

Title: Metrology for modern hearing assessment and protecting public health from emerging noise sources

Abstract

Ear simulators play a vital role in establishing traceability in hearing assessment. However currently available devices predate modern clinical practices and do not cover all combinations of patient age, test transducer and stimulus type that are now common. Thus traceability cannot always be assured and significant errors are known to exist in some circumstances. The EMRP EARS project has begun to address this by introducing new ear simulators, but additional technical challenges remain, especially around calibration. Most significantly, the new devices must find acceptance in clinical practice, through establishing equivalence, new clinical protocols and international standards, and a package of training and guidance material for users.

Also, the EU population is increasingly being exposed to intense acoustic fields just outside of the nominal frequency range of human hearing (16 Hz - 16 kHz). Certain individuals may be particularly sensitive to them, and across Europe there are increasing complaints about a range of symptoms (hearing problems, migraine, tinnitus etc.) from infrasound and from unregulated ultrasonic devices such as animal repellents deployed in residential and public spaces. The EMRP EARS project began to investigate metrological approaches for a health assessment of emerging noise by investigating human perceptual mechanisms, measuring and describing exposures and their impact on humans. That work should be extended to lay the ground for future technical and safety regulations.

Keywords

Hearing assessment, neonatal screening, hearing rehabilitation, ear simulator, hearing aids, hearing damage, hearing conservation, hearing threshold, quality of life, nuisance, infrasound, airborne ultrasound, risk assessment, magnetoencephalography, functional magnetic resonance imaging

Background to the Metrological Challenges

Virtually everyone will have a hearing test at some stage in their life. Ear simulators are measurement devices that establish traceability in hearing assessment, through their use in the calibration of audiometric equipment used in clinical practice. They also allow reference hearing thresholds to be established, which provide a benchmark for assessing if a measured hearing response is normal. Clinical hearing assessment takes many forms and uses a wide variety of transducers to provide the acoustic stimulus. These may fit around or on the outer ear, or in the ear canal (circumaural, supra-aural and insert earphones respectively). Stimuli may be pure tones or one of many short-duration signals tailored for a particular purpose, and the patient may be any age from new-born to very elderly. The basic need then is that the ear simulator provides a reliable and traceable representation of the acoustic stimulus level that will subsequently be applied during a hearing test, for any combination of transducer, stimulus type and patient age. While practicing audiologists might simply assume that this is the case, the reality is somewhat different, as all of the standardised ear simulators currently available are based on adult ear characteristics and were originally specified for pure tone audiometry only. Such limitations have caused the New-born Hearing Screening Programme (NHSP) in the UK to publish warnings such as “the sound pressure level in a neonate's ear canal is likely to be 10 - 20 dB greater than it would be in an adult's ear. This is an effect of canal volume and can mean that the stimulus rises to unsafe levels”, along with other guidance advocating departure from requirements of international standards on which ear simulator should be used, provided certain ‘corrections’ are applied. Audiologists therefore need validated and standardised measurement devices designed for the purpose at hand, together with clear and unambiguous protocols for their use in transferring measurement traceability to the complete range of audiometric equipment used in clinical hearing assessment.

The EMRP EARS project ('Metrology for a universal ear simulator and the perception of non-audible sound' 2011 Health Call JRP – HLT01) has taken massive strides to address a significant limitation - the extension of adult ear simulators (all of the standardised devices relate to adult characteristics only), to applications for children and neonates. It has:

- Developed initial specifications for a family of ear simulators covering all age groups and developed universal concepts for their design, realisation and use.
- Outlined a modular design approach, systematically mapping ear simulator sections or components to the outer ear, concha, ear canal and tympanic membrane, providing the versatility to meet the requirements of a given application.
- Produced an occluded ear simulator for neonatal applications and validated its performance in the laboratory

EARS has also provided samples of the neonatal occluded ear simulator to selected clinical users and calibration laboratories, but the outcome of these activities has not yet fulfilled the demanding requirements of providing traceability to the majority of users of clinical audiometric equipment.

There are numerous indicators that infrasound and airborne ultrasound events influence human beings and that sound at such frequencies can be perceived. However at present, the precise mechanisms of sound perception at these frequencies are unknown and this lack in understanding is reflected by the status of existing regulations and standards. The few governmental guidelines for ultrasonic exposure mainly refer to the same very limited literature and knowledge basis, usually assessing 1/3 octave band exposure limits of about 110 dB to 115 dB for the ultrasonic frequencies. Within the EU, there is still a lack of objective and reliable metrology in the ultrasound frequency range. There are poorly organised risk assessment strategies and nearly no rationally proven regulations or standards in force within the EU or in individual Member States. Moreover, the cited guidelines often give no clear definition or measurement method and are extremely heterogeneous concerning measurands, measurement procedures, and accuracy requirements. This means that effectively no standard for workplace safety and for living areas exists.

