FINAL PUBLISHABLE JRP REPORT

JRP-Contract number	HLT01
JRP short name	Ears
JRP full title	Metrology for a universal ear simulator and the perception of non-audible sound
Version numbers of latest contracted Annex Ia and Annex Ib against which the assessment will be made	Annex Ia: V1.0 5 April 2012 Annex Ib: V1.0 5 April 2012
Period covered (dates)	From 1 May 2012 To 30 April 2015
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Report Status: PU Public

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1 Executive Summary

Introduction

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.

The Problem

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.

The Solution

After evaluating user requirements and defining specifications a new ear simulator with a universal concept of application for the complete age from newborns till adults was designed. The device for neonates was realised by a careful manufacturing process. New calibration methods were developed for the new device and reference data, including equivalent threshold sound pressure level values, were provided in a form suitable for subsequent international standardisation. A selection of clinical users was engaged to evaluate the new device in audiological practice and provided valuable feedback on usability.

The issues of non-audible sound were addressed by an application of a combination of subjective and objective methods from audiology and brain imaging. New measurement techniques for the determination of brain responses were developed and applied and first estimation of brain response thresholds were obtained and compared to newly determined hearing thresholds and equal loudness contours. First proposals for both, the assessment of non-audible noise and safety limits were made. A new primary standard for airborne ultrasound was developed as the first calibration facility of this kind in the word. New measurement methods for airborne ultrasound were developed and, for the first time traceable exposure measurements can be made for noise in this part of the frequency range.

Impact

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.

2 Project context, rationale and objectives

2.1 Project context and background

Hearing is one of our most vital senses and impairment can lead to severe degradation in quality of life. Consequently national healthcare programmes invest heavily in both hearing diagnostics (through screening programmes) and rehabilitation (hearing aids). Aside from disease and inherent disability, hearing is put at risk, most commonly, from excessive noise exposure. Aside from any ethical perspectives, the high economic burden of both treatment and non-treatment approaches give strong favour to preventative approaches to hearing conservation.

The frequency range of human hearing has long been regarded as extending from 16 Hz to 16 kHz. However concerns exist that inaudible sound outside of this range still presents a hazard to hearing or creates annoyance. Evidence for this is difficult to establish, but there is strong and growing support that there is a real problem to be solved and an urgent need for mitigating safety criteria and for a risk assessment protocol. New technologies and industrial processes emit infrasound or airborne ultrasound either intentionally or as a by-product of their operation. Examples include wind turbines, heat pumps, sonochemical reactors, ultrasonic cleaning and dentistry. Definitive evidence linking energy content to health hazard has so far been unavailable, but the need for mitigating safety criteria and a risk assessment protocol exist nevertheless. This holds for both the public sector and the safety at workplaces.

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, exposure limits and standards. First steps in determining safety criteria for inaudible infrasound and ultrasound is to apply objective methods from audiology and brain imaging to establish hearing and perception thresholds as a first reference for human response to infrasound and airborne ultrasound.

Producers of machinery for new technologies or industrial processes require noise emission regulations to be well founded and not unnecessarily restrictive. In order to ensure safety at workplace a risk assessment is obligatory according to EU directive 2002/49/EC ("Assessment and management of environmental noise"). For establishing such an assessment reliable safety criteria and risk assessment processes are needed.

An important prerequisite for all noise assessment is the quantitative description of the noise by acoustic measurement on the basis of clearly defined measurands. However primary standards do not yet exist in the ultrasonic frequency range and measurement procedures and strategies have not been developed so far. Only when the metrology infrastructure of primary standards and methods of calibrating measuring devices have been established can any damaging effect of airborne ultrasound and infrasound be quantified.

Ear simulators are reference devices which underpin quantitative hearing assessment by enabling audiometric equipment to be calibrated. However established standards and practices currently relate primarily to pure tone audiometry for adults. As a result of initiatives to capitalise on the benefits of early diagnosis and treatment of hearing disorders in neonates and children, alternative objective audiometric methods (e.g. evoked brainstem responses and otoacoustic emissions) using non-sinusoidal stimuli are now mainstream. The greater focus on testing neonates and children and the expanded range of methodologies, transducers and test stimuli used, have created new user requirements for ear simulators. The quality and reliability of testing is vital to the success of the screening and early diagnosis. However the range of existing devices and protocols for their use is already complex, and further provision demands a new approach. A device that can be applied universally for all age groups, earphone types and test stimuli, has enormous

advantages to hearing assessment practitioners. However to gain acceptance, such a device needs supporting IEC and ISO specification standards.

2.2   Objectives

This project has supported preventative strategies to hearing conservation through two major interdisciplinary research and development activities. The first aimed to establish new understanding of human perception of non-audible sound based on an application of objective methods from audiology and brain imaging as well as the metrology infrastructure necessary as prerequisite to put in place effective safety criteria in the future. The second aimed to improve the relevance of metrology in modern audiological practices, to bring about improved quality and reliability of results by developing a novel ear simulator which can be used also to test devices used in neonate diagnosis.

These two issues were addressed in two congruent scientific and technical objectives:

- 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 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.

3   Research results

The two objectives were met by the work made within the project and described within this section. Subsection 3.1 to 3.4 highlight the results concerning objective 1 and contain in summary the following steps:

- New measurement techniques for the determination of brain responses of deeply lying sources by magnetoencephalography (MEG) were developed. New transducers appropriate for delivering and measuring the acoustic stimuli in magnetically critical environment were designed and manufactured. Magnetoencephalography (MEG) and functional magnetic resonance imaging (fMRI) were applied to non-audible sound and brain areas were determined where infrasound and air-borne ultrasound generate brain responses. The minimum sound pressure level where the onset of brain activation occurs was estimated for both infrasound and ultrasound.

- Hearing thresholds and equal loudness contours were determined for infrasound, and hearing thresholds were determined for ultrasound. They objectively describe the hearing sensation of non-audible sound. They were compared to the brain response measurements, improving understanding of the perception mechanisms and underpinning the definition of future safe exposure limits for non-audible sound. First proposals for both the assessment of non-audible noise and safety limits are made.

- A new primary standard for airborne ultrasound was developed as the first calibration facility of this kind in the word. New measurement methods for airborne ultrasound were developed and, for the first time traceable exposure measurements can be made for noise in this part of the frequency range.

Subsection 3.5 to 3.6 describe the results concerning objective 2 and contain in summary the following steps:

- User requirements and specifications for a universal ear simulator were compiled from literature and a stakeholder survey leading to general specifications of a device which could meet all requirements. The design and modelling of a universal device was made using a new principle of including anatomical structure details into the concept. The device for neonates was manufactured within a dedicated process fulfilling the hard tolerance conditions.

- New calibration methods were developed for the new device and reference data are provided in a form suitable for subsequent international standardisation. A fist set of reference equivalent threshold sound pressure level values for common earphones were provided for the new neonate ear simulator. A selection of clinical users was then engaged to evaluate the new device in audiological practice and provided valuable feedback on usability.

3.1 Development of techniques and methods for the investigation of brain responses with non-audible acoustic stimuli

### 3.1.1 Methods for determination of deep lying sources

A phantom was manufactured by PTB to simulate suggested centres of human auditory processing and to model later measurements within the deep lying auditory cortex. Four dipoles were included, one representing the cortical auditory processing centre and three representing prominent centres in brainstem. Each dipole is made up of platinum wire and is soldered to a twisted wire running to the outside of the sphere. The length of the dipoles used in the phantom is around 10 mm in length. The principal of operation is the following: A current flowing through two opposing electrodes results in a magnetic moment and a magnetic field is generated. In this way the artificial centres of hearing are activated. The magnetic field is a function of the current between the dipole electrode tips through the saline water solution, which fills the sphere.

The magnetic measurement was performed in magnetically shielded rooms of the PTB, the BMSR II and the Ak3b, and were carried out by a 304 channel vector magnetometer with a planar sensor array and a helm gradiometer MEG made by Yokogawa/Japan. The phantom was located directly underneath the centre of the Dewar. All dipoles were consecutively activated for 50s. According to the driving signals and the length of the dipoles the applied magnetic moment ranged from 6000nAm to 50nAm.

The results in Figure *Phantom Results* show, that deep lying source have weaker magnetic fields due to the increased distance between sensor and dipole (Fig. 1). More important, the deep lying sources generate very different field patterns compared to the cortical surface dipoles. Mainly cortical sources were found in the subsequent measurement series with human subjects and no dominant deep lying sources were found, but this is still possible for more complex acoustic stimuli.
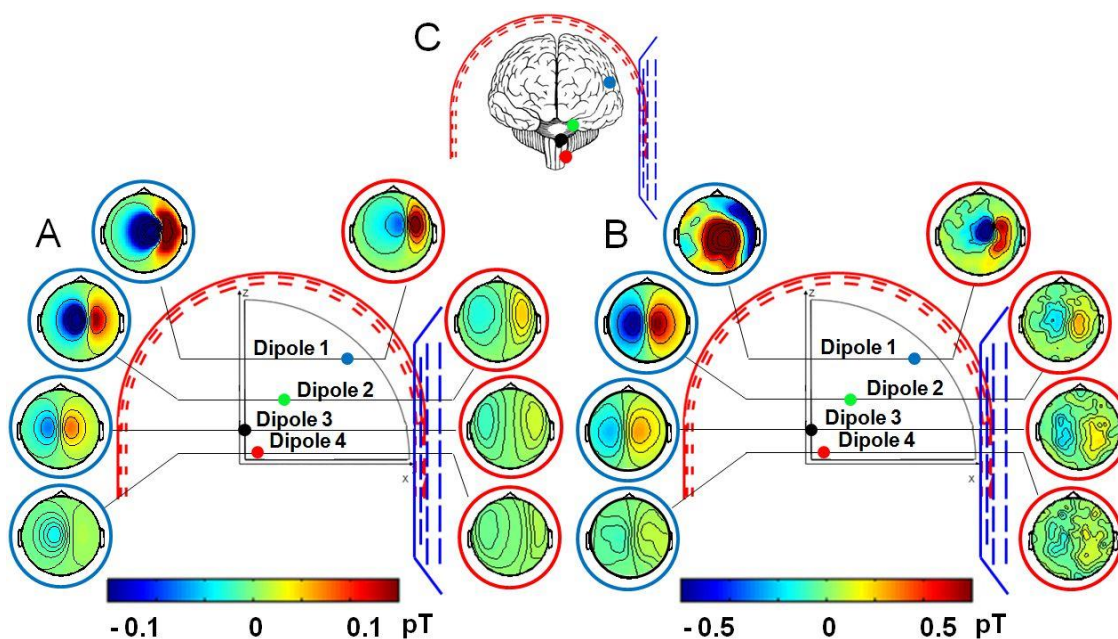
Figure 1: Phantom results: Field maps of the four simulated (A) and measured (B) dipoles representing the human auditory pathway. For the magnetometer system the field values in the sensor plane closest to the spherical volume conductor and in z direction are shown, for the helmet shaped gradiometer system the three dimensional sensor positions are projected into a two dimensional view with nose and ear sketches added to the outline. Part (C) shows the anatomical positions in relation to both measurement system geometries for a measurement with a subject. The figures show the geometry of both systems superimposed for a better understanding. The measurement features a 4 times higher electric dipole moment compared to the simulation in (A) to show the typical dipole pattern.
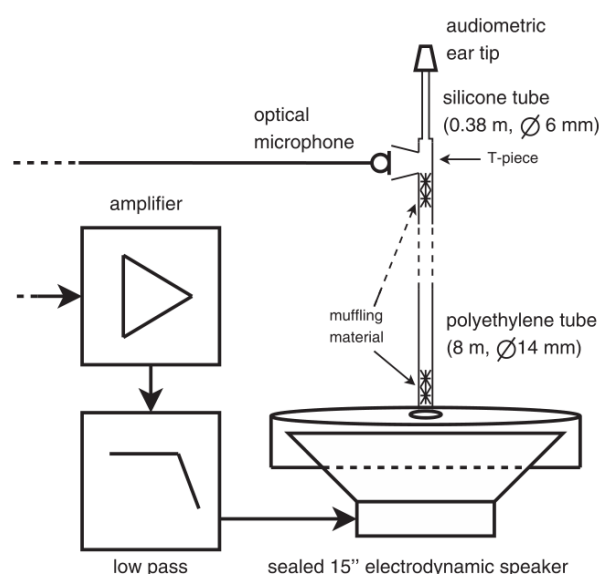
3.1.2 Development of infrasound-source for magnetic critical environment

A major challenge to measure auditory evoked brain responses using MEG and MRI lays in the sufficient auditory stimulation inside these magnetically critical environments. It was not possible to use conventional headphones or loudspeakers due to their magnetic interferences and limited frequency range. To meet the criteria we developed a new infrasound source inside the project in cooperation with the brain imaging group. The electroacoustic transducer used for this source is an electrodynamic loudspeaker with a strong magnet and a warp-resistant chassis. The loudspeaker is mounted hermetically sealed into a damped wooden box, and is coupled to the ear by a polyethylene tube (length: 8 m, inner diameter: 14 mm) and an audiometric ear tip (see Figure 2) at the end. The electromagnetic compatibility of the source and the used materials (tube, ear tip) were consistently tested to indicate whether an interference due to small amounts of ferromagnetic components were observed. For appropriate stimulation in the infrasonic frequency range it is necessary to ensure that higher-frequency harmonic components have levels below the normal hearing threshold. Therefore, the sound tube itself acts as a passive low pass filter and furthermore contains sound absorbing material, which, in combination with an additional second-order electric low-pass filter (Figure 2), effectively attenuates high-frequency harmonic components. The suppression was sufficient to reach levels below the normal hearing threshold.

