A new approach to hearing assessment

A guidance document for researchers, calibration service providers and audiometric clinicians

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1. Background

The human senses are fundamental in enabling us to lead fulfilled and productive lives. Our sense of hearing enables us to communicate effectively, serves as warning of danger, empowers us to appreciate and react to the soundscape around us and enjoy music. Since it is so vital, it is important that we take all necessary steps to preserve, protect and where necessary, restore our hearing at all stages of life.

As a result, virtually everyone will have their hearing tested at stages throughout their life. It is essential for effective diagnosis that these tests are accurate and quality assured, and that test results are universally consistent and meaningful.

A basic principle of ensuring the correctness of any quantified measurement, is that it somehow related to a primary realisation of the quantity in question. This is called measurement traceability and is usually assured through calibration.

In hearing assessment, we essentially determine the response of the test subject to the sound pressure presented in the ear canal. However, due to the non-linear nature of our hearing function, the measurement is normally made in terms of sound pressure level in decibels, relative to the sound pressure level considered to represent normal hearing, which is based on an average value from a selected population. This metric is known as the hearing level, also in decibels. Nevertheless, the metric is derived from sound pressure and ultimately it is this quantity for which traceability must be established, through the calibration of the audiometric equipment.

Ear simulators provide the basis for measurement traceability. These are devices for measuring the sound pressure level produced by an audiometric earphone, under acoustic conditions approximating that of a real human ear and are therefore used to calibrate audiometric equipment.

However, ear simulators in routine currently, use are designed for adult ear characteristics only.

A second limitation is that they were designed and intended for use with sinusoidal signals only.

This remains acceptable in supporting pure-tone audiometry. However, initiatives to capitalise on the benefits of early diagnosis and treatment of hearing disorders in neonates and children, have been in place on a global scale from the early 2000s. Universal hearing screening programmes for neonates and infants have driven the widespread and mainstream use of alternative objective audiometric methods such as evoked auditory brainstem responses (ABR) and otoacoustic emissions (OAE) using non-sinusoidal stimuli.

The greater focus on testing neonates and children, and the expanded range of hearing assessment methodologies used, have created new use requirements for ear simulators. So far, attempts to address these have simply extended the use of the available ear simulators to applications for which they were never intended.

The development of the next generation of ear simulators suitable for modern hearing assessment practices has been the subject of a joint-European research effort funded

the European Metrology Research Programme (EMRP) and European Metrology Programme for Innovation and Research (EMPIR) of EURAMET.

Key objectives were:

- The design, test, and validation of a range of ear simulators for calibrating audiometric equipment used for hearing screening on adults, young and new-born children in the frequency range from 125 Hz to 16 kHz.
- The development of new ear simulator calibration procedures.
- The determination of new reference threshold data.
- Demonstration of the equivalence in results derived from the current measurement regime and that for the new ear simulator and reference data, where such comparison can be made (i.e. for adult test subjects).
- Initiation of international standardisation.

The development of new ear simulators also took into consideration that the range of existing devices and protocols for their use is already complex, and further provision demands a new approach. The concept of devices that can be applied universally and unambiguously for all uses including both existing and emerging applications has enormous advantages for hearing assessment practitioners.

In the course of development, it became clear that to introduce the benefits targeted by the research, a new approach to hearing assessment overall would be required.

This document therefore outlines some of the technical developments, but mainly focusses on the consequences of these for hearing assessment practice, calibration services and instrumentation development.

2. Outline of new approach to hearing assessment

The goal to create new ear simulators for infants and young children leads quickly to the questions of which age groups to provide for and how many devices are practical. There is also the issue of anatomical variations, especially amongst neonates and young children which can result in a poor match between actual ear canal characteristics at a given age and the characteristics of the designated ear simulator.

We are therefore proposing a scheme restricted to three ear simulators, including the adult ear simulator. These devices provide for three calibration points on the audiometric equipment.

A rapid in-test procedure is then proposed which will match an individual's physical ear canal characteristics to the ear simulator with the closest matching characteristic. A range of normative corrections and a process to interpolate between the calibration reference points based on the result of the in-test procedure, will then be established. This should be an automatic process implemented within the audiometric equipment itself.

The major benefit of this approach is that it results in an individualised calibration of the test stimulus for the test subject, which will help reduce inter-subject variation. Ultimately this reduces the band where test results are neither a certain pass or a

certain fail, leading to improved confidence is the test result and reduced false-positive results. In the case of neonatal and infant screening, the associated unnecessary referrals for further testing and the associated parental anxiety from false-positive results are also reduced.

However, the proposed new approach also has implications throughout the service supply chain. Those delivering hearing assessment services will need to implement the additional test of the ear canal characteristics. Calibration service providers will need to increase their offering to cover the three calibration reference points, and developers and manufacturers of audiometric equipment will need to provide for the new calibration arrangements, including the provision of the interpolation function.

3. Ear simulator specifications, target age groups

The original research into ear canal characteristics as a function of age, identified five age groups with statistically distinct characteristics. The age groups were; neonate, young infant (1-3 months old), infant (3-24 months old), child (2-7 years old) and adult (7+ years).

The decision to use a reduced set of three ear simulators was reached through consultation with health service policy makers, clinical audiologists and calibration service providers, taking into consideration the balance between practicality and additional precision. The question then is which age group to assign to each device.

Taking into account the reduced need for quantitative testing of neonates, and the benefits of targeting a specific age rather than an age group (e.g. reduced variance in the target response to be simulated), the final specification was for ear simulators appropriate for:

- young infants at 3 months of age,
- infants at 24 months of age
- adults (including children over 7 years old).

The chosen ages of 3 months and 24 months represent key stages in ear canal growth and allows a focus on early development of the auditory system. Clinical assessment and hearing aid fitting also target the period between these two age-points.

The purpose of an ear simulator is to enable an estimate to be made of the sound pressure produced by an earphone when coupled to a real ear. A number of factors are important in this regard. In the case of a real ear, the acoustic output of the earphone when driven at a specific level, is governed by the acoustic impedance of the ear canal. In fact two acoustic impedance parameters are important. The acoustic input impedance at the surface where the earphone is presented determines how much sound pressure is fed into the ear canal, and the acoustic transfer impedance refers to the sound pressure at the ear drum. The two parameters are related by the internal geometry of the ear canal and the stiffness of the surrounding tissue. The relationship is also frequency dependent.

