Final Publishable JRP Summary for HLT01 Ears
Metrology for a universal ear simulator and the perception of non-audible sound

Overview
This project, known as EARS, addressed two separate aspects of human hearing. The first was to seek improvements in the quality of hearing impairment diagnosis, particularly for neonates and children, through the development of new instrumentation for calibrating the acoustic stimuli used in assessment. The second was to better understand the physiological responses to sound outside of the conventional frequency range of hearing, and use this as the basis for new guidance on the hazards presented by infrasound and ultrasound.

Need for the project
The first part of the project responded to needs arising in the hearing assessment community, for new ear simulators that are better fit-for-purpose. Ear simulators are used to calibrate the acoustic stimuli used in the wide range of hearing assessment methods currently in mainstream use. In particular tests of newborn children are carried out routinely and extensively throughout the EU, yet the procedures used are based on data derived from the adult population. Consequently stimulus levels applied to neonates and children are ambiguous, and the quality and reliability of testing, which is vital to the success of the hearing screening programmes, are degraded as a result. New ear simulators designed specifically for the patient age groups are therefore needed. However, the range of existing devices is already complex, so a device that can be applied universally across both existing and emerging applications has significant practical and economic advantages. To gain acceptance, such a device also needs supporting IEC and ISO specification standards.

The second part of the project addressed growing concerns that exposure to sound outside of the frequency range normally considered audible by humans (infrasound and ultrasound), nevertheless presents a risk of hearing damage. However the measurement capability to allow levels of infrasound and ultrasound to be quantified, and current understanding of the hazard presented by this type of exposure is very limited. Reports of symptoms are often the only indications that a problem might exist. Concerns are exacerbated by new technologies, products and industrial processes which increasingly produce such emissions either intentionally or as a by-product of their operation. New evidence-based safety criteria, and risk assessment and mitigation protocols are therefore needed by occupational safety specialists, local authorities and the noise control community, including those involved in standardisation. Prerequisites to these needs are new data on the perception thresholds and a better understanding of the physiological response to infrasound and ultrasound, together with a new measurement infrastructure, from primary measurement standards through to instrumentation and methods enabling noise exposure to be assessed and quantified.

Scientific and technical objectives
The scientific and technical objectives of the project were:

- Ear simulator development: To design, model, manufacture and validate the performance of a new class of ear simulator for the calibration of earphones used in hearing assessment. The ear simulators to be universally suitable for hearing assessment in the frequency range from 125 Hz to 16 kHz, regardless of the patient age, and the assessment method, earphone type and acoustic stimulus to have a particular focus on the testing of neonates and children. Then, to develop calibration procedures and reference hearing threshold data, and to test the practical application of the ear simulators in clinical trials. Finally, to use the resulting knowledge and data to make recommendations for future international standards.
- Perception and measurement of non-audible sound: To develop neuro-imaging techniques utilising magnetoencephalogphy (MEG) and functional magnetic resonance imaging (fMRI) to identify the deep

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areas of the brain that respond to infrasound and airborne ultrasound stimuli. Then, through the development of new acoustic sources capable of operating in the extreme environments used in neuro-imaging, and by establishing the world's first primary standards for airborne ultrasound, to determine the brain response activation threshold in terms of the applied acoustic level, with accuracy better than 5 dB. Through correlation with established hearing thresholds, to use these activation thresholds as the basis for recommendations on maximum exposure criteria for infrasound and ultrasound. Finally, to develop methods and instrumentation for the assessment of hazards from non-audible noise.

Results

Ear simulator development

A family of ear simulators, each targeting a specific age group, can now be designed, modelled and manufactured. Project resources precluded the manufacture of all variants, but prototypes of the device for neonates were produced for evaluation through a thorough series of laboratory tests. The results show that the performance is suitable for international standardisation. Further user trials indicate that the ear simulators are ultimately capable of being adopted in mainstream practice for hearing assessment in the frequency range 125 Hz to 16 kHz, to improve the quality and reliability of test results, and bring a degree of rationalisation to instrumentation requirements. The most significant outcomes from the key research stages are highlighted below. Aside from restricting the range of devices that could be manufactured, it can be seen that these outcomes represent full completion of the first objective above.