3.1.3 Development of ultrasound-source for magnetic critical environment

Similar to the case of the infrasound-source, a sufficient insert-earphone sound source for very high and ultrasonic frequencies was needed. This source should also be usable in magnetic critical environment. First ideas led to so called MEMS-transducers (micro-electro-mechanical systems) since these transducers are very small to fit inside the ear canal and they were attested magnetic interference free by measurements of the brain imaging working group at PTB in Berlin. Further testing showed that the output sound pressure level was not sufficient for hearing threshold measurements in the ultrasonic frequency range. Also the planned monitoring of the sound pressure level inside the ear-canal during subjective and objective hearing

experiments using MEMS microphones was cancelled due to not solvable problems with electrical disturbance and crosstalk of the devices themselves. As a compromise solution a piezoelectric transducer was used as a sound source instead. Piezo-material is innately free of ferromagnetic material and thus usable inside MEG and MRI. The piezoelectric loudspeaker is coupled to a funnel which leads to sound tube (silicone) of 30 cm length. The tube is connected to the ear via an audiometric ear tip similar to the infrasound source. To monitor the sound pressure level inside the ear-canal during subjective and objective hearing experiments a so called 'coupler' is inserted between the end of the sound-tube and the audiometric ear tip. A commercial 1/8" microphone fits in the coupler and can now be used to measure the sound pressure level inside the tube at the entrance of ear canal. The calibration is done 'off-line' before the start of the MEG and MRI measurements. After calibration, the microphone is removed and replaced by a non metallic microphone-shaped dummy for the MEG and MRI sequences.

Figure 2: Schematic setup of the infrasound source. Harmonic distortions in the audio frequency range are minimised by a second-order low-pass filter and acoustic muffling material inside the tube.

3.2 Development of primary calibration technique and traceable measurement techniques for airborne ultrasound

3.2.1 Primary calibration standard for microphones at high frequencies

The investigation of the perception mechanisms of ultrasound requires that the sound sources used in the tests are well characterised and traceable throughout the frequency range of interest. Setting up a well-defined traceability chain, necessary as a basis of quantitative noise assessment in ultrasound frequency range, has started with a realisation of the unit for sound in air, the pascal, via the calibration of measurement microphones in the frequency range of interest (up to at least 80 kHz).

In order to extend the frequency range of free-field calibration, previously existing measurement systems and measurement methods must undergo a series of changes and adaptations including the type of measurement signal, methods for eliminating unwanted reflections from walls, cross-talk, etc. A measurement system and a calculation procedure that allow for the determination of the free-field sensitivity of working standard microphones (IEC type WS3) at frequencies up to 150 kHz was developed. The microphones calibrated in this system were be used to characterise the sound sources used in the investigation of the perception of ultrasound, and to provide traceability at ultrasound frequencies.
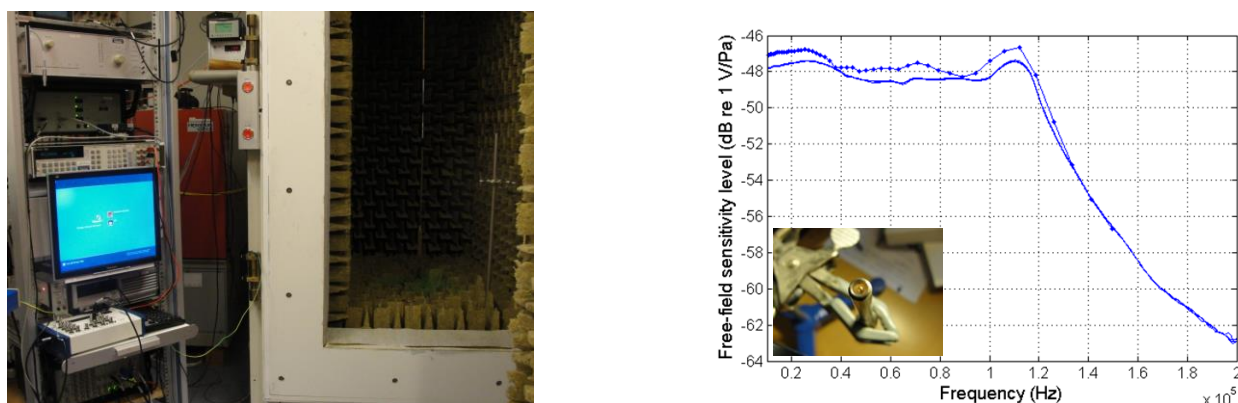
Figure 3: Left: Picture of the free-field reciprocity set-up; instrumentation and the small anechoic room in which the microphones are measured. Right: Free-field sensitivity of a WS3 microphone Brüel & Kjær type 4939 with its accompanying adapter. The free-field sensitivity is compared to data provided by the manufacturer.

The free-field sensitivity determined from measurements carried out with the measurement system, and the calculation procedures has been compared against theoretical values and manufacturer data accompanying the microphones, even though there is no information on how these accompanying data has been obtained by the manufacturer. Nevertheless, the agreement between the free-field sensitivity obtained experimentally and the manufacturer data is reasonable providing first traceable support for these data.. The main source of difference is the microphone adaptor used in the measurements of the electrical transfer impedance. As a result, it is strongly recommended to match the pair adaptor-microphone and use this matched pair as a single unit at any time. This emphasises also the importance of standardising the guard ring configurations used together with WS3 microphones. Reproducibility for such a combination is typically better than 0.1 dB, and the uncertainty is better than 0.3 dB in the whole frequency range.

3.2.2 Traceable measurement techniques for airborne ultrasound

For a general assessment of noise in the ultrasound frequency range measurement techniques and methods need to be developed which does not exist so far. A first setup was build up within the project to obtain first results for typical ultrasound sources and different measurands were acquired. Based on the primary calibration setup of section 3.3.1 for the first time the setup was traceable to a national standard. The results and experience was used to make a first attempt to relate hearing thresholds and brain response data to real application conditions.

The ultrasound measuring system consists of a quarter-inch measurement microphone on a preamplifier, a power module and an external amplifier with a flat frequency response up to 100 kHz and a fast-sampling sound card. The measurement is controlled and analysed by software on a personal computer. The setup is shown in figure 4.
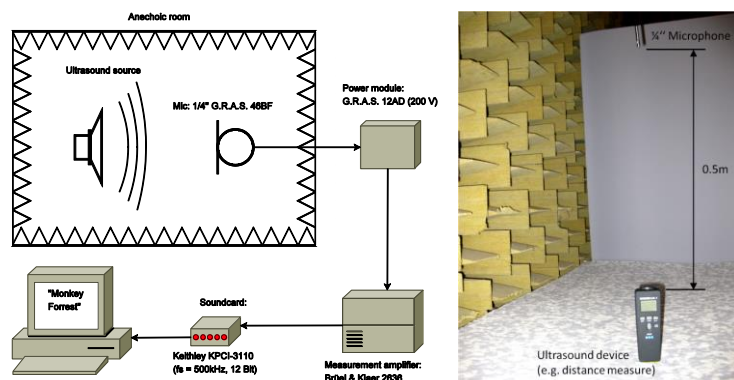
Figure 4: Setup for the measurement of airborne ultrasound. The photo shows a source being measured under anechoic conditions.

The setup makes use of a WS3 measurement microphone according to the international standard IEC 61094 and it is mounted on a half-inch preamplifier by an appropriate adaptor. This microphone-adaptor combination is suitable to be calibrated by the reciprocity calibration procedure (section 3.2.1) up to frequencies of 150 kHz. By this, traceability was obtained that most of existing measurement systems and literature measurement results have lacked of so far.

Several ultrasound sources were studied from different application sites such as pest deterrents, distance measurers, small and professional cleaning vessels and others. To establish controlled sound fields and to find reproducible results, the sources were studied under free-field conditions to exclude sound reflections from the environment. As an example, figure 5 shows the spectrogram of a sound field emitted by a small cleaning vessel with a driving frequency of about 43 kHz. The table below gives numbers of several assessment quantities that were determined, from which the maximum peak sound pressure level of L_{Zpeak} = 139.7 dB nearly exceeds the limit of 140 dB given in the German guideline VDI 3766.

L_{Zpeak}	L_{Zeq}	L_{Aeq}	L_{Ueq}	L_{AUeq}
139,7	126,9	105,6	86,4	78,8
Levels in dB (re 20 µPa)				
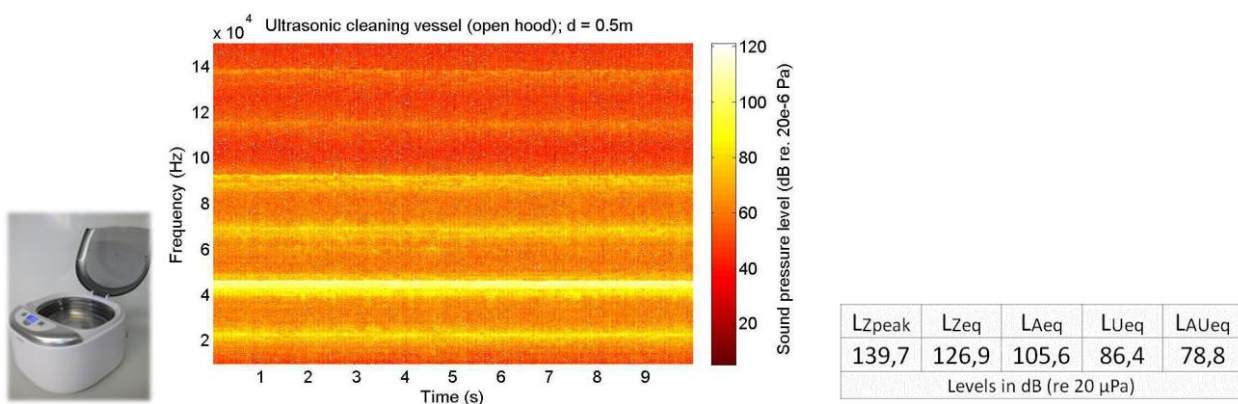
ure 5: Left: Spectrogram of a small ultrasonic cleaning vessel (shown in the photo). Table: Values for different assessment quantities measured under free-field conditions in a distance of 0.5 m above the vessel.

In general, the overall sound pressure levels, measured in free-field at a distance of 0.5 m in the main emission direction, are up to about L_{Zeq} = 130 dB (139 dB for a modified sonotrode) and L_{Zpeak} = 147 dB. The spectral characteristic is usually multi-tonal because most devices are driven at a fundamental frequency (typically in the range of 20 kHz to 50 kHz) and produce several higher and sub-harmonics. Now, sound pressure levels at ultrasound frequencies up to 100 kHz can be reliably measured with traceability to a primary standard and different assessment quantities can be determined to characterise the ultrasonic noise of devices.

3.3 Hearing thresholds and loudness of non-audible sound

3.3.1 Determination of hearing thresholds for infrasound and ultrasound

Measured across frequency, hearing thresholds are an important measure for the overall sensitivity of the human auditory system. ISO 389-7:2005 contains standardised hearing threshold values from 20 Hz up to 18 kHz butlittle is known below and beyond those frequencies limits. Hence individual hearing threshold values outside the normative audible frequencies were measured. The new threshold values are also intended for individual stimulus calibration in subsequent brain imaging investigations.