In an ear simulator where a microphone represents the ear drum in a real ear, the design goal is to match both the acoustic input impedance and the acoustic transfer impedance of a real ear as closely as possible. This requires measurements on test subjects of the appropriate age, which presents a number of challenges.

While acoustic input impedance of a real ear can be measured, (even for the youngest test subjects) determination of the acoustic transfer impedance requires measurement of the sound pressure at the ear drum which is scarcely possible (regardless of age). However, if the ear canal length and radius profile is known, the acoustic transfer impedance can be derived.

There is also the matter of inter-subject variation to account for, which requires a large number of test subjects to be measured and use of a statistical process to determine the nominal representative response.

The specifications for the three ear simulators were derived from published data sources. This came mostly from reflectance measurement used to study middle ear conditions, from which it was possible to derive the acoustic input impedance for the tested ear canal. However, the data needed substantial re-working and assumptions to be made when required details were missing.

While the source data is not without its limitations, provisional specifications for the three ear simulators detailed above have been produced and presented to the International Electrotechnical Commission (IEC) for publication as a Publicly Available Specification (PAS) within the IEC 60318-series of documents.

4. Specification of new research to acquire further clinical data

Noting that there are limitations with the anatomical data upon which the ear simulator specifications have been prepared, for example in terms of the sample size, precise details of the measurement locations and of the ear canal geometry, there is now a call for further research to gather data more appropriate for the specification of ear simulator family.

The detailed research requirements are elaborated in Annex A

5. Specification of new research to develop an in-test procedure for establishing patient ear characteristics

A key requirement of the approach of using ear simulators targeting specific nominal ear canal characteristics of specific age groups to provide reference calibration points, is that a means of interpolating between these is available for an individual test subject with measured ear canal characteristics. This has two requirements for further development.

1) Development of the in-test procedure itself
2) Development of the model for interpolating between calibration reference points based on the in-test procedure result.

A proposal for an outline procedure is given below. This has yet to be tested but provides a starting point for further research and development.

Probably the most practical basis for the in-test procedure is the use of probes that contain both a sound source and a microphone (as usual for OAE measurements) also for AEP measurements. A combination of ear-simulator calibration (at higher frequencies, to avoid interference by standing waves in the occluded ear canal) and in-ear calibration (to obtain the individual occluded volume for RECD correction) would be a fast and robust procedure, which could be easily used in daily clinical work if provided as ready-to-use device.

The proposed procedure outline is:

a) Use a (DP)OAE probe with known (pe)RETSPLs

b) Calibrate at least one low-frequency pure tone (250 Hz or 1000 Hz) by means of the standardized IEC 60318-4 occluded-ear simulator

c) Calibrate the probe microphone for the low-frequency pure tone, e.g. by means of the low-frequency pure-tone stimulus in the IEC 60318-4 occluded-ear simulator.

d) In the ear to be tested, measure the sound pressure level produced by the probe transducer playing the pure-tone stimulus at a given moderate hearing level (say 50 dB HL) and compare the ear-canal-sound pressure level to (RETSPL+HL).

e) From the level difference measured in d) and the IEC 60318-4 ear simulator effective volume, estimate the test ear effective occluded volume, e.g. based on the simplified assumption that the sound pressure level is inversely proportional to the occluded volume.

f) Based on the test ear effective occluded volume, select the universal ear simulator family member with an effective volume that provides the best approximation to the test ear characteristics.

g) Calibrate the stimuli intended for the audiometric test (OAE or AEP) by means of the selected universal ear simulator family member.

h) If the test ear effective occluded volume differs from that of the selected universal ear simulator family member, derive a low-frequency single-number correction for the stimulus level and apply this correction in the whole frequency range used for calibration. The difference in short-term stimulus waveform between the adult reference and the test ear will be accounted for by the different frequency-dependent transfer impedances of the IEC 60318-4 occluded ear simulator and the selected universal ear simulator family member.

The single-number correction mentioned above should ideally be based on a model derived from a study of the relationship between ear canal volume, geometry (length and radius profile) and acoustic input impedance, using test subjects of different ages. The hypothesis is that the acoustic input impedance, and thus the transfer impedance, is a function of the ear canal geometry and this geometry is a function of low frequency equivalent volume and age.

The desired output of the study is a model linking all of these parameters, so that an estimate of the acoustic transfer impedance can be determined from the measured low frequency volume. This estimate can then be used to interpolate between the fixed points provided by the ear simulators to adjust the level of the calibration stimulus for the given test subject. In the case of a transient stimulus, the result is a single-valued correction, but for pure tone audiometry, a correction for individual frequencies can also be determined and applied.

6. New approach to ear simulator calibration

The increasing reliance on objective methods of audiometry noted in the *Background section* above leads to some concerns over calibration and traceability. Such methods are founded on the use of transient or short-duration acoustic stimuli that are delivered by a variety of supra-aural and in-the-ear earphones and probes.

Just as with pure-tone audiometry, the stimulus level of these short-duration signals needs to be known, and traceability should be assured through appropriate calibration. However, the meaning of the *stimulus level* is currently not well defined. From an auditory perspective it is clear that the level somehow characterises the loudness of the stimulus as perceived by a nominal test subject. However, the way the stimulus level is currently quantified derives more the available measurement capability than from auditory considerations.

Consequently, ad-hoc calibration methods have been developed that derive from the use of steady-state signals, and ear simulators that were never intended for measuring transient stimuli. The method currently standardised in IEC 60645-3 uses the peak-to-peak amplitude of the short-duration stimulus to characterise its level. This level is measured in terms of the steady-state level produced in the ear simulator designated for the transducer, when the transducer driven by a pure tone with the equivalent peak-to-peak amplitude. The frequency is usually 1 kHz regardless of the frequency content of the original signal, unless the short-duration signal is a tone-burst, when the base frequency of the tone burst is used. This process gives rise to a measurand called the peak-to-peak equivalent sound pressure level, which is not at all equivalent to the perceived level of the short-duration stimulus. Alongside this calibration scheme, reference equivalent hearing thresholds (peRETSPLs) have been established using the same measurand and are given in ISO 389-6 for a selection of earphones.