A first serious step forward to address this was made during the EARS project. Using a newly developed sound source, the brain response to infrasound could be measured with test persons whose hearing thresholds and loudness perception were thoroughly determined before. Also, appropriate psycho-acoustical procedures were developed for loudness assessments. A relation between loudness and brain response could objectively be derived with artificial test stimuli but only for a very small number of loudness level values inappropriate for serious threshold estimation. Functional magnetic resonance imaging measurements showed that infrasound strongly excites the primary auditory cortex but there were indications that other processes or sensory pathways, for example somatosensory excitation, within or around the ear contribute to the sensation. The EARS project provided results which constitute a significant first contribution to the establishment of metrology for non-audible and emerging noise, but as might be expected from the first thorough research on a topic, it raised more questions than it was able to answer.

Objectives

Proposers should address the objectives stated below, which are based on the PRT submissions. Proposers may identify amendments to the objectives or choose to address a subset of them in order to maximise the overall impact, or address budgetary or scientific / technical constraints, but the reasons for this should be clearly stated in the protocol.

The JRP shall focus on traceable measurement and characterisation of Hearing Level to improve the wellbeing of European citizens through supporting hearing conservation, particularly against the effects of emerging and poorly understood noise sources, and diagnosis and rehabilitation of hearing loss, particularly in children.

The specific objectives are

1. To further develop 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 to improve upon the compromises in the current approach to short-duration stimulus calibration.
2. To generate robust normative reference threshold data and validated technical performance specifications for the universal ear simulators, quantify the degree of equivalence with currently established practices and develop a strategy for managing any differences; together enabling the next generation of international standards for ear simulators to be produced.

3. To exploit neuro-imaging and audiology to further develop models of the auditory processes and response thresholds for infrasound (4 Hz – 16 Hz) and ultrasound (16 kHz – 80 kHz); together with the development of instrumentation and methods for assessing noise hazards in this frequency range 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 influence on sound within the normal hearing range and their contribution to annoyance, 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 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 guidelines and policy framework to enhance the wellbeing of European citizens and protect them from health hazards associated with infrasound and ultrasound.

These objectives will require large-scale approaches that are beyond the capabilities of single National Metrology Institutes and Designated Institutes, and it is expected that multidisciplinary teams will be required. To enhance the impact of the research, the involvement of the appropriate user community such as medical practitioners, medical (academic) hospitals and industry is strongly recommended, both prior to and during methodology development.

Proposers should establish the current state of the art, and explain how their proposed project goes beyond this. In particular, proposers should outline the achievements of the EMRP project HLT01 EARS and how their proposal will build on those.

EURAMET expects the average EU Contribution for the selected JRPs in this TP to be 1.8 M€, and has defined an upper limit of 2.1 M€ for this project.

EURAMET also expects the EU Contribution to the external funded partners to not exceed 35 % of the total EU Contribution to the project. Any deviation from this must be justified.

Any industrial partners that will receive significant benefit from the results of the proposed project are expected to be unfunded partners.

Potential Impact

Proposals must demonstrate adequate and appropriate participation/links to the “end user” community, describing how the project partners will engage with relevant communities during the project to facilitate knowledge transfer and accelerate the uptake of project outputs. Evidence of support from the “end user” community (e.g. letters of support) is also encouraged.

You should detail how your JRP results are going to:

- Address the SRT objectives and deliver solutions to the documented needs,
- Feed into the development of urgent documentary standards through appropriate standards bodies (e.g. IEC TC29),
- Transfer knowledge to the acoustical instrumentation sector.

You should detail other impacts of your proposed JRP as specified in the document “Guide 4: Writing Joint Research Projects (JRPs)”

You should also detail how your approach to realising the objectives will further the aim of EMPIR to develop a coherent approach at the European level in the field of metrology and include the best available contributions from across the metrology community. Specifically the opportunities for:

- improvement of the efficiency of use of available resources to better meet metrological needs and to assure the traceability of national standards
- the metrology capacity of EURAMET Member States whose metrology programmes are at an early stage of development to be increased
- organisations other than NMIs and DIs to be involved in the work

Time-scale

The project should be of up to 3 years duration.