The hearing thresholds for infra- and ultrasound were determined monaurally using the newly developed insert-earphone sound sources described in section 3.1.2 und 3.1.3. The experiment itself was controlled by a MATLAB-based software framework controlling a 24 bit DA converter. 18 otologically normal subjects aged 18 to 25 years participated in the infrasound-, and 26 otologically normal subjects (19 – 33 years) in the ultrasound measurements. The experimental paradigm was an unforced weighted up-down adaptive procedure as described by Kaernbach (2001). Figure 6 shows the resulting median threshold values for infra- and ultrasound frequencies (blue lines with symbols). Additionally shown are the normative free-field threshold values ranging from 20 Hz to 18 kHz from ISO389-7:2005 (solid black line) and the normative RETSPL values between 125 Hz and 8 kHz for an insert-earphone from ISO389-2:1994 (broken black line). For the first time threshold values in the infra- and ultrasonic frequency range are shown together which are

partly based on the *same* test subjects. This means that our threshold values link the existing normative threshold data to values in the lower (infrasound) and higher (ultrasound) frequency range. It should be mentioned that all subjects were able to hear the low frequency stimuli down to 2.5 Hz whereas only 3 subjects could hear the highest used stimuli of 24.2 kHz. So median values are only shown up to 20.7 kHz which was heard by 21 out of 26 subjects.
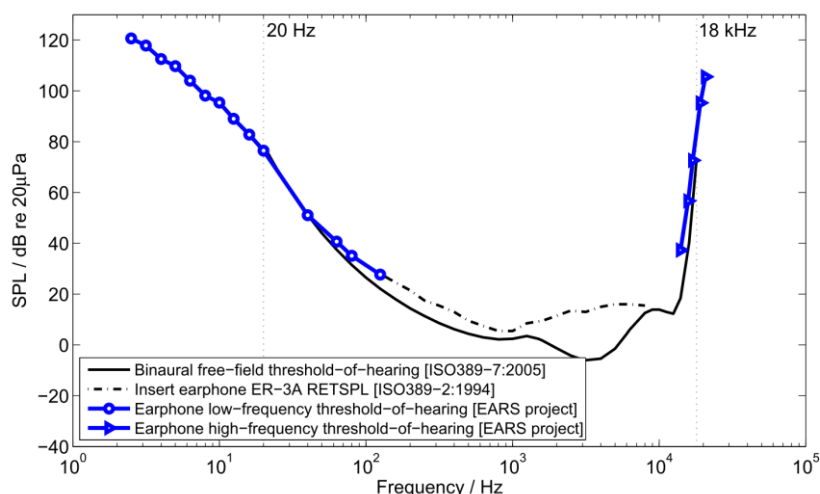
Figure 6: Average monaural threshold of hearing (solid blue lines with symbols) for low and high frequency pure tone stimuli compared with literature data: Binaural free-field threshold of ISO389-7:2005 (solid black line) and insert earphone RETSPL from ISO389-2:1994 (broken black line).

3.3.2 Determination of equal loudness contours for infrasound

Loudness is one of the key sensations of sound in everyday life and in case of unwanted noise it plays a crucial role for annoyance. Narrowing of equal loudness contours at very low, or very high frequencies means, that a small sound pressure level enhancement causes great enhancement in loudness. This is important for safety margins to be provided when setting up exposure limits for noise at those frequencies. Little is known about the loudness perception at low and infrasonic frequencies especially in the transition area between the normal hearing and the infrasonic range around 20 Hz. To investigate the loudness perception for low and infrasonic frequencies we determined equal-loudness-level contours (ELC) below 125 Hz using two different methods.

A) Categorical loudness scaling

To investigate the loudness perception for low and infrasonic frequencies we extended the method of categorical loudness scaling standardised in ISO 16832 (2006) to frequencies below 125 Hz. Categorical loudness scaling provides an easy and fast procedure to determine the loudness over the whole dynamic range of the auditory system. The loudness is rated by the subject on a scale with named categories such as soft, medium loud, loud, etc. It was the first time to use this method to frequencies below 250 Hz. Thirty otologically normal subjects performed the categorical loudness scaling for monaural stimulation. The resulting loudness in categorical units (CU) from 0 to 50 represents the subjectively perceived loudness expressed in the mentioned 11 response alternatives (see figure 7). After completion of a measurement cycle, a model loudness function (loudness in CU vs. stimulus level) was fitted to the data according to [Brand and Hohmann, 2002]. Median loudness functions showed a significant decrease of the dynamic range for lower frequencies (recruitment). The resulting average ELCs, shown in figure 8, were derived by taking the arithmetic mean over all individual ELCs.

B) Gradient field estimation

Tones below 20 Hz (infrasound) lose their tonal quality, and the term "loudness" gets less appropriate to judge its intensity. Thus, below 8 Hz, subjects made hardly use of the upper loudness categories, and the loudness growth functions could not be obtained over its full extend. Loudness scaling is therefore not

applicable for infrasound below 8 Hz, and we developed a method that is based on loudness comparison like the standard procedure for ELC measurements (ISO226:2003). Because of the rapidly changing sound character of tones with frequency below 100 Hz, we suggest to compare tones of close spectral distance of each other to make this task easier and the comparisons more accurate. The problem with having no fixed reference tone is that the sound pressure levels of the various reference tones cannot be pre-set to a specific ELC because these are not known in advance. A loudness gradient field over a range of sound pressure level has to me measured.
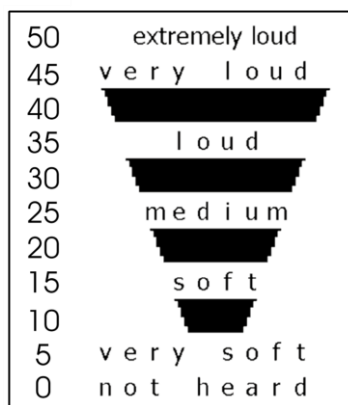
Figure 7: Category scale with 11 response alternatives including intermediate steps used by the subject to rate the loudness. The numbers on the left side indicate the categorical units (CU) which were not visible to the subjects.
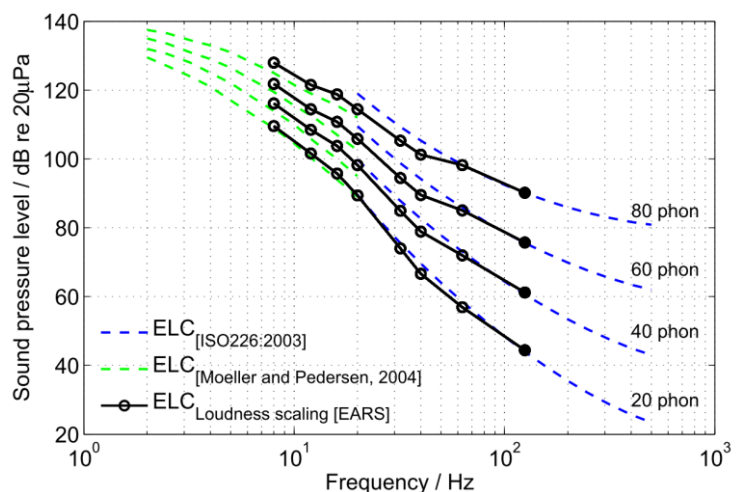
Figure 8: Equal-loudness-level contours (ELC) for 20, 40, 60 and 80 phon derived from the categorical loudness scaling functions (CLF) compared to ELCs from ISO226:2003 and [Moeller and Pedersen, 2004].

REG1 at University College London developed a novel maximum-likelihood tracking procedure that was specifically suitable for low-frequency and infrasound. It was used to adjust the probe tone level within the various adjacent tone pairs, until it was judged by the listener as being loud as the reference tone that had either 20 phon or 70 phon. From the obtained loudness gradients at these two levels the level-dependency of the loudness gradient of each tone pair was estimated by linear interpolation, and so the gradient field over the whole frequency-level area of interest constructed. The ELCs can then be obtained by following the local gradient, starting from a frequency for which the loudness levels are known (figure 9). We started the ELC estimation from the reference loudness levels at 125 Hz (ISO 226:2003).

In summary, the amount of compression of the loudness dynamic range below 20 Hz is very similar in the loudness scaling data and the gradient field. This dynamic range is in agreement with the infrasound isophons suggested by Moeller and Pedersen (2004), which do not connect well with the ELC dynamic range of ISO226:2003 for 20 Hz. Moeller and Pedersen, as well as, our measurements suggest that these reference data suggest a too large dynamic range
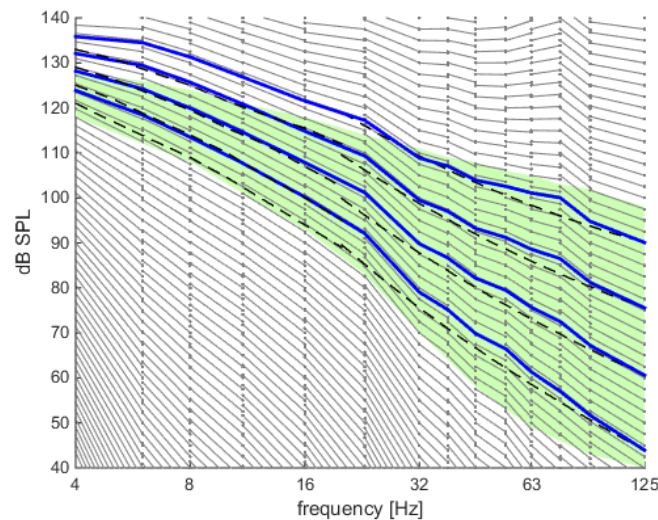
Figure 9: Loudness gradient field and derived ELC for 20, 40, 60, and 80 phon. The loudness judgements of 14 subjects were combined by fitting a single psychometric function per stimulus condition to the responses of all subjects. The ELCs from ISO226:2003 and Moeller and Pedersen (2004) are shown as dashed lines. The measurement software limited the range of the sound pressure levels to the green area.

3.3.3 Measurement and model of the middle-ear transfer

The so-called middle-ear transfer function (METF) is a basic element to understand the physiology underlying the shapes of the psycho-acoustically obtained equal loudness contours (ELCs) The transfer of the low-frequency sound pressure from the ear drum to the basilar membrane was measured in the same subject population for which loudness gradient fields were measured. It was determined by applying tones of various frequencies (20 Hz to 250 Hz) to suppress by a fixed amount the generation of oto-acoustic emissions (DPOAE), a distortion product generated by the healthy inner ear in resonance to two beating tones in the 2 kHz range. Assuming that this constant suppression by the LF tone indicates constant LF-displacement amplitude of the basilar membrane at the DPOAE generation site, an equal-output function (similar to the ELCs) was obtained. This has the inversed shape of the METF.
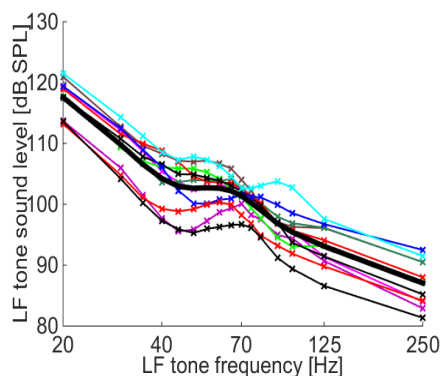

Figure 10: Inverse METF of 12 subjects (coloured lines) and their average (bold black).
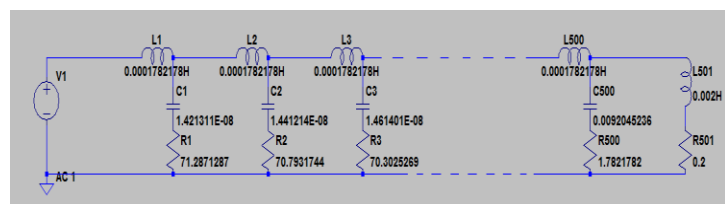
Figure 11: 1D-transmission line model of the cochlear acoustics at low-frequencies implemented in LT Spice.