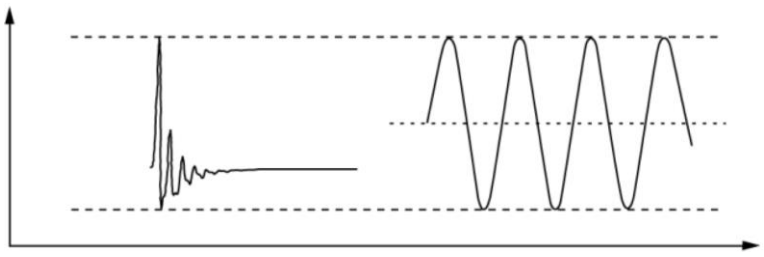

Figure 1. Example of the peak-to-peak equivalent representation of a transient signal by a steady state sinusoid.

So, it is fair to argue that developments in appropriate calibration methods and instrumentation have not kept pace with the rapid development of objective methods

of hearing assessment. With doubts over the suitability of the peak-to-peak equivalent sound pressure level to represent the perceived loudness of the stimulus, the development of the next generation of ear simulators provides an opportunity to also review the calibration process for such stimuli.

While IEC 60645-3 specifies certain reference short-duration stimuli, these are rarely used for practical hearing assessment. Manufacturers have developed propriety stimuli to compliment and optimise the particular signal processing schemes used within their instruments. Consequently, there is little consistency in the stimuli found in practice. Nevertheless, we require the results from using these different instrument and stimuli to somehow be consistent. This is the calibration challenge we face.

Putting side for the moment the issue of an alternative metric to the peak-to-peak equivalent sound pressure level, the objective was **to develop an ear simulator calibration method that enables the waveform of the sound pressure acting on the microphone diaphragm to be determined, when the ear simulator is driven by an audiometric earphone producing a short-duration acoustic stimulus.**

Technical details of the calibration method subsequently developed are described in Annex B.

By enabling full characterisation of the acoustic waveform, any future requirement to extract particular parameters from this waveform will be supported. In addition, the transient calibration of the ear simulator will provide a better estimate of the peak-to-peak amplitude of the stimulus with which to compare alternative methods.

In everything stated above, there is an implicit (and in general, false) assumption that the ear simulator provides a perfect match to a real human ear. The prototype ear simulators developed in the EARSII project make substantial improvements with this assumption by utilising anatomically derived geometries and age-specific devices. However, no ear simulator can properly account for population variations in ear canal characteristics. For this reason, it is proposed that ear simulator based calibrations are supplemented by corrections determined at the time of test of an individual, based on real-ear characteristics obtained at the time of test, as described above.

7. Reference Threshold Levels

Use of appropriate age-related ear simulator

Hearing threshold reference data, as they are behavioral data, need to be determined by means of listening tests with otologically normal test subjects. ISO 389-9:2007, “Acoustics: Reference zero for the calibration of audiometric equipment - Part 9: Preferred test conditions for the determination of reference hearing threshold levels” specifies an age range from 18 to 25 years for these test subjects. Hence, for the determination of the reference zero ear simulators that represent the adult age range need to be applied. Presently, reference hearing thresholds are given as Equivalent Threshold Sound Pressure Levels (ETSPL), where the equivalence denotes remaining systematic differences between the acoustic impedance of the average human ear and of the ear simulator.

If one assumes, simply by lack of proof to the contrary, that the hearing thresholds of healthy children are virtually equal to those of young, normal-hearing healthy adults, then also the sound pressure at threshold near the eardrum can be assumed to be equal between children and young adults. Hence, in principle, the task of a proper ear simulator is to emulate the sound pressure level at the eardrum with the sound pressure level in front of its built-in microphone. This, however, will only succeed if the volume as well as all other acoustic features of the ear simulator, represented by its input impedance and transfer impedance, match those of the peripheral ear of the human target age group.

If, supposedly, one measured the ETSPLs of the adult subject group in an infant ear simulator – by applying the adult group's median threshold terminal voltage of the insert earphone to the latter when it is connected to the infant ear simulator – the measured SPLs would be much higher than those measured in the adult ear simulator with the very same terminal voltages. The enhancement in SPL would be essentially equal to the enhancement of SPLs in the real ears of infants if the earphone and the audiometer to which it is attached were (erroneously, as we know now) calibrated using the (correct) adult ETSPLs and the (inappropriate) adult ear simulator for that purpose. The SPL enhancement due to the usage of adult calibration for infant applications is shown in Figure 2 for the RadioEar IP30 insert earphone. To measure this enhancement, the (inappropriate) measurement described was really performed. The tube of the respective earphone was coupled to both the 24-month and the 3-month EARS occluded-ear simulator. The difference shows how much greater the SPL in 3-month and in 24-month ears is than the nominal value, if the (inappropriate) calibration method described is applied. On the other hand, if the appropriate calibration is applied, using a non-adult ear simulator for calibration when non-adult hearing is to be assessed, the terminal voltage level of the earphone must be lower by just that very difference to induce the very same correct threshold SPL both at the non-adult ear simulator's microphone and at the real non-adult's eardrum.

