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, they 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 methods for transient calibration 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 transient 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 transient 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.

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 concept has now been developed for the practical implementation of the new EARS 2 ear simulators. A user consultation has confirmed the proposal for three ear simulators to provide three discrete calibration points for test instrument used in hearing assessment. The devices target test subjects of 3 months, 24 months and adults (actually 7 years upwards), and will be supplemented by an in-test procedure to match actual ear characteristics to those of the ear simulators. A further process for interpolating between the calibration points will then be implemented automatically. In this way, an optimum arrangement of fewer ear simulators and better calibration for individual test subjects is achieved. The range of earphones for which the ear simulators can be used has also been expanded by the use of adapters and couplers, and experimental versions have been designed for all of the commonly used transducer and hearing aid types identified through user consultation.

The new EARSII ear simulator family is supplemented by a newly developed method of calibration suited particularly to short-duration stimuli typically employed in testing. The method involves the determination of the transient response of the ear simulator which in turn enables the waveform of the stimulus applied to the microphone diaphragm (a proxy for the ear drum) to be reconstructed. This new capability is intended to be used in conjunction with the results of studies of the waveform features relevant to auditory perception and loudness. Together they form the basis for a completely new and improved approach to audiometric calibration.

Objective 2

Now that the technical development of the new ear simulator is nearing completion, the newly manufactured device samples will be tested and validated and used to define robust normative data. First steps for preparation of measurement have started.

Objective 3

In the absence of suitable measurement instrumentation of airborne ultrasound, the project has been developing its own tools for measurement in both public spaces and workplaces. A miniature array of MEMS microphones has been designed and produced to allow the location of ultrasound sources to be identified and visualised, when the location of sources is not obvious (in public spaces primarily). The device is currently in testing and is intended to supplement the single-microphone systems that have also been developed for use as ‘ultrasound level meters’. Four of these single-microphone systems have now been built and calibrated, and are already in use.

Initial surveys of public spaces have been completed using the single-microphone system to confirm the presence of ultrasound. These surveys have identified five candidate sites for more detailed study using both the MEMS array and calibrated measurement systems. Approval for making measurements at these sites has been obtained.

Two reference workplaces have been built simulating typical industrial conditions, so that new assessment methods for airborne ultrasound in the workplace can be tested and optimised in a controlled environment. A sample machine has been provided on loan from an industrial collaborator and used to evaluate different measurement protocols, ranging from practical, relatively rapid measurements, to sampling with high spatial resolution to obtain a detailed map of the sound field. Such experimentation would be impractical in a real industrial setting. Experience gained so far with the reference workplaces has led to a working measurement procedure that is currently undergoing further refinement.

A high-power ultrasound source combined with an in-ear monitoring has also been developed, allowing the presentation of a known level of ultrasound at the ear entrance, and capable of producing levels thought to be necessary to elicit brain responses. The sources are designed for use in fMRI and MEG machines and are the first of their kind. These sources are now in place at two sites where fMRI measurements are being made.

Pilot experiments with fMRI in response to infrasound stimulation have also been performed to optimize the final experimental design. The results obtained so far indicate that all effects related to supra-threshold infrasound stimuli are very small. The stimuli in the low-frequency audible range evoke a slightly lateralized activation pattern for unilateral stimulation and is largely restricted to primary auditory cortex as expected. Whereas, the results for infrasound stimulation are much less distinct, and rather distributed across various cortical regions, including auditory areas, but not restricted to primary auditory cortex. In addition, measurements using electroencephalography showed a first indication of activation at infrasound frequencies which needs further investigation.

Objective 4

New sound sources have been designed to support the planned studies, 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.

For studies on annoyance, a questionnaire has been prepared to survey the general public on the awareness and perception of infrasound and ultrasound. One purpose is to estimate the percentage of the population that may be particularly sensitive to such stimuli and another is to identify and recruit individuals to take part in psychoacoustic and neuroimaging tests as part of the EARSII research. So far there have been 300 responses, and around 20 potentially suitable test subjects identified.

The design of psychophysical procedure to quantify annoyance for infrasound stimuli is currently in progress. The first tests have been conducted and results generally correlate with findings from the first

EARS project, validating the new setups and methods for the EARS-II project. One other early observation is that careful experimental design is needed to differentiate between loudness and annoyance.

Particular sources have been designed which emit infrasound and ultrasound at a level just below the hearing threshold and are capable of running for several hours and or even days to simulate continuous exposure to infrasound and airborne ultrasound. A longitudinal study is under preparation which will determine the influence of these sounds on humans.

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.

In standardisation, several new proposals are envisaged 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. This process has already been initiated and project results are being communicated to the relevant 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.

While benefits from standardisation will flow to stakeholders, the consortium will also work 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 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. New measurement services for infrasound and ultrasound also developed in the project and the new understanding of human factors such as perception and annoyance will begin to assist industry and local authorities in mitigation of noise hazards in a systematic way with scientifically robust approaches.

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 consortium has been active in many dissemination activities to compliment the research work. 7 journal and conference proceedings papers have been published, 29 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 2 Newsletters.

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 so that the intended impact of the project is fully realised.

Project start date and duration:	1 May 2016, 36 months	
Coordinator: Christian Koch, PTB, Germany Tel: +49 531 592 1600 E-mail: christian.koch@ptb.de Project website address: http://www.ears-project.eu/empir/ears2.html		
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