Almost all of such individual curves exhibit a pronounced resonance, and even with inconsistent frequency locations, this feature can still be observed in the average curve in form of a step (figure 10). It is likely that this resonance provides the explanation for the hump observed in population ELC between 40 Hz and 90 Hz.Of great importance for understanding the low-frequency acoustics within the inner ear is to study the effects of the helicotrema, a small opening at the apical tip of the inner ear that connects the fluid chambers on either side of the cochlear partition. At acoustic stimulation below approximately 50 Hz, the wave,

travelling along the cochlear partition, reaches the helicotrema, and the differential pressure between both fluid chambers is shunted. This is generally assumed to underlie the sharp decline of human hearing sensitivity below 50 Hz. An electrical 1D transmission line model of the inner ear was developed (figure 11) to study its principle acoustical properties below 100 Hz and also the origin of the resonance feature. Our model was able to explain the latter as a combination of two resonance phenomena. The resonance near 40 Hz is caused by an interaction between the compliant apical end of the cochlear partition and the mass inertia of the fluid within the helicotrema. The anti-resonance near 60 Hz is due to an interaction of this apical compliance with the inertia of the fluid in the cochlear chambers located basally. The longitudinal extend of the model allowed simulate the effect of the resonance on the basilar membrane excitation pattern (figure 12, left). The results show that its effect extends over the full length of the cochlea (right). The development of a 3D finite-element model (FEM) has now started in order to constrain the parameters purely to geometry, and to study the displacement of a more realistic 2D basilar membrane. This will enable us to estimate the excitation of the cochlear sensory cells, auditory nerve fibre firing rates, and finally to explain the threshold and loudness data obtained in this project.
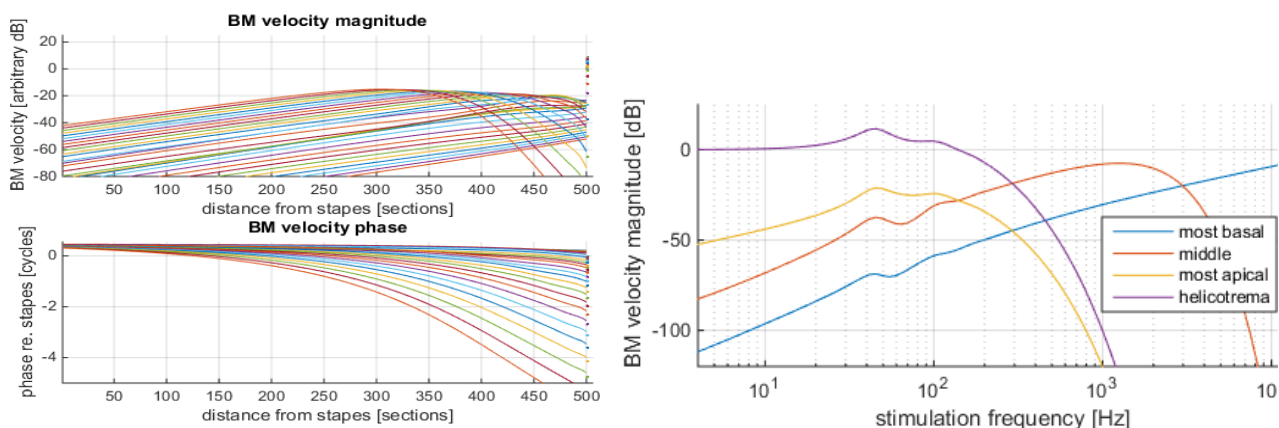
Figure 12: *Left:* Basilar membrane excitation pattern (i.e. the currents through R1 to R500) in response to stimulation frequencies 4 Hz to 512 Hz. Data are normalised to the stapes movement (current through the voltage source). The curves forming the dense region (approximately in the middle of the magnitude figure) correspond to the frequency range where the irregularity in the METFs occurs (40 - 80 Hz). The dots on the right quantify current through the helicotrema (i.e., R501). *Right:* METFs at various longitudinal basilar membrane positions.

3.4 Brain responses for non-audible acoustic stimuli and their potential for a rational underpinning of noise assessment

3.4.1 Brain responses by magnetoencephalography

Loudness contours are the description of the subjective perception of a hearing sensation. To support this by objective means of investigation brain responses of the same test persons were measured. In the first series the loudness was kept constant and the frequency was varied in steps using 250 Hz, 125 Hz, 63 Hz, 40 Hz, 20 Hz, 12 Hz and 8 Hz. The sound pressure level setting for the 16 subjects was determined individually from the categorical loudness scaling results for each subject. MEG measurements were carried out inside a magnetically shielded room (Ak3b). The different frequency stimuli were presented in random order with a total measurement time of 45 minutes. This led to 75 epochs for averaging in MEG.

All subjects reported a perception of the stimuli down to 8 Hz. The brain responses to tones with a frequency between 250 Hz and 20 Hz showed nearly the same amplitude of around 250 fT to 200 fT. The response amplitude to the very low frequencies of 12 Hz and 8 Hz reduced to around 100 fT and 50 fT, respectively. After subtracting the duration of the onset ramp a stable latency of 120 ms is observed. The recorded field maps in figure 13 show two different groups of subjects. The first group has a stable dipole response down to the 8 Hz stimulus, the other group shows only noise instead of a dipole pattern below 40 Hz. Most of the dipole patterns observed in the response to the 12 Hz and 8 Hz stimuli are different to the dipole patterns observed for the stimuli between 20 and 250 Hz. The time series of the channel with the strongest amplitude

in the evoked response is shown on the left, the associated field map at the peak of the time series in the middle. The map on the right is another subject showing the vanishing of the dipolar patterns below 40 Hz.
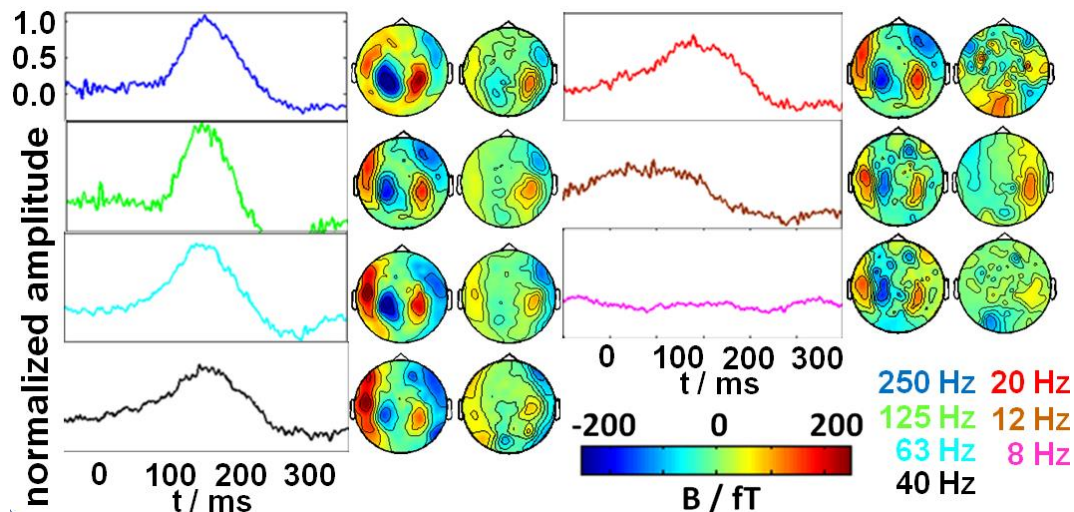

Figure 13: Time series and field maps of two different subjects. The time series shows a stable latency of 120 ms down to 20 Hz after subtracting the duration the onset window. The amplitude also remains stable within 20% in the frequency range between 250 Hz and 20 Hz. The responses to 12 Hz and 8 Hz differ from the results at higher frequencies. The field maps are representatives of two groups of subjects, for one group a dipole pattern is observed down to 8 Hz stimulation and for the other group the very low frequency stimulation leads to noise field maps instead of a dipole pattern in the field map.

All active dipoles locations are estimated in the area of the auditory cortices. The confidence interval of the dipoles representing activity relating to the 20 Hz, 12 Hz and 8 Hz tones is wider than the other dipoles. This is due to the fact, that the electric current dipole model didn't fit the noisy data of the very low frequency responses of some subjects (right column of maps in figure 13.

In the second series the loudness was varied at two frequencies.The acoustic setup and stimuli shape was the same as described above. Only two frequencies could be sampled as the session time inside the MEG is limited because subjects cannot focus their attention much longer. The results cover event related fields of 10 subjects. At 125 Hz the minimal SPL was the hearing threshold, because lower SPLs were below the ambient noise in the MEG room. At 12 Hz the lowest volume level was 10 dB below the hearing threshold. For hearing threshold no meaningful MEG maps were obtained for 125 Hz as can be seen from figure 14. No meaningful maps were obtained at 12 Hz.

Considering the results for the loudness contour surface for the group with more than 10 subjects it can be stated, those MEG responses are congruent with behavioral responses. A MEG response for stimuli below hearing threshold was not found and hearing threshold is a suitable threshold for safety measures.
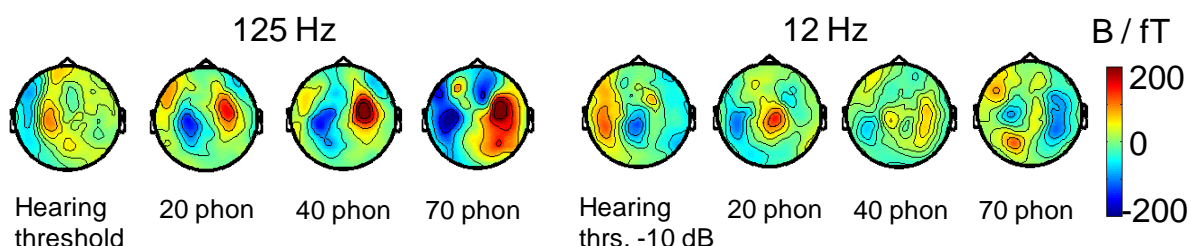
Figure 14: The MEG maps at 125 Hz from one subject show the decreasing magnetic field as a function of decreasing acoustical amplitude. This cannot be seen at 12 Hz.

For ultrasound the stimuli were tone bursts consisting of 3 pure sine tones of 400 ms and a pause of 100 ms in between. Frequencies of 14 kHz, 16.9 kHz, 19.1 kHz, 20.7 kHz and 24.2 kHz were used. The sound

pressure level setting for the 9 subjects was determined individually from an audiologic pre measurement, which is comparable to categorical loudness scaling. The subjects had to listen to two consecutive time windows. In one of the two time windows a sound burst was played and the subject had to decide in which one the sound occurred. The frequencies 16.9 kHz, 19.1 kHz, 20.7 kHz, 24.2 kHz were played 10 dB below individual hearing threshold and at 5 dB above hearing threshold. A brain response was observed only for the 14 kHz stimulus played at a higher SPL of 20 dB. No response could be found apart from the response at 14 kHz. A suitable threshold for safety purposes is the hearing threshold.

3.4.2 Brain responses by functional magnetic resonance imaging

In our first fMRI study we presented sounds at the frequency of 8, 12, 20, 40, 63, 125 and 250 Hz at random. Moreover there were also trials in which participants expected to hear a tone, but none was presented in order to have a baseline to compare the other sound presentations to („nullevents"). In order to ensure that the brain activity is not disturbed by scanner noise we used a so-called sparse sampling MR sequence which is quiet while the sound is presented and only produces the typical scanner noises when the data is acquired right after the sound presentation. To analyse the data we used the typical preprocessing steps including slice timing correction, spatial realignment, co-registration and normalisation to a template brain as well as smoothing. We modelled each sound frequency and the "nullevents", where no tone was presented, as a separate regressor. We contrasted each sound against "nullevents".

All subjects reported a perception of the stimuli down to 8 Hz. The results indicate a processing of all the presented stimuli in the auditory cortices (Fig. 15). No other activity is observable for the statistical threshold at $p < 0.001$ and a cluster size > 22 voxel. Interestingly no significant activation was found for the 20 Hz stimuli.
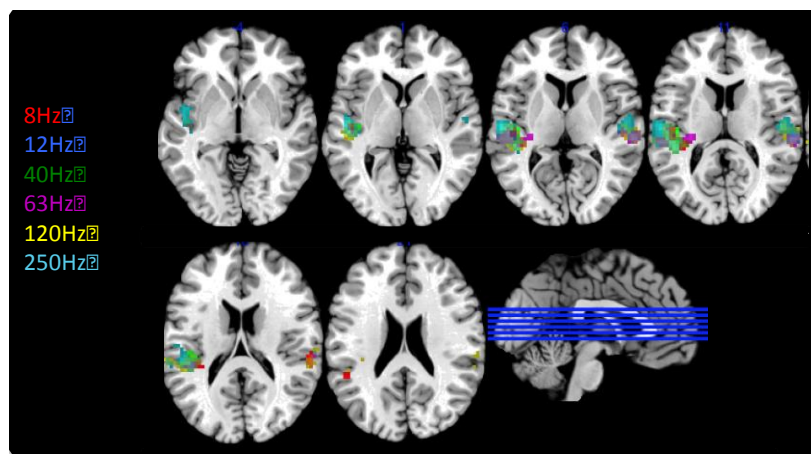

Figure 15: Results of the fMRI measurements plotted as a contrast against the baseline condition. Activation restricted to the auditory cortices is observed using $p < 0.001$ as statistical threshold and a cluster size > 22 voxel. A small shift of the activation towards central with decreasing stimulus frequency is visible.