- Through an extensive literature review and consultation with leading paediatric audiologists, five key development stages from neonates to adults have been identified. For each of these a corresponding specification for the ear characteristics to be simulated, has been developed and published.
- The concept of an ear simulator family with a universal approach to design and application has been established. The concept has been generalised, and may be applied to all of the existing age-related specifications and any that may develop in the future. A novel feature of the design was to use anatomical geometry for the simulated ear canal to achieve the correct acoustic characteristics. The process for transforming a basic specification into a fully manufactured device, employing analytical and numerical modelling, was documented for the first time and published.
- Five prototype devices for neonatal use were produced using advanced manufacturing facilities available within the project consortium.
- Calibration methods were developed for these prototypes and results confirmed the performance expectations and conformance with the target specification, thereby validating the complete design process noted above.
- A round-robin comparison of the prototype neonate simulator resulted in a data set which established the reproducibility of the calibration methods and consensus in the collected data. From this it was concluded that the ear simulator is suitable for future standardisation. A new work item proposal has therefore been submitted to the working group responsible for the international standardisation of ear simulators.
- The reference equivalent thresholds values have been determined for the ear simulator. These are used during calibration to establish the baseline for a hearing assessment instrument. This process of determining these values is the subject of another new work item proposal to the working group responsible for hearing thresholds.
- User trials and a hands-on session at a project workshop have confirmed the usability of the neonatal ear simulator and illustrated the errors that result from the devices used in current mainstream practice.

Perception and measurement of non-audible sound

Research in this part of the project has fulfilled part of the objective relating to capability development, such as novel detection techniques for MEG and fMRI, a traceable measurement capability through the development of new primary standards for airborne ultrasound, and the development of specialised acoustic sources. Significant progress was also made on determining brain response thresholds, particularly for

infrasound. However, limitations with the output level capabilities of the ultrasound source has meant that results obtained in this frequency range were not fully conclusive. Nevertheless, recommendations have been prepared on exposure criteria for infrasound and ultrasound, and measurements on real-fife sources have been made using instrumentation developed ion the project.

The key outcomes from this part of the project

- New MEG techniques have been developed for identifying and distinguishing deep-lying activity in the brain. In addition, new acoustic sources to provide infrasound and ultrasound stimuli were developed especially for use in MEG and fMRI test environments. Together they represent a new brain imaging capability for auditory stimuli in the infrasound and ultrasound ranges.
- Brain imaging results from both MEG and fMRI showed activation of auditory cortex by infrasound, but results for ultrasound were inconclusive, most likely because the ultrasound sources had difficulty producing acoustic levels above the perception threshold in most cases. The results have led to a new hypothesis about the perception mechanism of infrasound, where two detection mechanisms may be acting. However further work is necessary to confirm this.
- New techniques for subjective hearing threshold and equal loudness evaluations have been developed and successfully implemented down to 8 Hz and up to 26 kHz. Results confirm and improve on the limited amount of existing data for infrasound. As well as standing in their own right, the results provided valuable input on the acoustic levels to be used in brain imaging experiments.
- Brain imaging and subjective hearing threshold results indicate that so-called non-audible sound both below and above the conventional hearing range *is* actually perceivable by humans. From these results initial recommendations are being made available on future safety criteria.
- The world's first primary measurement standards for airborne sound pressure extending to 160 kHz have been established, enabling ultrasound fields to be reliably quantified for the first time.
- A protocol has been developed for measuring airborne ultrasound sources in the laboratory and a selection of typical sources has been investigated. The results indicate significant local hotspots in the field produced requiring a scanning approach to the measurement.

Actual and potential impact

The project used a diverse mix of dissemination activities to engage stakeholders ranging from specialists to the general public. A project website was established from the outset and updated on a regular basis and 6-monthly newsletters were published and sent to subscribers which grew to 92 in number by the last newsletter. Ad-hoc flyers and press releases were produced highlighting specific aspects of the project. Dissemination to scientific communities included 21 published or planned peer reviewed journal papers, 35 presentations at conferences and meetings, to both general audiences such as the acoustics and brain imaging communities, and targeted stakeholder groups such as standardisation bodies. Dissemination activities culminated in 2 workshops attended by over 60 participants; one on the development of the universal ear simulator and a second on non-audible sound perception. The first included a practical training session for the universal ear simulator, which built on the user trials that were an integral part of the project. Many of these dissemination activities are set to continue beyond the end of the project.