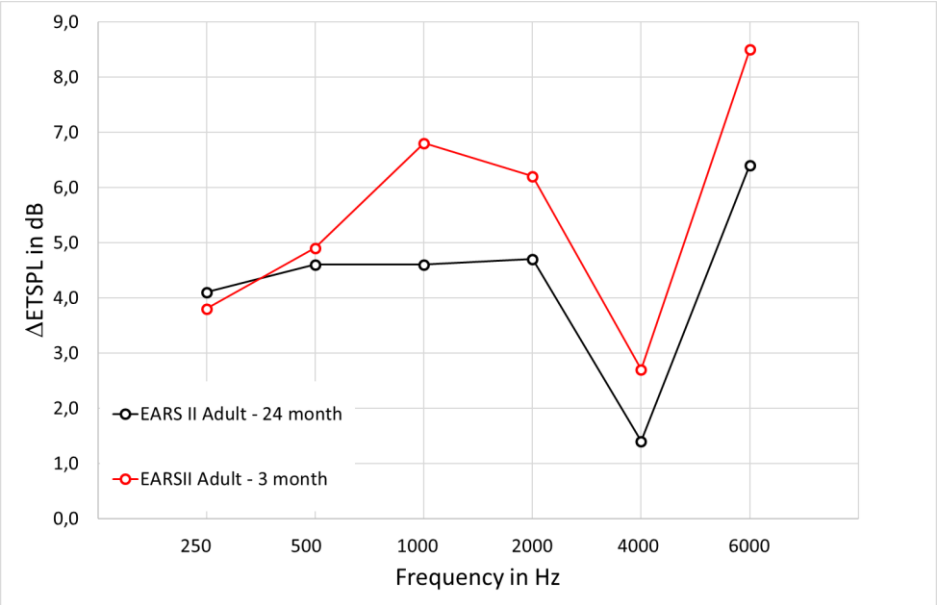

Figure 2. Differences between ETSPLs measured in an adult occluded-ear simulator and the EARS occluded-ear simulator prototypes for 24-month and 3-month infants for the RadioEar IP30 insert earphone.

The following recipe can be derived for calibrating stimuli for infants:

a) Determine reference data in adult ear with adult occluded-ear simulator
b) Calibrate stimuli for non-adult ear with suitable member of the EARS occluded-ear simulator family (with corrections, if applicable, see Section 5 above)

This recipe, however, is based on the general assumption that the hearing thresholds for non-adults belongs to the same ear drum sound pressure as for adults.

RMS-based measures for calibrating short-term stimuli

The concept of expressing their reference thresholds by means of peak-to-peak equivalent Reference Equivalent Threshold Sound Pressure Levels (peRETSPL) according to IEC 60545-3 is easy to implement, even with rather basic instrumentation. However, this concept frequently results in calibration values which do not correlate at all with either the behavioural hearing thresholds or the spectral energy of the periodically repeated stimuli. Elberling and Esmann (Elberling 2017[1]) therefore propose a root-mean-square (RMS)-based approach for calibrating short-term stimuli by directly measuring the unweighted RMS sound pressure level (L_{Zeq}) of the short-term stimulus presented periodically at a given repetition rate. In the following, this measure is being referred to as LZeqETSPL. Furthermore, they describe a procedure to transform peRETSPL values to LZeqETSPL values for a given combination of stimulus, repetition rate, transducer, and ear simulator. This procedure is based on the determination of the relation of the peak-to-peak value of the sound pressure waveform as measured in the ear simulator to the RMS value, calculated over the period that corresponds to the repetition rate.

This procedure was applied for determining RMS-based LZeqETSPL values, directly measured as the L_{Zeq} of the periodically repeated short-term stimuli by a Norsonic 840 real time analyzer for a RadioEar IP 30 insert earphone. Excellent agreement was found between measured and estimated levels, with typical differences of 0.2 dB and a maximum deviation of 0.5 dB.

The concept for specifying equivalent hearing threshold levels by an RMS-based measure turned out to be well applicable for the RadioEar IP30 insert earphone in conjunction with a Norsonic RTA 840 analyzer (IEC 61672-1 Class 1) used for measuring the Z-weighted equivalent continuous sound pressure level of the periodically repeated short-term stimuli.

8. Continuity and equivalence considerations

The proposed new approach to hearing assessment is somewhat different to established practices and has a potential impact on results for test subjects of all ages. The new approach includes new ear simulators, new calibration methods for short-duration test stimuli, new RETSPL values for these stimuli and will require changes in instrumentation and not least in clinical assessment procedures.

[1] Elberling, C., Esmann, L.C. 2017. Calibration of brief stimuli for the recording of evoked responses from the human auditory pathway. J. Acoust. Soc. Am. 141 (1), Jan 2017, 466-474.

These developments aim to improve the reliability of hearing assessment decisions by ensuring that the new devices, data and procedures are better fit-for-purpose. However, it is also necessary that hearing test outcomes are not radically altered by the new developments. Hence, it is necessary here to define the terms under which equivalence (or otherwise) with existing practices will be demonstrated based on measurable criteria.

The basic criteria for the assessment of equivalence is the difference in calibration results of audiometer's transducer performed by using a standardized ear simulator and its associated calibration and reference data, and procedures using the new ear simulators, the new calibration methods and reference data as appropriate.

Equivalence for adults and pure tone stimuli is demonstrated when the measured difference does not exceed the acceptance limits given in IEC 60645-1 for pure-tone audiometers. Equivalence for other age groups is more difficult to conceive because there is no reliable established data comparable with the data obtained according to the proposed new procedures.

This whole matter of demonstrating equivalence requires further longitudinal clinical studies to be carried out over a suitably long time period, and will therefore be reported in the literature in due course.

9. Consequential changes with hearing measurement instrumentation

The proposed new approach to hearing assessment based on three ear simulators providing age-related calibration reference points, has a direct impact on the design of the audiometric equipment used for routine testing. This extends to hardware, software, transducers and calibration. However, implementation of these changes requires acceptance of the proposals from the clinical hearing assessment community, which then drives the development of improved instrumentation.

In terms of hardware, three calibration settings will be necessary corresponding to each of the ear simulators. An automated facility should then be included for carrying out the in-test assessment of the test subjects ear canal volume, and the instrument will need to record the result and the precise stimulus level settings used as a result, for a given test.

Software or firmware within the instrument will need to accommodate three sets of calibration data and implement the model for acoustic transfer impedance vs. ear canal volume. It shall then use these together with the result of the in-test assessment of the test subjects ear canal volume to make consequent adjustments to stimulus levels for the individual test subject. The stimulus level settings used during a particular test shall then be reported.

Earphone manufacturers will need to ensure that any new designs are capable of being coupled to a standardized ear simulator interface by some means and have responsibility for specifying the coupling adapter and its characterization.

Calibration service providers will need to extend their services to cover the three reference point settings and invest in the set of new ear simulator. Furthermore, short

duration signals will need to be calibrated based on energy content using the proposed RMS-based approach rather than peak-to-peak equivalent sound pressure.

However, the proposed changes do not have an impact on the stimuli forms and transducer types that can be used (subject to the requirement for coupling to the ear simulators), and most importantly pass/fail criteria will not change.

10. Standardisation

International standards play an important role in achieving quality assurance and consistency in hearing assessment. These standards ensure that equipment is fit for purpose, is used as intended and is properly calibrated, and that internationally agreed reference data is applied.