Plotting the BOLD response in the primary auditory cortex (as defined by an Atlas provided by the SPM Anatomy toolbox) as a function of frequency a U-shaped curve is found having a dip at 20 Hz in primary auditory cortex (Fig. 16). The curves look very similar when using an anatomically defined region of interest consisting of Heschl's gyrus. This behavior shown may hint at two different processing pathways for auditory stimuli above and below 20 Hz. It has previously been shown that not only auditory stimulation (white noise), but also somatosensory stimulation (stimulation on the middle and index finger) can result in activation of the auditory cortex (Foxe et al., 2002). The authors find significant overlap between both types of stimulation in bilateral superior temporal gyrus. Our present hypothesis is that potentially sounds below 20 Hz are represented based on their somatosensory properties, whereas sounds above 20 Hz are represented based on their auditory properties.
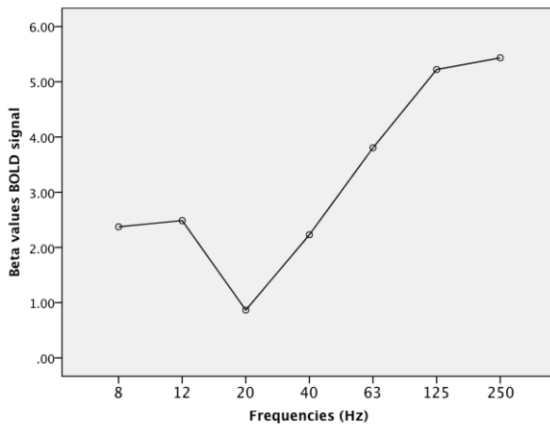
Figure 16: BOLD activity during infrasound in the functionally defined primary auditory cortex showed a U-shape with a dip at 20 Hz

To study ultrasound perception in fMRI we presented sounds with 14 kHz at a sound pressure level 20 dB above the individual hearing threshold (IHT), with 16.9, 19.1, and 20.7 kHz 5 dB above and 10 dB below IHT, and with 24.2 kHz only 5 dB above IHT. We succeeded in recruiting 13 healthy participants who were actually able to hear the sounds. The design was the same as previously described for infrasound including "nullevents" and using a sparse-sampling fMRI sequence. We performed the similar preprocessing steps and analysis. Opposite to the infrasound study we found significant activation in auditory cortex only when 14 kHz sounds were presented above IHT. At all the other sound levels significant auditory activity was not elicited.
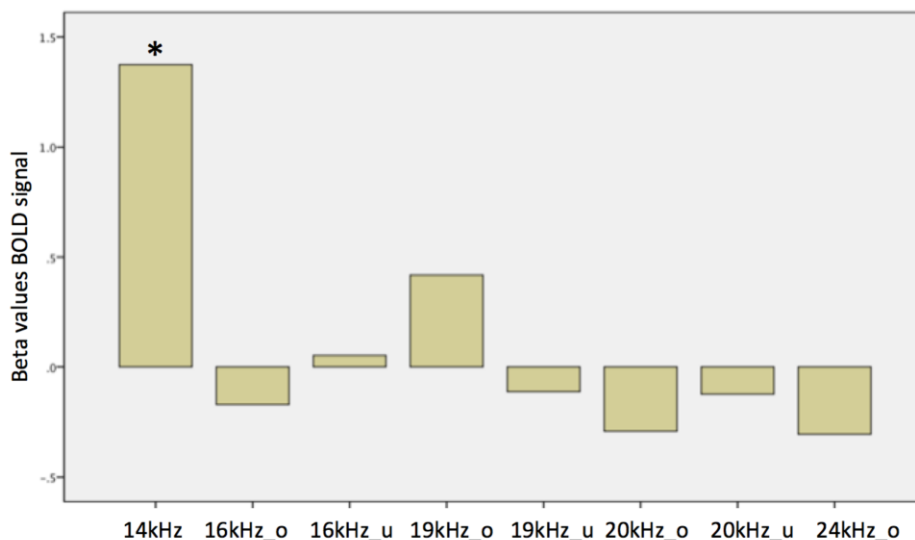
Figure 17: BOLD activity during ultrasound exposure in the functionally defined primary auditory cortex showed significant activity only at 14 kHz; sound was presented above individual hearing thresholdAbove (o) and below (u) individual hearing threshold

To examine the potentially detrimental effects of infrasound on cognitive task performance and affect we conducted two additional studies one using a cognitive task which is based on working memory, a so-called nback, and one using an affective task by a rating of the pleasantness of pictures. We expected to find differences in the network utilised to master the task at hand.

During the cognitive task participants had to keep the position of dots in a grid in mind and indicate whenever the current position was equal to the one presented 3 items back. To study affective processing participants were presented with Mondrian like stimuli, after which participants were asked to indicate how much they liked the picture. Since participants have difficulties in judging whether Mondrian like pictures are repeated, each picture was shown twice, once combined with an infrasound of 12 Hz (duration 2 s), once without. Our hypothesis was that if infrasound is perceived as irritating they should influence the aesthetic judgment. The data did not reveal any indication of an alteration of the typical working memory networks or the typical areas involved in pleasantness judgments.

Comparing task performance in the nback task revealed no significant difference between tone and no-tone blocks. However, we saw a tendency for more correct trials in tone blocks, compared to no-tone blocks (t(12)=1.86, p=0.087).

In order to explore whether participants scoring high on scales assessing depressivity (Beck Depression Inventory, Beck, Steer, Ball, & Ranieri, 1996), anxiety or neuroticism (as assessed by means of the neuroticism subscale of the NEO-Five Factor Inventory, McCrae & John, 1992) have a tendency to suffer more from infrasound exposure, we correlated the nback performance difference between tone and no-tone trials, as well as the differences in affective ratings between both trial types with these scores. We neither found any significant correlations nor associations between signal intensity in auditory cortex and these scales.

3.4.3   Strategies for incorporation of brain response into noise assessment for non-audible noise

The specific concept of the project gave the opportunity to combine subjective hearing test measurements with objective brain activity measurements. The perception of infrasound and ultrasound frequencies was clearly approved and the relation between the underlying mechanisms of sound perception and the behavioural and physiological responses at these frequencies could be studied. Even though this finally resulted in many new scientific questions not known at the beginning of the project, brain imaging could significantly contribute to the assessment of infrasound and airborne ultrasound noise. Combining the objective brain measures with the subjective hearing properties, the following noise assessment strategies are suggested.

Infrasound

The investigations described in section 3.4.1 (MEG) and 3.4.2 (fMRI) showed that infrasound with sound pressure levels above the hearing threshold activates the auditory cortex down to frequencies of 8 Hz. Brain imaging yielded first indications that below about 20 Hz the mechanism of perception possibly changes so that other sensory processes may produce input into the auditory cortex. By fMRI resting state experiments auditory cortex activation was detected for sound pressure levels even slightly below the individual hearing threshold. Additionally, for the very same stimulation, activation of regions was found where the brain processes emotional activity. These findings suggested that the health risk linked to infrasound exposure is most probably more due to annoyance and arousal than to real damage of the inner ear mechanics (cochlear amplifier). Hence we recommend that the exposure limits are set along the hearing threshold itself. As does the German standard DIN 45680, the 'sensation threshold' should be set to represent 90% of the population; i. e. the exposure limit should be set at the 10 % percentile of a subject group representing the part of the population with healthy hearing.

This strategy is of course still under discussion with respect to the discovery of emotion-linked brain response even for sound pressure levels below hearing threshold. Further data from both sides, objective brain imaging and psychoacoustic investigation of annoyance, are required for a serious estimation in particular of this matter.

Ultrasound

Also for ultrasound, brain imaging methods were applied, but in contrast to the infrasound stimulation no activation could be detected for frequencies at 16.9 kHz and higher. This holds also for the cases where test persons reported to hear a tone. Owing to the limited data base this result is interpreted only as a first hint that perception of airborne ultrasound by the auditory system exists in some subjects, but its objective measurement is limited. Note that no assumption can be made for bone conduction ultrasound.

After the hearing experiments all test persons were asked to rate the annoyance of the test stimuli. All test persons who heard sound above 16 kHz reported that this had been rather annoying. The findings of this study lead to the proposal of the following strategy for the assessment of ultrasonic noise: Prevent any annoyance as fundamental impact on humans by avoiding even the perception of airborne ultrasound. The basis for this strategy is again the measured hearing threshold data. At frequencies between 10 kHz and 20 kHz they are more individual and diversified than at conventional audible and even at infrasound frequencies. Additionally, the age related effect that younger adults and children perceive frequencies between 10 kHz and 20 kHz at lower levels than older adults do, is also much more pronounced in

comparison to conventional audible and infrasonic frequencies. For ultrasound above 18 kHz, this effect decreases, but there the thresholds are very near to loudness levels that cause annoyance. To account for this, the 1 % percentile or the minimum threshold of an appropriate data set should be used as an exposure limit. It is also proposed to provide extra margins for groups of individuals with specific ultrasound hearing sensitivity.

All conclusions drawn are a first attempt to improve the rational underpinning of noise assessment in the frequency ranges of infrasound and airborne ultrasound by staying on the safe side of the problem, until we will have data from greater cohorts, and from age-specific groups. The project team is well aware that many problems still have to be solved in future.

3.5 Specifications, design, and manufacturing of the universal ear simulator

3.5.1 Finding and definition of specifications

In the process aiming at designing and producing a new prototype universal ear simulator, the first task consisted of establishing its specifications in accordance with user requirements. Thus, the methodology of designing an ear simulator has been tackled to emphasise the key parameters of its design. From this methodology study, it has been shown that both the input impedance and the transfer impedance of the ear canal are two key parameters that must be included in the specifications. Thus, a literature review has been undertaken to gather experimental data for these two key parameters for several ages, from newborns to adults. Data for the acoustic input impedance of the ear canal have been gathered for several ages, unfortunately, it has been highlighted that there is no available data in the literature for the acoustic transfer impedance of the ear canal. This lack of data has been overcome by determining the transfer impedance using a transmission line model, provided that both the input impedance of the ear canal and its geometry are known. Thus, geometrical dimensions of the ear canal have also been gathered for several ages.
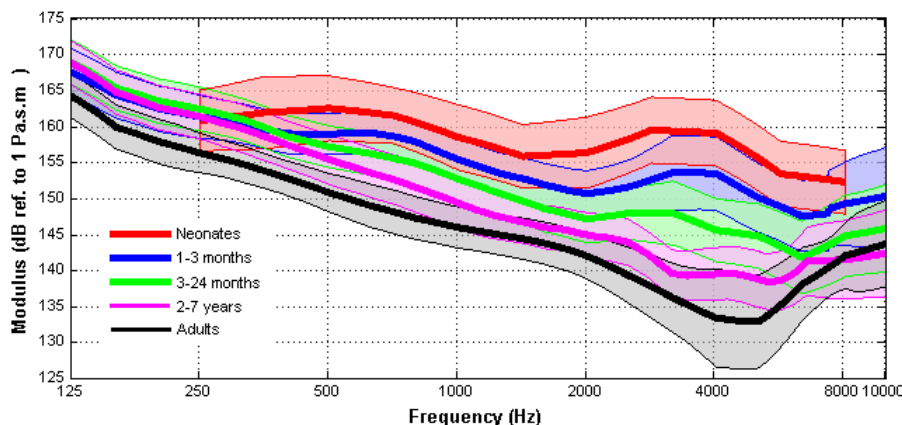

Figure 18: Modulus (in dB ref. to 1 Pa.s.m-3) versus frequency (in Hz) of the input impedance for the neonates group (red line), the 1-3 months group (blue line), the 3-24 months (green line), the 2-7 years (magenta line), and the adults group (black line). Color areas represent the standard deviations.

Besides the literature review, a questionnaire has been developed and sent to audiologists in order to identify their expectations and requirements for the ear simulators. As a result, it was expected to use principally short term signals in order to mainly calibrate insert earphones but also circum-aural and supra-aural earphones as well as insert probes. In accordance with the questionnaire results, and from the input impedance data collected, five age groups have been defined: neonates, 1 to 3 months, 3 to 24 months, 2 to 7 years, and adults. For each age group, the input impedance data have been transferred to a reference plane previously defined, and then averaged (Figure 18). The average length, radius and volume were also collected for each age group, besides the area function of the ear canal (namely its cross-sectional area as a function of the distance from the eardrum) which is available only for adults.

3.5.2 Design of the universal ear simulator and development of numerical methods for description

The study focusing on the methodology of designing an occluded ear simulator shows that the process of designing an ear simulator requires four steps: (i) define the geometry of the artificial ear canal based on experimental geometrical data, (ii) determine the terminal impedance of real ears from experimental data (geometry of the ear canal and input impedance), (iii) choose the microphone (according to its dimensions and impedance), and (iv) design a network of Helmholtz resonators composed of cavities and capillary holes or slits, in order to simulate the terminal impedance of the ear simulator.

A part of these tasks have been accomplished using both an analytical model and a numerical model (finite element model). Both models were based on the linearised equations of acoustic in thermoviscous fluid i.e. the Stokes-Navier equation, the heat conduction equation and the conservation of mass equation. For the numerical model, these equations were implemented in the software COMSOL Multiphysics using their weak formulation.

a)   b)
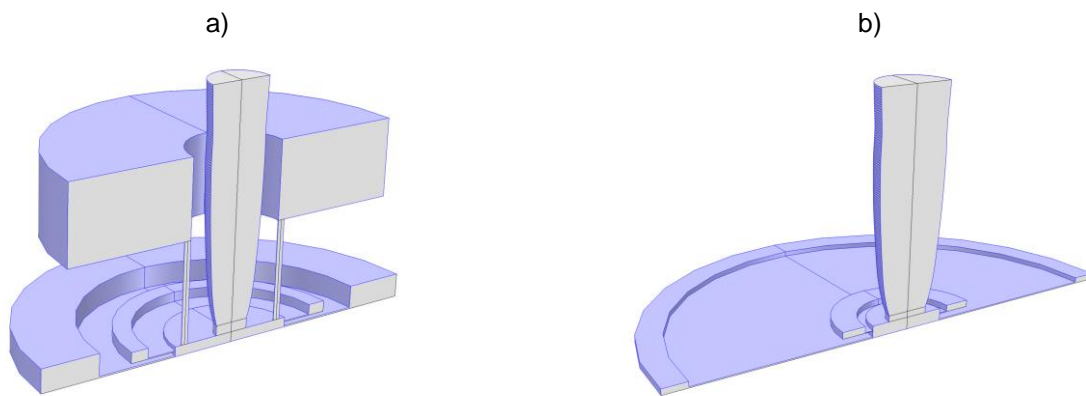
Figure 19: Global designs of the family of ear simulators. a) Neonates, 1-3 months and 3-24 months children groups; b) 2-7 years children and adults groups.

