrasound frequencies by functional magnetic resonance Imaging (fMRI) and magnetoencephalography (MEG)*, Proceedings of the 22nd International Congress on Acoustics, Buenos Aires, p. 195, 2016.
2. Kling, C. *Microphone calibration service for airborne ultrasound*, INTER-NOISE Congress and Conference Proceedings, InterNoise2016, Hamburg, Germany, p. 2863, 2016.

3. Wolff, A. *Airborne ultrasound at German workplaces*, INTER-NOISE Congress and Conference Proceedings, InterNoise2016, Hamburg, Germany, p. 943, 2016.
4. Jodko-Władzińska, A., Władziński, M., Palko, T., Sander-Thömmes, T. *Development of high-frequency acoustic source for auditory stimulated magnetoencephalography*. Proceedings of the 15th International Conference on Global Research and Education Inter-Academia, pp. 197-202, 2016.
5. Kühler, R., Weichenberger, M., Bauer, M., Kühn, S., Sander-Thömmes, T., Ihlenfeld. A., Ittermann, B., Hensel, J., Koch, C. *Investigation of hearing perception at ultrasound frequencies by functional magnetic resonance Imaging (fMRI) and magnetoencephalography (MEG)*. Proceedings of the 22nd International Congress on Acoustics, pp. 195-195, 2016.
6. 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.
7. Burke, E., Hensel, Johannes, Fedtke T. *Hearing threshold measurements of infrasound combined with audio frequency sound*. 12th ICBEN Congress on Noise as a Public Health Problem, 2017.
8. Koch, C. *Hearing beyond the limit: Measurement, perception and impact of infrasound and ultrasonic noise*. 12th ICBEN Congress on Noise as a Public Health Problem, 2017.
9. Ullisch-Nelken, C., Schöneweiß, R., Kling, C., Wolff, A. *Ears II - Development of an ultrasound measurement technique for use in occupational safety*. Proceedings of the 12th ICBEN Congress on Noise as a Public Health Problem, 2017.
10. Kling, C., Schöneweiß, R., Wolff, A., Ullisch-Nelken, C. *Investigations on airborne ultrasound at working places*. 24th International Congress on Sound and Vibration, 2017.
11. 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.
12. Ullisch-Nelken, C., Wolff, A., Schöneweiß, R., Kling, C. *A measurement procedure for the assessment of industrial ultrasonic noise*. Conference proceedings of the 25th International Congress on Sound and Vibration, ICSV 25, 2018.
13. Koch, C., Kling, C., Wächtler, M., Schöneweiß, R. *Novel measurement techniques and measurement methods for the determination of ultrasound noise exposure at work places*. Conference proceedings of the 25th International Congress on Sound and Vibration ICSV 25, 2018.
14. Barrera-Figueroa, S. *Pressure calibration of WS3 microphones*. Conference proceedings of the 25th International Congress on Sound and Vibration ICSV25, 2018.

<table>
<tr><td colspan="2">Project start date and duration:</td><td>1 May 2016, 36 months</td></tr>
<tr><td colspan="3">Coordinator: Christian Koch, PTB, Germany
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Project website address: http://www.ears-project.eu/empir/ears2.html</td></tr>
<tr><td>Internal Funded Partners:
1 PTB, Germany
2 BKSV, Denmark
3 DFM, Denmark
4 NPL, United Kingdom (withdrawn from Sep-2016)
5 TUBITAK, Turkey</td><td>External Funded Partners:
6 DGUV, Germany
7 UCL, United Kingdom
8 UKE, Germany
9 UL, Slovenia
10 Uni-Oldenburg, Germany
11 UoS, United Kingdom</td><td>Unfunded Partners:
12 METAS, Switzerland</td></tr>
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