The scientific and dissemination activities have already led to the following impacts and benefits:

The project has motivated the formation of a UK action group on the Health Effects of Ultrasound in Air (HEFUA) to undertake complementary work that raises the political profile of airborne ultrasound as a new public health hazard. The significance of the issue has attracted high-level participation in HEFUA from science and government as well as members of the public. The group has already been successful in gaining funding to expand the work of EARS into the area of environmental noise nuisance.

New measurement services directly traceable to the airborne ultrasound primary standard established in the project, have been delivered to industrial users. These include, a supplier to the cell phone industry who secured new business from a world-leading manufacturer by demonstrating a significant and credible new

capability underpinned by traceable measurements, and a team studying the behaviour of bats who benefited by improved characterisation of their detection equipment.

The project outputs also have significant potential impact for future realisation, as follows:

The new understanding that brain centres normally associated with auditory stimuli are also activated by infrasound, improves knowledge about perception mechanisms and provides a good basis for future guidance on exposure limits. A communiqué has been produced which summarises main conclusions from the project and gives first advice for improved assessment of infrasound and ultrasound. It recommends a first provisional set of limit values which need more support in future, as a first step to establishing safety criteria. This will be used to provide input to the International Commission on Non-Ionizing Radiation Protection (ICNIRP) who provide guidance on the health effects of infrasound and ultrasound to the World Health Organisation and other national and international bodies, and who are currently updating their guidance on airborne ultrasound.

Newly determined equal loudness contours for infrasound confirm and improve on the quality of prior data, as they show no evidence of the unexpected discontinuity in the transition into the audible sound region. Together with the newly obtained hearing threshold and brain imaging results for both infrasound and ultrasound they provide the first data on the perception thresholds of the physiological response to non-audible sound, which will be extremely valuable in justifying exposure limits based on the assumption that any physiological response in these frequency regions should be considered hazardous due to the high energy levels involved.

The newly established primary and secondary calibration facilities for airborne ultrasound have a significant impact in the acoustical metrology community as no such capabilities existed prior to this project. Moreover, the new measurement capabilities they underpin for determining the airborne ultrasound output from typical sources is as significant as the new understanding of human perception, as without this capability exposure criteria are clearly meaningless. The progress made to develop measurement systems and laboratory methods provides the basis for the future assessment of sources in the field, whether for environmental protection or occupational safety.

The dissemination workshop on the universal ear simulator has extended the number of stakeholders now aware of the developments, and ready to assist in bringing the devices to mainstream practice. These stakeholders include leaders of national neonatal screening programmes in the UK and Germany, who provide an excellent basis for extending engagement to national services in other EU countries.

Manufacturers of audiometric equipment are also eager to investigate the implications of the new ear simulators for their own instrumentation developments. The availability of professionally manufactured prototypes that can be passed out to such users for evaluation is a significant advantage. The ear simulator itself has strong potential to be developed as a commercial product for the medical device market.

The move to the new family of ear simulators will ultimately improve the calibration of transducers used in the hearing assessment of neonates and children, thereby improving the overall quality and reliability of the test protocol. Stakeholders have already stated the enormous value of such developments, as the quality and reliability of test results is becoming an important issue for families of the patients. There is also economic impact in terms of reduced re-testing to identify borderline and false-positive results.

The new ear simulator family will also impact the medical physicists and calibration laboratories responsible for calibration and traceability, by simplifying the current complex situation where very specific rules exist in which ear simulator should be used in the calibration of a given transducer. This simplification requires new international standards to be agreed (see below), but will result in a situation where a single unambiguous ear simulator configuration is specified for a given transducer type, thus ensuring the uniformity and equivalence of measurement traceability wherever these international standards are adopted.

New work item proposals and documents submitted to IEC and ISO working groups on the specification of ear simulators for neonates and children, and the process for establishing reference thresholds respectively, address strategic drivers identified by these working groups and are expected to lead to the preparation of new international standards that will underpin the use and calibration of ear simulators in hearing assessment practices.

List of publications

A list of publications is appended to the Final Publishable JRP Report.

JRP start date and duration:	01 May 2012 and 36 months	
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