The design (Fig. 19) proposed in this project differs from the one presented in IEC 60318-4 for occluded ear simulator with respect to two major aspects which were basic innovations obtained in this project. First, the shape of the wave guide, i.e. the cylindrical tube that guides the acoustic waves to the microphone, is based on the average ear canal geometry of human ear; this part is called "artificial ear canal". This means that for the first time anatomical properties were included into an ear simulator concept. Second, the Helmholtz resonators that simulate the impedance of the eardrum are placed near the microphone location and not along the wave guide as is usually the case. A cylindrical cavity was placed at the end of the artificial ear canal in order to ensure the coupling with the microphone, and that a short cylindrical tube was placed between the simulated ear canal and the small cavity so as to avoid sharp edge.

a)   b)
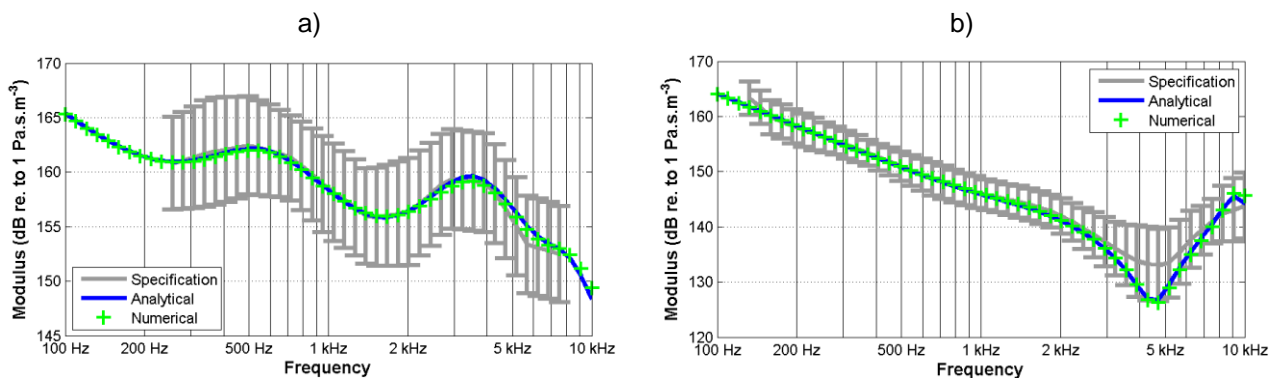
Figure 20: Acoustic input impedance of the ear simulators: a) neonates, b) adults. Modulus (in dB re. to 1 Pa.s. m-3) versus frequency. Gray curve: Specifications and standard deviation. Blue curves: Analytical model. Green crosses: Finite element model.

The possibility of defining a single device for the universal ear simulator made with adjustable ear canals, cavities, slits and holes was considered as not realisable in practice. Therefore, five devices with two global designs were developed. The first one, which includes three Helmholtz resonators, is intended for the neonates, 1-3 months and 3-24 months children groups (Figure 19a), and the second one which includes two Helmholtz resonators, is intended for the 2-7 years children and adults groups (Figure 19b). The shape of the simulated ear canal is based on the average area function of adult's ears, and it is then sized according to the average dimensions (length, radius and volume) of the ear canals for each age group. Dimensions of the Helmholtz resonators were determined using the analytical modelling and then adjusted using the numerical modelling. A ¼ inch pressure microphone was selected to avoid cluttering space and to keep a satisfying sensitivity.

Figure 20 shows examples of the acoustic input impedances computed using both the analytical and the numerical model for all groups. The comparisons of these theoretical results to the specifications show a good agreement with differences about 1 dB, excepted around the ¼ wavelength anti-resonance frequency where the differences are larger. Thereby, the geometries, dimensions and tolerances of the family of ear simulators were provided for manufacturing the prototypes. They represent a demanding challenge for the mechanical engineering and the requirements could only be meet because of a fruitful collaboration of a manufacturer and the design team which both were part of the project team.

3.5.3 Manufacturing of the universal ear simulator

The purpose of this task was to manufacture physical prototypes implementing the acoustical design based on the literature study and questionnaire. Within the framework of the project, one design could be implemented. The neonatal occluded ear simulator design, described above, was selected for two reasons. One of the primary focus points of the project was metrology for neonatal hearing screening programmes, and due to complexity and size it was considered the most challenging of the five age group designs. Thus, the neonatal ear simulator prototype would meet a primary purpose and serve as a solid proof of concept.

Two versions of the prototype were made. The purpose of the first was to verify the design, to provide items for development of a calibration method and round robin comparison of the method, to determine temperature and static pressure dependence of the ear simulator, and to identify issues that could be solved with the second version. The purpose of the second prototype was to provide items for clinical testing.

The manufacturing of the prototype consisted of transferring the acoustical design into a design feasible for practical manufacturing and use of the device, and subsequently manufacturing the physical devices. The developed acoustical design was followed as close as possible. A few, acoustically insignificant, modifications were necessary for the practical design. The microphone is a ¼" pressure field microphone, Brüel & Kjær Type 4938. The microphone is removable for calibration purposes. From discussions on how to calibrate and verify the ear simulator, it was clear that this would be advantageous.

Five samples were made of the first prototype. After manufacturing and before it was used for calibration method development, the uniformity of their acoustical design was verified using a simple measurement method.

The second prototype was designed on basis of the experience with the first prototype. As there were no indications that the acoustic design needed revision, the primary changes were an improved interface for adaptor mounting and a more consistent assembly process. Six samples were made of the second prototype, and as for the first prototype their uniformity was verified before they were used for clinical testing.

As a universal device useful for many different ear tips and earphones for different applications, the ear simulator prototypes are of a modular design. For the first prototype an ear canal extension was made following the geometry of neonate ears found in literature and with the same mechanical interface as at the ear canal entrance. However, it turned out to be impractical for ear tip mounting, as it is not soft as a real ear and all available ear tip types do extend the outer part of the real ear canal. In the second prototype, the mechanical interface of the ear canal entrance was improved with maximum flexibility (extending ear canal, flush mounting, etc.), allowing for virtually any shape of adaptor. Three different ear tip adaptors for the

clinical testing of the prototype and a calibration adaptor for a LS2P transmitter microphone (e.g. Brüel & Kjær Type 4180) were provided for use with the prototypes.

Figure 21:   Photographs showing second prototype of neonatal ear simulator and adaptors

3.6   Calibration and testing of the universal ear simulator

3.6.1   Test of features and development of calibration techniques

The purpose of this task was to conduct an experimental investigation to establish the calibration process for the new neonatal occluded ear simulator, both as a means of verifying the design goals for the acoustic characteristics, and for demonstrating the effectiveness of this essential practical consideration.

Two key metrology developments were required; (1) the pressure calibration of the IEC type WS3P microphone fitted within the ear simulator, and (2) a method for determining the acoustic transfer impedance of the complete device.

That the universal ear simulator design allowed for the removal of the microphone from the device housing, greatly simplified the task of calibrating the microphone. However the microphone used is a quarter-inch type, and demands for calibrating this type of microphone are relatively uncommon. A number of techniques were considered, including comparison methods and techniques similar to that used to establish primary standards (i.e. reciprocity methods). However in the end, the simplicity of electrostatic actuator methods was preferred, considering that secondary calibration laboratories may eventual take-up the methods.

The acoustic transfer impedance is a key factor distinguishing the neonatal ear simulator from adult ear simulators, and effectively determines the sound pressure produced by a give transducer. A calibration method has been developed, that like primary calibration of microphones, exploits transducer reciprocity. Four participants in the project developed suitable apparatus for determining this parameter, but the suitability of the proposed technique was evaluated initially at NPL (Figure 22).

This work then progressed with a round-robin robin comparison of results from the four independently developed apparatus, before reaching its final conclusions (see below).
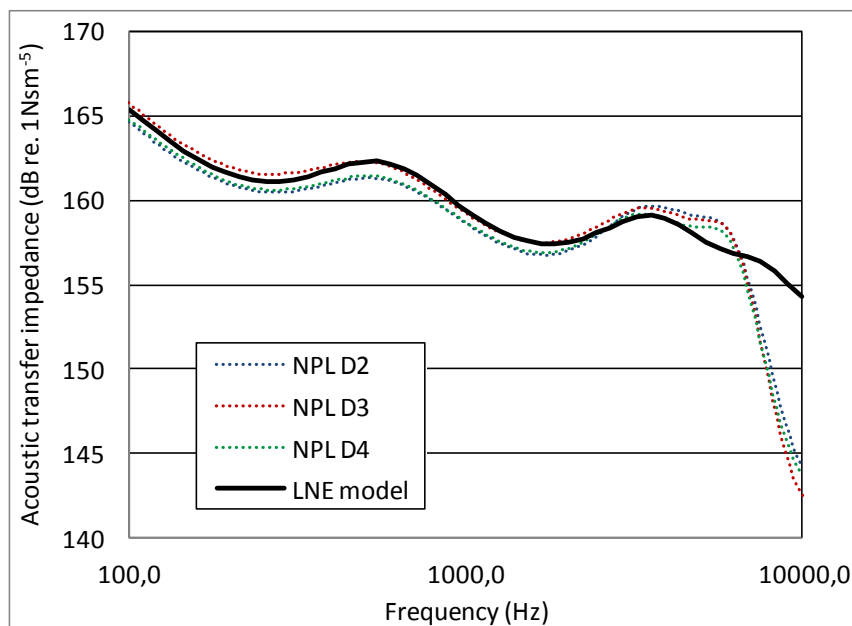
Figure 22: Acoustic transfer impedance for a sample of three universal ear simulators demonstrating both good conformance with the LNE numerical model (the design goal) and good consistency in performance between devices.
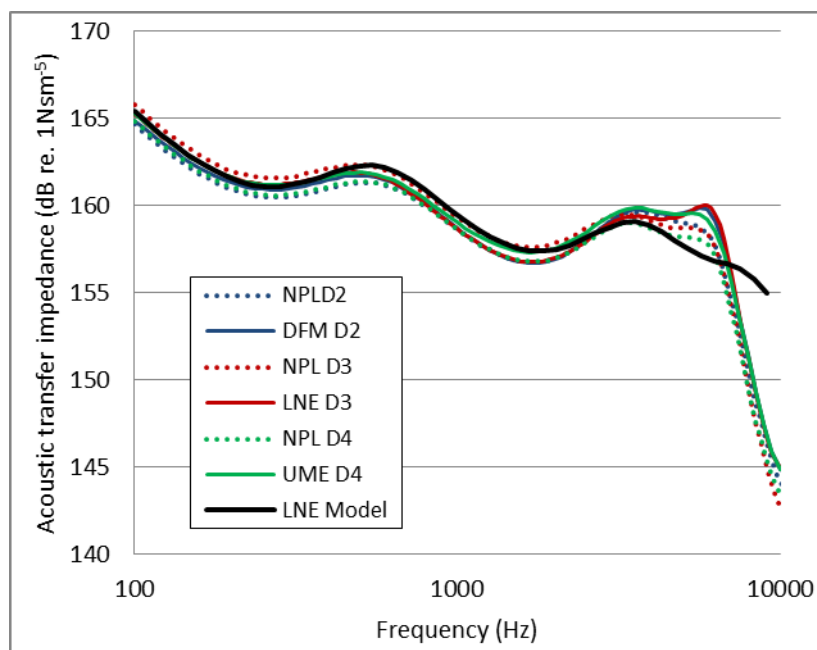
The acoustic transfer impedance of ear simulator has been determined under wide environmental conditions. Acoustic transfer impedance measurement set up was coupled with pressure and temperature chambers separately. Pressure and temperature dependence measurements of ear simulator have been performed. Acoustic transfer impedance of ear simulator changed less than 0.5 dB between 18 °C and 28 °C temperatures and less than 1.0 dB between 90 kPa and 99 kPa pressures as it is seen in Figure 23.
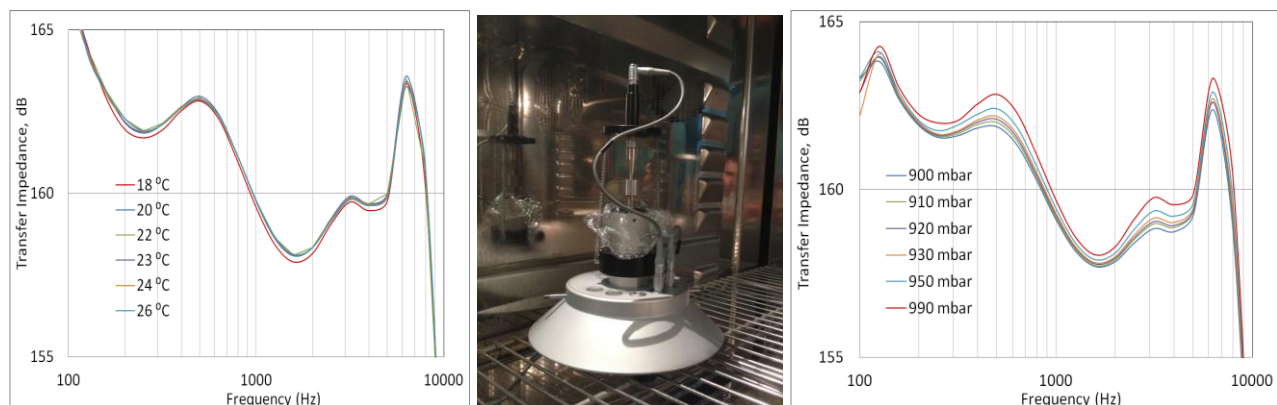
Figure 23: Pressure and temperature dependence of acoustic transfer impedance of ear simulator

3.6.2   Round robin comparison

A round-robin comparison of results from four independently developed apparatus was carried out to demonstrate the efficacy of the measurement principles, validate the design and manufacturing processes and establish the potential for future specification of such devices in international standards. Figure 24 shows the key result of arising from this series of developments.