A body of IEC and ISO standards therefore exist to support technically correct and quality assured hearing assessment. The IEC 60645-series specifies internationally recognised minimum performance requirements for audiometric equipment, the ISO 8253-series outlines the essential operational aspects, including maintenance and calibration of equipment. The ISO 389-series specifies the reference equivalent threshold levels that provide the datum for assessment, and the IEC 60318-series specifies the ear simulators that facilitate the objective calibration of the transducers fitted to the audiometer.

The introduction of the proposed new approach to hearing assessment and the family of ear simulator on which it is based, will require many of the calibration and clinical application aspects to be written into new standards. Most obviously, new standards specifying the ear simulators, and the reference threshold data will be required. These topics have already been raised with the appropriate technical committees responsible for the associated standards.

In due course, additional standards covering new calibration methods and the model governing the specification of individualised calibration of the stimulus level will also be needed.

Outside of international standardisation, national health services will also need to prepare local protocols for carrying out the in-test procedure for determining the effective ear canal volume. Guidance on preparing such documents should be one outcome of the proposed new research on this topic (see Section 5).

11. Benefits of the new approach

The driver for the new approach to hearing assessment was to improve the quality of routine measurements through improved calibration and traceability provision. As has been shown, ear simulators are at the heart of this, but are not a feature of every-day use of audiometric equipment. Yet the benefits of the new approach as a whole are intended to be felt by individuals undergoing routine hearing assessment, and the families in the case of infants and children. Some of these benefits were elaborated in Section 2 above.

It is appreciated that positive diagnoses lead to parental anxiety. One goal with the new proposals is to eliminate as far as possible the unnecessary anxiety brought about by false-

positive test results arising from uncertainty in the performance of the test equipment and the resulting referral margins necessary within the clinical protocols.

The metrology community responsible for preparing this Guidance Document, is not specialised in audiology, but this community is equipped to ensure that the underpinning measurement and instrumentation considerations are optimised. Hearing assessment service providers are then enabled to apply their professional knowledge and judgment based on the most reliable measurement data possible, leading to all round quality improvements for patients and their families. If this can be realised, then the original goals of the research described here will have been achieved.

12. Acknowledgements

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Annex A: Requirements for future research on data for ear simulators

A1. Introduction

Research leading to the specification, design and production of the current prototype ear simulator family has included a meta-analysis of published data to yield the target acoustic impedance specifications. It is now proposed that new real-ear measurements be carried out to gather new data, as the basis for improved specifications. This document briefly describes the information needed and suggest that a protocol for data collection is established.

A2. Data necessary for ear simulator specifications

In general terms, the need is for coherent and sufficient data for ear geometry, input impedance and transfer impedance of real human ears for people of all ages, ethnicity and sex.

The impedance data shall cover the full frequency range of human hearing.

Furthermore, in order to utilize the information, there is need for consistent methods to align data and form the most appropriate generalized shape and impedance data.

In the following, the data elements of required for ear simulator specifications and how they may be obtained are briefly discussed. The predominant requirement is, however, that data are coherent. The ear canal geometry and the placement of the impedance probe must be known accurately for the measured impedance data to be used for ear simulator specification.

A3. Ear canal geometry

Although it has long been recognized that the ear canal geometry is needed for improved characterization of ear properties, measurement method are only just emerging. Two such methods are an inverse method proposed by Rasetschwane and Neely[2] and a method based on MRI scanning developed by Darkner et al.[3]. The hearing and anatomy research communities are encouraged to use these methods or other methods to acquire the data.

Required geometrical features include the ear canal length and radius as profile (radius as a function of length).

[2] Rasetshwane, Daniel M.; Neely, Stephen T. Inverse solution of ear-canal area function from reflectance, J. Acoust. Soc. Am. **130** (6), 3873-3881, December 2011

[3] Darkner, Sune; Jønsson, Søren; Sommer, Stefan. In-vivo Study of the Human Ear-Canal Using Contrast Enhanced MRI, presented at ISMRM 25th Annual Meeting & Exhibition, Honolulu, USA, 2017.

A4. Ear canal input impedance measurement

Measurement of the input impedance (or reflectance, which amounts to the same measurement) of the ear canal is not as simple as it may seem, despite the numerous publications that can be found on the topic. A significant issue is the need to make an unambiguous impedance measurement over a well-defined cross section in a real ear. Ear canal acoustic impedance is normally measured with a probe containing a sound source and a microphone, which due to the size constraints are connected to the ear canal through narrow tubes with openings far smaller than the cross-sectional area of the ear canal. Recent research[4] has shown that the geometrical discontinuities at the probe can cause errors in the measured acoustic impedance measurements, but methods presented by Nørgaard et. al.[5], can reduce the errors.

For the specification of ear simulators, the complex input impedance data must be measured with high resolution to account for the time and frequency resolution of human hearing.

As research is still in progress on valid calibration of impedance measurement probes, it is important that the measurement configuration and any information on the calibration of the measurement equipment is documented. The value of the possibility to apply new knowledge in use of the data cannot be underestimated.

A5. Ear canal transfer impedance

For a specification point of view, the transfer impedance is a convenient and important parameter of an ear simulator, as it can be measured using the ear simulator microphone in combination with an external calibrated volume velocity source. However, the transfer impedance of a real ear is difficult to measure, as it requires a probe microphone to be placed near the eardrum in the sealed ear canal. Therefore, it is not realistic to develop the transfer impedance as a primary specification parameter of ear simulators.

If the ear canal geometry is known, and the ear canal wall impedances are known (or can be assumed), the transfer matrix of the ear canal can be calculated from the geometry and wall data, and the transfer impedance of the ear can be calculated from the input impedance and the transfer matrix. Thus, the transfer impedance can be a considered a secondary or derived parameter in the specification of an ear simulator. If measured, it can be used for verification of the calculation, or the calculation can be considered unnecessary.

A6. Data alignment and averaging

In order to utilize data for impedance and geometry for specifications of the ear simulator family, the data must in some way be normalized to form the basis for the specifications. A qualified representation of the geometry and impedance data must be made for each of the three ear simulators. It is, however, not a simple or unambiguous task to create these

[4] Nørgaard, Kren Rahbek; Fernandez-Grande, Efren; Laugesen, Søren, Incorporating evanescent modes and flow losses into reference impedances in acoustic Thevenin calibration, J. Acoust. Soc. Am. **142** (5), 3013-3024, November 2017.

