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## 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.

#### 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 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 outputs expected against each of the project objectives described above are:

#### **Objective 1**

- A final specification for the universal ear simulator family, including the hardware necessary for different types of earphone
- New selection criteria based on anatomical characteristics of the auditory system rather than age of the patient
- New demonstrator for ear simulators
- New calibration method for transient acoustic stimuli

#### **Objective 2**

- Data set from a laboratory inter-comparison on the characteristics of the universal ear simulator variants
- The first draft of a new document on the specification of the universal ear simulator presented in IEC TC29
- Data sets on the degree of equivalence between existing and new hearing assessment protocols and a strategy for handling any differences
- Data sets on reference hearing thresholds for the universal ear simulator
- User guidance on the application of the universal ear simulator in clinical practice



Objective 3

- New instrumentation and calibration techniques for the measurement of airborne ultrasound sources
- A protocol for measuring airborne ultrasound sources in-situ, validated by measurement trials
- A database of high-intensity ultrasound devices that are commonly deployed in public spaces
- Two reports providing input to ISO TC43 and national committees on the status of ultrasound noise in public and in the workplace
- An ultrasound source for generating 130 dB in the ear canal up to 40 kHz, combined with a means of measuring the sound pressure level *in-situ*
- Data sets relating brain activation levels to ultrasound stimuli
- A journal paper describing the perception mechanism for infrasound and ultrasound

Objective 4

- Data sets leading to proposals for annoyance thresholds in the frequency ranges of 8 Hz and 250 Hz and 8 kHz and 40 kHz
- Derivation of further annoyance thresholds accounting for key parameters and descriptors (stimulus intensity, perceived loudness, and perceived annoyance) within the noise
- A paper recommending possible modification of ISO/CD 532 loudness model to improve performance below 100 Hz
- Data sets to enable potential long-term effects of exposure to infra- and ultrasound onto brain structure, brain function, and subjective wellbeing to be determined

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. 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 will be given access to the ear simulators emerging from the project, 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.

Project start date and duration:		1 May 2016, 36 months
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