Figure 24: Results of the inter-laboratory comparison on the determination of the acoustic impedance of the universal ear simulator as a function of frequency, demonstrating both good consistency and conformance with the target response. Measurement repeatability at individual NMIs was found to be typically 0.2 dB or less, and the reproducibility found to be typically 0.5 dB.

These results confirm the suitability of the measurement techniques that have been developed and indicate a good basis for developing recommendations for a future IEC standard specifying this device. Indeed the reported measurements are vital for establishing tolerances on the acoustic transfer impedance required to establish such a conformance specification in the first instance. The excellent agreement between the measurements reported here and the modelled target specification, also serve to validate the design and manufacturing processes with respect to the acoustic transfer impedance, and that these processes can be used as the basis devices for other target age groups.

Together, this family of ear simulators will ultimately improve the measurement quality of hearing assessment for all patient age groups, and provide enhanced reliability in diagnosis.

3.6.3   Determination of reference hearing thresholds and application of the neonate occluded-ear simulator prototype for stimulus calibration

In this task reference hearing thresholds have been determined for the Otodynamics EchoScreen PRE-T otoacoustic emission (OAE) probe and the Biologic Navigator SINSER insert earphone intended for measurements of auditory evoked potentials (AEP), both for pure tones and for standardised short-term stimuli. Both transducers are commonly used for audiometric hearing assessment of neonates and toddlers. Though manufacturers and users apply specific calibration procedures, no reference zero determined according to the preferred test conditions specified in ISO 389-9 has been available for these devices so far.

The reference thresholds were measured with at least 25 otologically normal test subjects aged between 18 and 25 years fulfilling the requirements of ISO 389-9. Pure tones in the audiometric frequency range from 125 Hz to 8 kHz, the 100-µs-duration reference click and reference tone-bursts (IEC 60645-3) with fundamental frequencies of 500 Hz, 1 kHz, 2 kHz, 4 kHz, 6 kHz (all short-duration signals with 20 Hz repetition rate) were used as stimuli.

The reference thresholds, both pure-tone Equivalent Threshold Sound Pressure Levels (ETSPL) and short-duration-signal peak-to-peak-equivalent ETSPLs (peETSPL), were specified in the IEC 60318-4 occluded-ear simulator (Brüel & Kjaer type 4157). The peETSPLs for the short-term stimuli were determined according

to IEC 60645-3 and ISO 389-6 by means of a 1-kHz continuous sinusoidal signal that had the same peak-to-peak value as the short-duration signal. The results are shown in Figure 25.
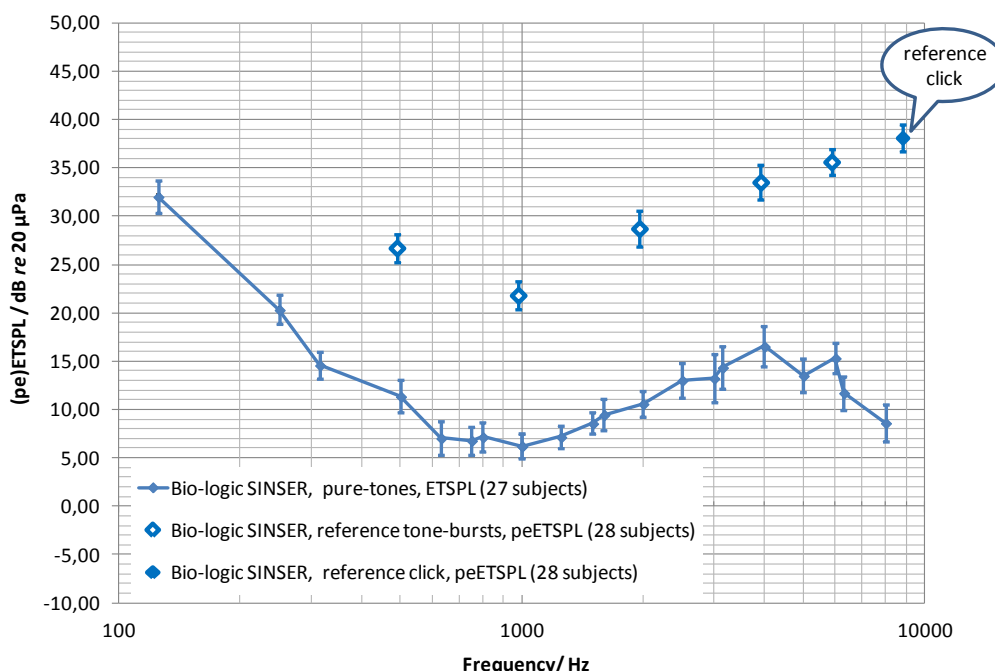
Figure 25: Biologic Navigator SINSER insert earphone reference hearing thresholds (mean ± 1 STD) for pure tones (ETSPL) and short-term stimuli (peETSPL) in occluded-ear simulator IEC 60318-4 (B&K 4157, with Adapter DP0370)

These data now provide reference for every hearing assessment in clinical practise using the above mentioned transducers.

However, since reliable behavioral reference thresholds can only be determined with adults, whereas the target age groups are neonates and toddlers, a concept for appropriate stimulus calibration for these age groups was developed in the second part of this task.

Assuming that the hearing threshold of neonates and toddlers is reached at the same ear drum sound pressure as for adults and that the peak-to-peak value in the average ear of the target age group is, for the same transducer and stimulus, essentially equal to that in the age-related occluded-ear simulator, the following procedure can be used:

a) Determine the reference thresholds in the adult ear with the standardised IEC-60318-4 occluded-ear simulator

b) Calibrate the stimuli for neonate or toddler ears with the suitable age-related ear simulator from this project.

The neonate occluded-ear simulator prototype described in 3.5.3 was used for step b). Figure 26 depicts the stimulus level increase obtained for the Biologic SINSER insert earphone when calibrated in the neonate prototype compared to the adult ear simulator.

Note that the increase in level represents the underestimation of the stimulus level at the neonate eardrum that would occur if step b) was omitted. In the frequency range around 1 kHz this error is greater than 10 dB. Calibration errors in this order involve the danger of both an undue sound exposure of the neonate ear during the audiometric measurement and an insufficient estimation of the degree of the hearing disorder. By the aid of the new ear simulator this risk of calibration failure can be eliminated. The results of this task can considerably improve the quality and reliability of neonatal audiological diagnosis.
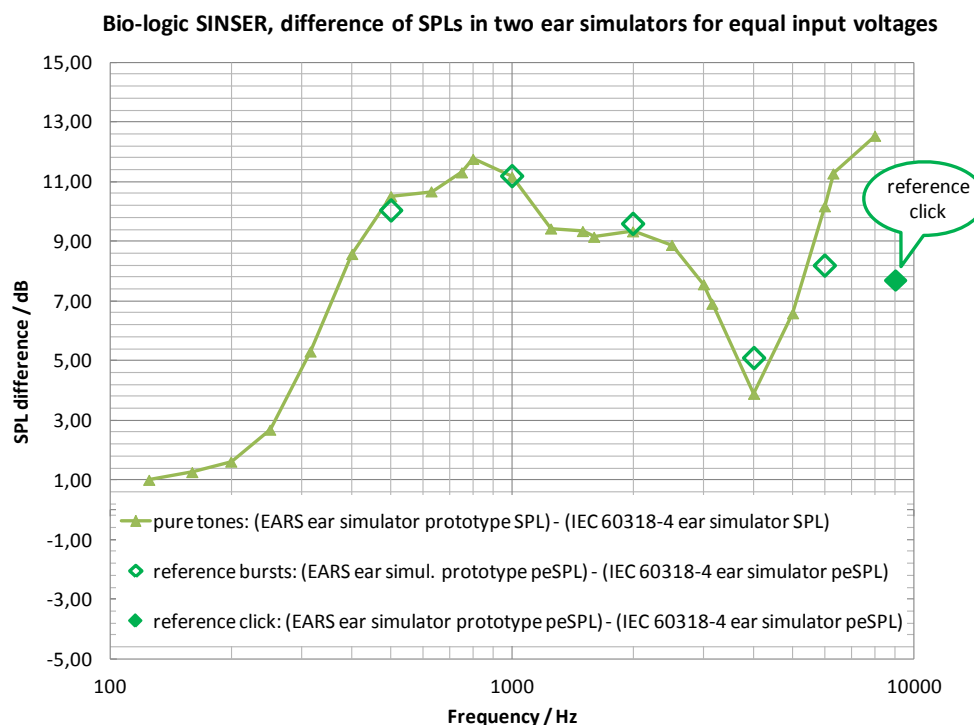
Figure 26: Biologic Navigator SINSER insert earphone stimulus level increase for pure tones (SPL) and short-term stimuli (peSPL) (EARS neonate occluded-ear simulator prototype – adult occluded-ear simulator according to IEC 60318-4)

3.6.4   First clinical testing

First clinical tests have been performed in the ENT department of Regensburg University (collaborator). Based on the reference data described in 3.6.3 and using the neonate occluded-ear simulator developed and manufactured within this project the calibration service provider carried out an on-site calibration of the AEP instrumentation used for neonates and toddlers. The devices calibrated this way were used for routine AEP measurements on very young children. The results of these tests revealed that the stimulus calibration was much more realistic when the new reference data and the neonate ear simulator were introduced. Furthermore, the usability and operability of the ear simulator prototype, including the specific coupling arrangements was proven during the on-site calibration.

In addition, in-situ ear canal sound pressure level measurements were done in order to verify the ear drum levels developed in different ear canal residual cavities. Because AEP threshold estimations with insert earphones are carried out almost exclusively at babies and toddlers in the Regensburg ENT department, it would be advantageous to do the basic calibration with an ear simulator which reflects the acoustic properties of small ear canals. Regardless of the method to achieve the correct sound pressure levels in small ear canals, the accuracy must be checked with an appropriate ear simulator.

The collaborator pointed out that the universal ear simulator provides great benefit for calibration and quality control measurements.

The same conclusion was drawn when the new ear simulator was also used in first clinical trials performed in İstanbul Turkey. An audiometer (Interacoustics AD226) equipped with an Otometrics insert earphone and two otoacoustic emission (OAE) devices (Otodynamics Otoport and Interacoustics Titan) were tested and measured by using the new neonate occluded-ear simulator prototype.