[5] Nørgaard, Kren Rahbek; Neely, Stephen T.; Rasetshwane, Daniel M. Quantifying undesired parallel components in Thévenin-equivalent acoustic source parameters, , J. Acoust. Soc. Am. **143** (3), 1491-1503, March 2018.

qualified representations, as ear canal geometries vary over a large range of forms and size[6].

The qualified representation of the impedance data for a certain age (or age group) may be some average of data valid for that age, but it is necessary to define how the average is calculated. Before an average value is calculated, the individual impedances must be aligned in some way, e.g. to be at the same distance to the ear drum. The alignment requires the knowledge of the ear canal geometry, and the alignment methodology must be decided.

Similarly, the qualified representation of the ear canal geometry for a certain age should be some average data valid for the age, but again the calculation of the average must be carefully defined. There is reasonable consensus in literature that an area – distance to eardrum function can be used, but that function does take different form depending on how the center axis is defined.

Rasetschwane's and Neely's inverse method (see above) inherently leads to an axi-symmetrical geometry, and as the geometry is estimated from the impedance data, the method relies on the quality of these data. If the abovementioned corrections for the impedance step at the impedance measurement probe are not made correctly, neither the impedance, nor the derived geometry are correct. On the other hand, as the geometry is derived from the impedance data in the method, alignment of impedance data to a given distance to the eardrum may be less ambiguous.

A7. Conclusion

The framework and methodology to design modern ear simulators from source date for the acoustic input impedance and ear canal geometry has now been established. However, the need for improved data before making the final specification of the ear simulator family has been outlined.

It is therefore suggested that a protocol is developed and a data repository established, e.g. in the framework of IEC technical committee TC 29.

The data that are needed are

- Age (chronological and postmenstrual age), sex, height and weight
- Side of ear
- Complex ear input impedance, covering at the least the full frequency range of human hearing and measured with high resolution
- Ear canal geometry with sufficient resolution to allow calculation of its transfer matrix in the full human frequency range
- The position of the impedance probe in the geometry
- Probe calibration configurations and probe responses in the configurations

[6] Rodrigues, Dominique; Lavergne, Thomas. Specifications for the universal ear simulator, EMRP project HLT01 "Ears" report WP4/1, deliverable 4.1.1, Laboratoire National de Métrologie et d'Essais, France, 2013

Annex B: Transient calibration of ear simulators

B1. Ear simulator calibration requirements

The objective of the ear simulator calibration technique for transient acoustic stimuli is to enable the magnitude and shape of the stimulus at the microphone diaphragm to be determined within the ear simulator when coupled with the test transducer.

Notice then, that the transient response of the earphone and of the acoustical transfer impedance of the ear canal (or ear simulator) both influence the waveform shape and level presented to the eardrum (or microphone diaphragm). When first faced with the calibration problem, one might assume that the ear simulator acoustical characteristics are part of the response to be determined. However, from the argument above it becomes clear that it is simply part of the production of the stimulus and it is the combination of earphone and its coupling to the microphone that we aim to characterise through calibration.

In an ear simulator measurement, this waveform is indicated by the output of the ear simulator microphone. The implication for calibration then, is that the impulse response of the microphone needs to be removed from the acquired waveform when the incident sound pressure is to be derived. This is identical to the case for steady-state signals, where the calibration of an earphone for pure-tone audiometry requires only the pressure sensitivity of the ear simulator microphone to be known. The acoustical transfer impedance needs to be verified for conformance with the standard specification, but does not feature directly in the calibration.

There are other features of the ear simulator, such as length resonances and reflection from the termination, that may influence the waveform of the acoustic pressure at the microphone diaphragm. The anatomically-based design of the new ear simulators aims to reduce such effects where possible, but the difference between real ear performance and the response determined with an ear simulator will depend on the test subject. Such effects will therefore be embodied in the correction arising from the real-ear test that supplements the calibration method described here.

The requirements for a transient calibration of an ear simulator therefore reduce to a determination of the microphone impulse response.

B2. Theory of calibration

It is well known that the frequency domain response and time domain response of a linear, time invariant system are related by the Laplace transform ($L\{\ \}$) for continuous responses and the z-transform for discretised responses. Furthermore, such a system may be fully characterised either by its (complete) impulse response or its frequency response (or transfer function in the terminology of systems theory).

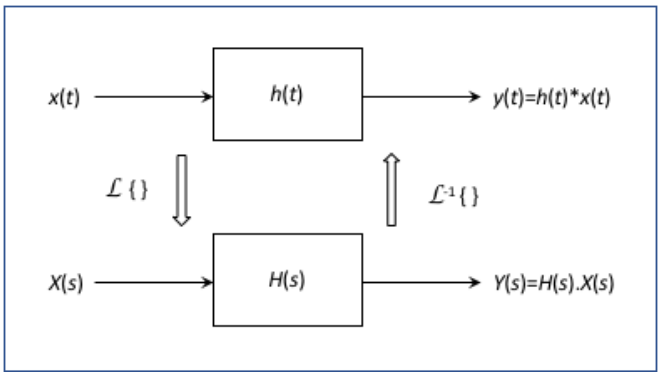

Figure 3. Relationship between time-domain and frequency domain representations of system response.

It is also well known that if the complex argument of the Laplace transform, s=jω the Laplace transform is equivalent to the Fourier transform. (Note, the Laplace argument is generally of the form, $s = \sigma+j\omega$ so s = jω represented a section along the j-axis in the s-plane)

The impulse response is somewhat idealised, in that it is the response of the system to the Dirac delta function (δ-function). However, it can be derived from the frequency response via an inverse Fourier transform as outlined above.

The benefit of the impulse response is that it fully describes the system and its response to any applied input signal through convolution. Conversely, it enables the form of the input signal (in the time-domain) to be determined from the system output, by deconvolution.

This is precisely the calibration problem we need to solve.

The input signal is the sound pressure waveform present at the diaphragm of the microphone, the system response is the transient sensitivity of the microphone and the system output is the recorded voltage waveform produced by the system.

By the considerations above, the deconvolution can also be performed in the frequency domain, when the process becomes one of simple division. The result is then subjected to the inverse Fourier transform to obtain the time-domain representation of the input signal.

$$X(j\omega) = Y(j\omega)/H(j\omega)$$

$$x(t) = \mathrm{FFT}^{-1}\{X(j\omega)\}$$

In practice the response of the microphone will be determined by the frequency response, and the output from the system when driven by the transient signal to be characterised, will be captured digitally in the time domain.

There are then two options available.

1) Convert the microphone frequency response to the time-domain by inverse FFT, and perform a deconvolution of the output response and the microphone

impulse response in the time domain, to yield directly the input signal in the time domain

2) Convert the digitally captured output signal into the frequency domain by FFT, and perform a deconvolution by simple division, then apply an inverse FFT to obtain the input signal time domain response.

B3. Practical implementation

The prerequisites to implement the calibration method outlined above are:

- The microphone is removable from the ear simulator to be calibrated.
- A method of measuring and/or estimating the microphone sensitivity as a function of frequency from 0 Hz to 100 kHz is available.
- A method of digitally capturing a transient signal produced by the microphone when fitted to the ear simulator, and when a transducer provides a short-duration stimulus is applied.
- Signal processing algorithm to either:
    - perform an inverse FFT on the microphone frequency response and a deconvolution of the output waveform and microphone transient sensitivity

      or

    - perform an FFT of the output waveform, division of two frequency domain signals and inverse FFT of the resulting response.

An example of a measurement system meeting these requirements was developed to verify the calibration methods.

Measurement setup
The measurement system used in the testing of short duration signals is the same used for the determination of the transfer impedance of the ear simulator. The DFM system is composed by a reciprocity apparatus (B&K 5998) together with the transmitter unit (B&K ZE 0796) and an insert-voltage preamplifier (B&K 2673). The EARS P1 ear simulator will be used with its B&K 4938 microphone as receiver, and the sound source will be a B&K 4180 microphone. The main difference with the system used for the measurement of the transfer impedance is the introduction of a data acquisition card which allows for recording the time signals from the signal generator, the transmitter and the receiver microphone. Figure 4 shows a schematic representation of the measurement system.

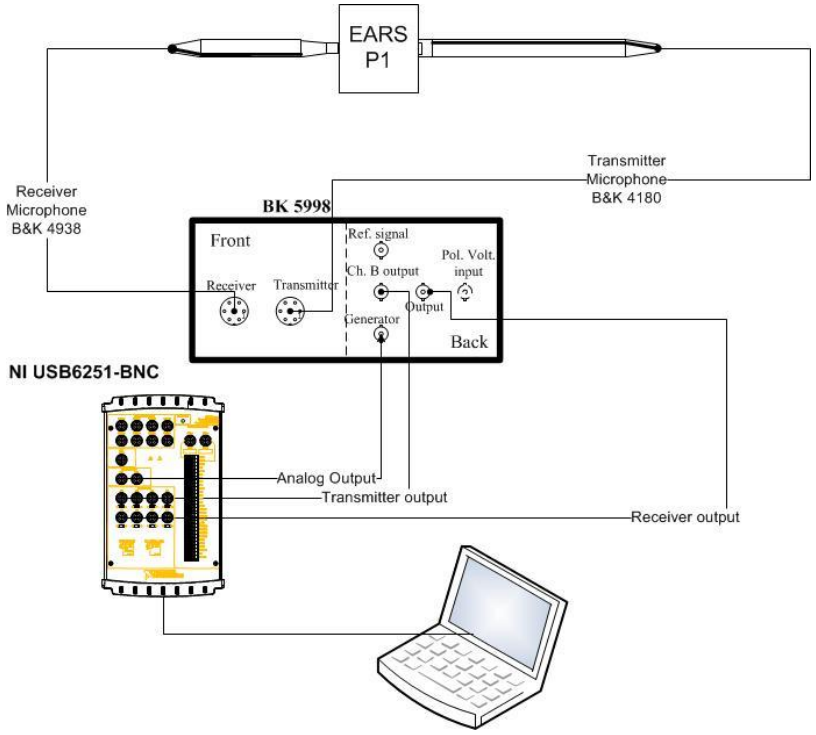

Figure 4. Schematic representation of the set-up for measuring the transient response of the ear simulator.

Signals

IEC 60645-3:2007 specifies two types reference signals, a rectangular pulse, and tone bursts. Because in this exercise a microphone is used as a source, the tone-burst will be used because we do not intend to overload the microphone with sudden impulsive signals. An example of the sine burst is shown in Figure 5.

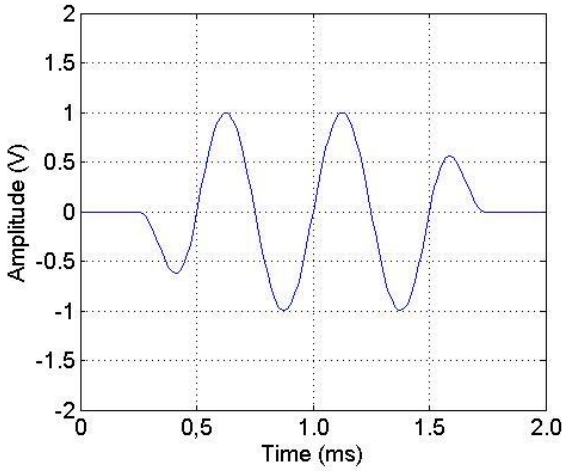

Figure 5. Illustration of a reference tone-burst. The base frequency is 1 kHz, and the amplitude is 1 V-peak.

The characteristics of the signal (amplitude, frequency, rising and falling times, duration) can be changed as it is generated as a file in the software.

Pressure response of the receiver microphone

Whether deconvolution procedures are carried out in the time or the frequency domain, the *complex* pressure sensitivity of the receiver microphone is needed. This implies that the sensitivity in the whole frequency range should be determined using the electrostatic actuator method, and the complex pressure sensitivity should be determined at least at a single frequency. This can be achieved by comparing the microphone to a reference microphone for which the phase of the sensitivity is known. Figure 6 shows the pressure sensitivity modulus and phase of the microphone within the ear simulator.