Measurement results showing a comparison of the IEC 60318-4 ear simulator and the new neonate ear simulator for the audiometer with Otometrics insert earphone phone are presented in Figure 27.
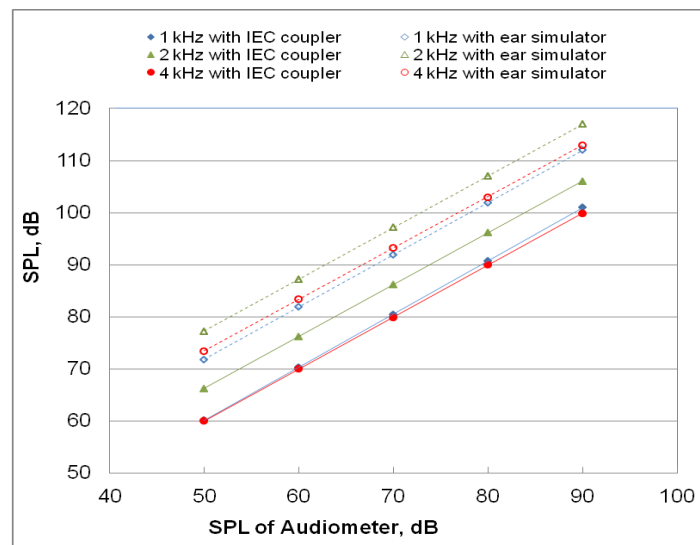
Figure 27: Sound pressure level differences between the neonate occluded-ear simulator and the standardised IEC 60318-4 device

4   Actual and potential impact

4.1   Approach to dissemination

From the outset of the project, dissemination activities were actively planned to produce tangible impact and benefits for the stakeholder community. Impact measures were defined and a dissemination strategy formulated, recognising the distinction between project outputs and the outcomes that actually provide the benefits ultimately aimed for. Dissemination activities have taken place alongside the scientific developments and caused the level of stakeholder engagement to grow throughout the project. The variety of dissemination activities and the resulting impact are described below.
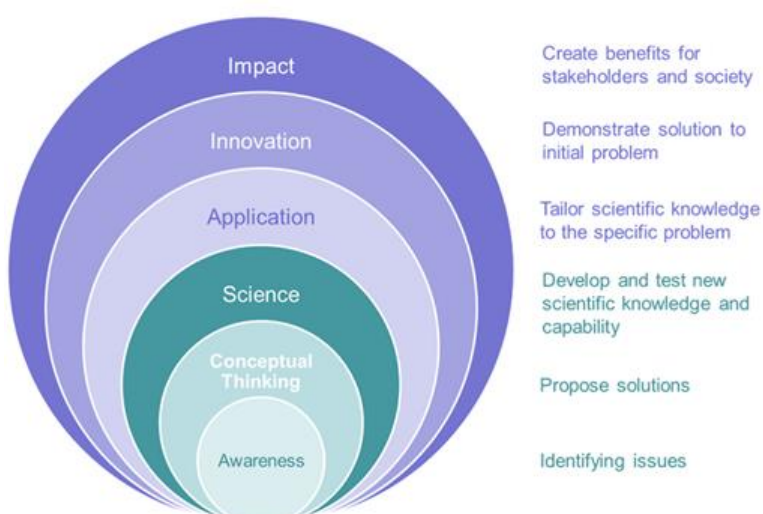
Figure 27: Route to creating impact developed at the start of the project

4.2 Dissemination activities

4.2.1 Scientific publications and presentations

High quality scientific research inevitably results in publications. The project has produced 21 articles that have either been published or are in the process of being published in peer-reviewed scientific literature and conference proceedings. These include publication in highly respected journals from the fields of acoustics, neuro-science and metrology, which are the key disciplines represented in the project. The Output Report accompanying this report provides full details.

In addition to the published output, some 35 presentation were made at scientific conferences and meetings. These included contributions to the leading international conferences in the specialist areas, dissemination to the metrology community at the highest levels, for example the Consultative Committee for Acoustics Ultrasound and Vibration (CCAUV) of the International Bureau of Weights and Measures (BIPM) and within EURAMET, and specialised groups at universities and professional societies.

4.2.2 Public dissemination

A project website was created at the start of the project, and a professionally designed logo gave the project a distinct identity across all published media. The website provided a rapid and accessible dissemination route for publicising project developments, results and events. It was found to be particularly useful for directing interested parties seeking an overview or more information about the project. The website was maintained and updated on a regular basis and access statistics presented and analysed whenever the consortium met.

To supplement the website and to provide a means of regular contact with all stakeholders, the project also produced a series of newsletters. During the course of the project in total 6 newsletters were published and sent to more than 92 stakeholders, interested persons and potential users of results of the project. An issue was published every 6 months and typically contained a comprehensive survey of the project status and achieved results. Several times feedback from recipients was received, prompting further and more detailed discussion of particular issues.

Since noise is high profile issue in everyday life, and is as important to the general public as to the specialists working in the field, many opportunities were taken to present the project more widely. Visiting groups to PTB and NPL were introduced into the matter, presentation were given to students at universities of Lübeck, Istanbul, Braunschweig, Berlin and Singapore, and ongoing discussions and advice given to individuals particularly burdened by non-audible noise. The final results of the project were announced to newspapers and journals by releasing a PTB-press information which was published by PTB press and information office.

4.2.3 Standardisation activities

Some final project outputs led directly to recommendations and technical input to international standards committees in IEC and ISO (see below), but before this, and on a number of occasions during the course of the project, the relevant working groups were informed of the project objectives and its alignment with their own strategic goals, given progress reports and presented with key results. These working groups included IEC TC29/WG5 *Measurement microphones*, IEC TC29/WG21 *Head and ear simulators* and ISO TC43/WG1 *Threshold of hearing.* That individuals within the consortium also held influential positions in these working groups guaranteed that aspects of the project could be directed at these strategic goals, and therefore create the necessary impact on standardisation that ultimately benefits the noise measurement and hearing assessment communities.

The status, challenges and results of the project were regularly presented at the annually meetings 2012, 2013, 2014, and 2015 of the technical committee "Acoustics, Ultrasound and Vibration" (AUV) by the project coordinator. In addition in June 2012 and October 2013 results were presented at the 8th and 9th meeting of the consultative committee for AUV at the BIPM in Paris. These presentations opened up the opportunity to inform distinguished persons and representatives of metrology in Europe and the whole world.

4.2.4 Measurement services

A complete measurement capability that allow for the determination of the free-field sensitivity of working standard microphones (IEC type WS3) at frequencies up to 150 kHz has been established at DFM. The

system represents the first primary calibration facility in this extended frequency range for microphones within the world, and marks the first time that traceable measurements of airborne ultrasound sources has been possible.

The newly established primary measurement standard for airborne ultrasound, has led directly to new calibration capabilities at a number of other NMIs. NPL for example was able to obtain reference microphones calibrated using the new primary standard, and use these in a new secondary calibration service offering, which has already seen take-up by a number of users. Both PTB and NPL also used the new capability established at DFM to calibrate microphones that have then been used to measure ultrasound sources in the laboratory and in the field.

4.2.5   Workshops

The cornerstone of the dissemination activities in the EARS project were two workshops covering distinct aspects of the project scope, on the development of the universal ear simulator, and on the perception of non-audible sound.

The first of these took place at the National Physical Laboratory on 26th March 2015 and covered the development of the universal ear simulator. The workshop had 28 attendees from clinical audiology, medical physics, national health services, audiological equipment manufacturers, calibration laboratories and NMIs outside of the consortium. Attendees came from UK, Denmark, Germany and Switzerland.

In formulating the workshop content, the project consortium was keen to avoid it being merely a series of presentations from the team. It was therefore conceived to include a variety of activities designed to engage the attendees, including a hands-on session where delegates could gain their first practical experience of using the newly developed ear simulators, and a panel discussion. We were also successful in inviting two distinguished guest speakers to present their experiences in establishing national services for neonatal hearing screening and rehabilitation for children with hearing impairment. Structured feedback was asked from the organisers and very positive response could be gathered. Particularly the hands-on session was appreciated which gave the opportunity of real handling with the new device to the participants. This was a very effective presentation of project results to stakeholders and possible users.

Figure 28: Workshop training session on the calibration of audiometric equipment with the universal ear simulator, introduced by a project collaborator from an accredited calibration laboratory.

From 16th to 17th of April 2015 the second workshop 'Metrology for the perception of non-audible sound' was held in Berlin and 35 participants from 6 different European countries met to discuss the results of the

project EARS and to show own contributions in talks and on posters. The intention of the workshop disseminate the results of the project which was to gain a better understanding of the relation between perception of non-audible sound and the underlying sensory processes. The workshop started with two key note talks giving the background for the following five short talks presenting the EARS results. This was an excellent possibility to transfer results and conclusions of the project to stakeholders and interested persons. The intensive discussion was further promoted by a round table discussion.

A second key note talk was followed by a guided poster tour of the nine posters prepared by the participants. The posters highlighted particularly the need for better regulation and standards for noise assessment at workplaces and in the environment which can only be achieved with more research and development in this field. This was also manifested in a communiqué which was signed by 17 researches. A second panel discussion closed the workshop and very positive feedback was given by many participants.

4.3 User uptake and delivered impact

4.3.1   Metrological impact for better measurement techniques and standards

New measurement service 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. A team studying the behaviour of bats have also used the new capability to improve the characterisation of their detection equipment.

4.3.2   Impact on better healthcare and health protection

The project came up with first results for an improved assessment of non-audible noise based on objective methods as brain imaging and audiometry. Although they are not yet final in many instances and by many reasons, first important conclusions could be drawn and a project communiqué was published at the project web page which contains a clear and concise summary of the conclusions. This could be a start for the development of future regulations supported by new research activities.

The project has motivated the formation of the UK action group on the Health Effects of Ultrasound in Air (HEFUA) to undertake complimentary work that raises the political profile of airborne ultrasound as a new public health hazard. The action group has been set up in response to growing concern over the health impacts of the numerous new sources appearing in general urban environment, and follows on closely from the work conducted in this project. The significance of the issue has attracted high-level participation in HEFUA from science and government and as well as members of the public. The group has already been successful is gaining funding to expand the work of EARS into the area of environmental noise nuisance.

4.3.3   Standards and regulations

At its formation, IEC TC29/WG21 noted the lack of ear simulators for age groups other than adults, and the need in particular for devices suitable for neonates. This project has taken the first steps towards addressing this need, and in this context, has culminated in a proposal for new standardisation activity to document the design and performance aspects of an occluded ear simulator for neonatal applications. The proposal outlines the expected content of the new standard based on what this project has shown to be realistic. However, the fulfilment of all the necessary requirements needs further pre-normative research to be completed. The ear simulator specifications need to be supported by new data on the equivalent hearing thresholds to enable earphones to be appropriately calibrated. Reports on the progress made in determining these for the new ear simulators have therefore been made to ISO TC43/WG1 responsible for the standardisation of normative hearing threshold data.

Two reports and a communique documenting the findings of the non-audible noise research have been produced for consumption by a variety of stakeholders. These documents will be presented to ISO TC43 as they have a strong bearing on future revisions of standards for the assessment industrial and environmental noise exposure, which TC43 is responsible.

4.4 Potential impact

4.4.1 Impact in hearing screening and general audiological assessment

The new ear simulator concept developed within the project, where the characteristics are matched to physiological data from a sample of subjects from the target age group, will improve the quality of hearing assessment for all patients, but particularly neonates and children. The quality improvement is founded on the improved calibration of the acoustic stimulus applied during testing, which can now be determined in an ear simulator that is fit-for-purpose, rather than having to rely on one originally designed for adults. With improved measurement quality greater reliability and confidence in test results comes, which in the case of neonatal hearing screening, is expected to reduce the number of false-positive results. Currently around 6 per 1000 test subjects are referred for more extensive testing, but of these only 1 in 13 (around 8%) will be diagnosed with a hearing disorder. There are targets to drastically reduce the level of false-positive diagnoses from 92% to around 4%, and the new ear simulators will be instrumental in helping achieve such a significant reduction.

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. This rationalisation will also address the absurd situation where calibration laboratories must currently maintain two types of ear simulator to ensure that both extant and more modern types of earphone can be calibrated, when in fact a single device would suffice. It will also put an end to manufacturers favouring one or other type of ear simulator and making recommendations to its users that contradict practices specified in international standard. Such practice is creating confusion and ambiguity about the calibration status of audiometric equipment and comparability of results between test centres.

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 significant advantage. The ear simulator itself has strong potential to be developed as a commercial product for the medical device market.

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.

Generally, the project has helped re-build links between the metrology and hearing assessment communities. In more recent times, hearing assessment techniques have raced ahead and ad-hoc arrangements for traceability put in place. This project gave these two communities the prospect of a better metrological basis for modern and future hearing assessment methods.

4.4.2 Impact on the control of non-audible sound exposure

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 summarises main conclusions from the project and give first advice for improved assessment of infrasound and ultrasound and 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-Ionising 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 provide the basis for the future assessment of sources in the field, whether for environmental protection or occupational safety. The calibration methods are also of interest to the international standardisation of microphone calibration techniques, embodied in the IEC 61094-series of standards, and will therefore be open and reproducible by other potential users, especially from the international NMI community.

5   Website address and contact details

Project website: http://www.ears-project.eu

The address for the website discussed above is:

http://www.ears-project.eu

Full contact details for the project co-coordinator and lead participants can be found at :

http://www.ears-project.eu/emrp/ears-contact.html

6   List of publications

1   M. Bauer, B. Piper, R. Kühler, R. Barham, J. Hensel, C. Kling, L. Trahms, C. Koch T. Sander, Magnetoencephalography of deep lying auditory sources using acoustical devices for infra- and ultrasound stimulation. In: Biomed Tech 2013; 58 (Suppl. 1) DOI 10.1515/bmt-2013-4135

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