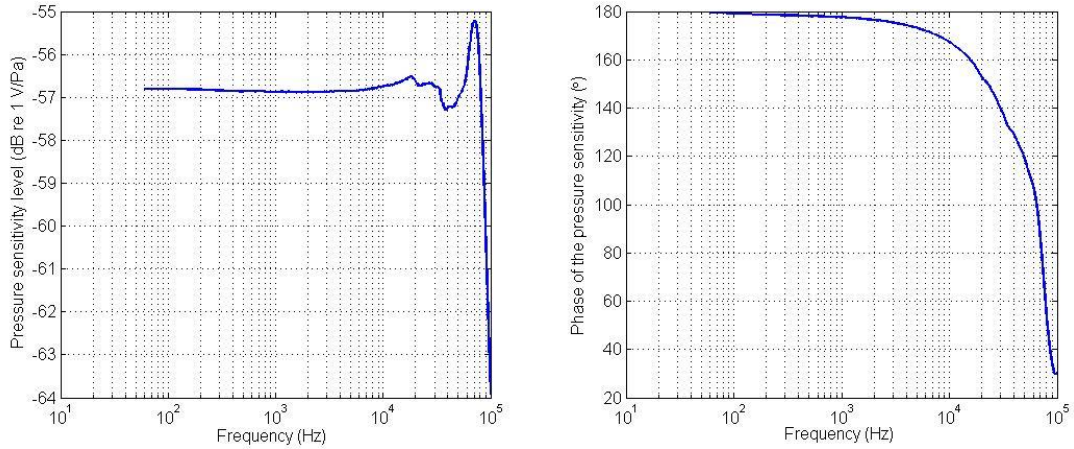

Figure 6. Pressure sensitivity of the type 4938 microphone within the ear simulator.

The electrostatic actuator response is measured over the frequency range from 30 Hz to 100 kHz with a linear step size of 30 Hz. The impulse response of the microphone can be determined by applying the inverse Fourier transformation to the frequency response of the microphone. The processing is performed in Matlab.

Figure 7 shows the impulse response of the type 4938 microphone. The duration of the impulse response is quite short (about 0.1 ms) which may lead to conclude that the influence of the receiver microphone will be mostly associated with a scaling of the input signal depending on the frequency of the burst-tone.

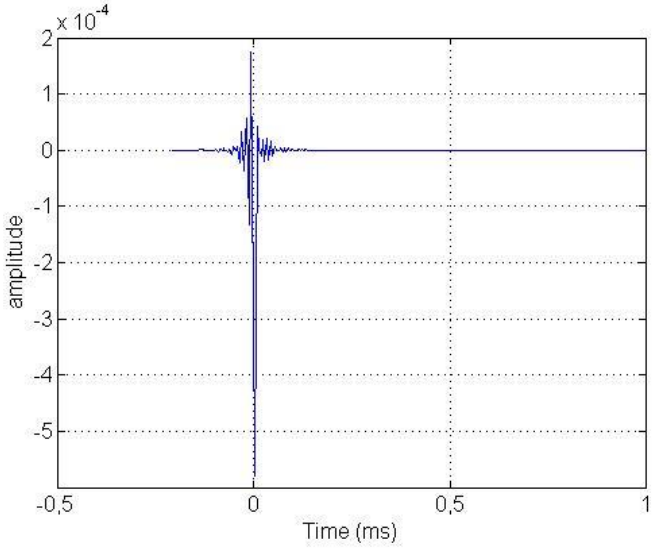

Figure 7. Impulse response of the type 4938 microphone.

Output of the receiver microphone mounted on the ear simulator

With the transient response of the microphone characterized, the ear simulator was re-assembled and driven with a type LS2P microphone in-lieu of an audiometric transducer. The coupled system was driven with the burst tone described above. Figure 8 shows an example of the voltages measured by the system on a tone-burst of 1 kHz.

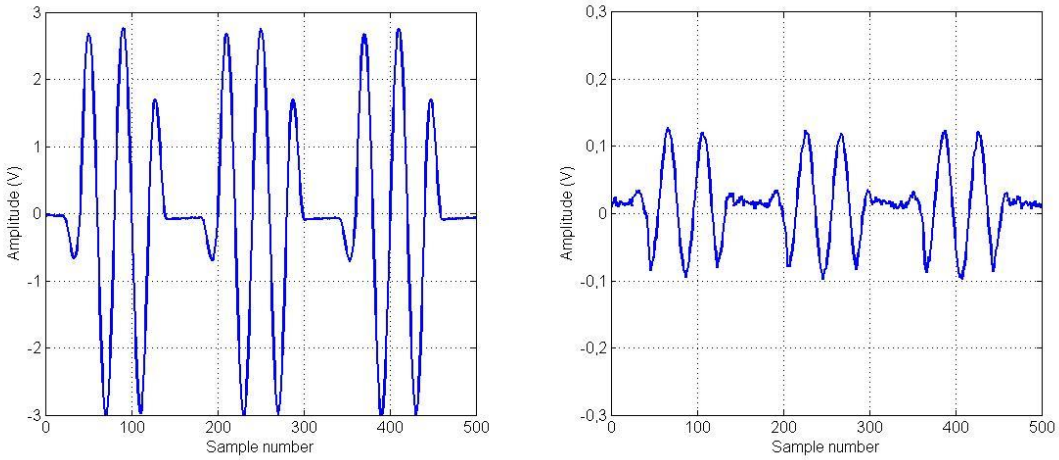

Figure 8. Example of the signals measured with the ear simulator. The plot on the left is the voltage measured on the terminals of the reference impedance of the transmitter unit; the plot on the right is the output voltage of the receiver microphone.

Notice some features of the two signals. One is that the signal on the reference impedance is a scaled-up copy of the signal shown in Figure 5, while the output voltage from the receiver microphone is further scaled down and with an evident phase shift. This phase shift should correspond to the additions of the phase of the receiver microphone and the combined phase shift from the transmitter microphone and the ear simulator. Deconvolution of the microphone response should result in the latter.

The other type of reference signal is the rectangular pulse. This is considered an extreme transient signal due to the sharp rise and fall. So, it is valuable to evaluate the response of the simulator to this type of signal. For this purpose, an arbitrary rectangular pulse signal was designed and is shown in Figure 9.

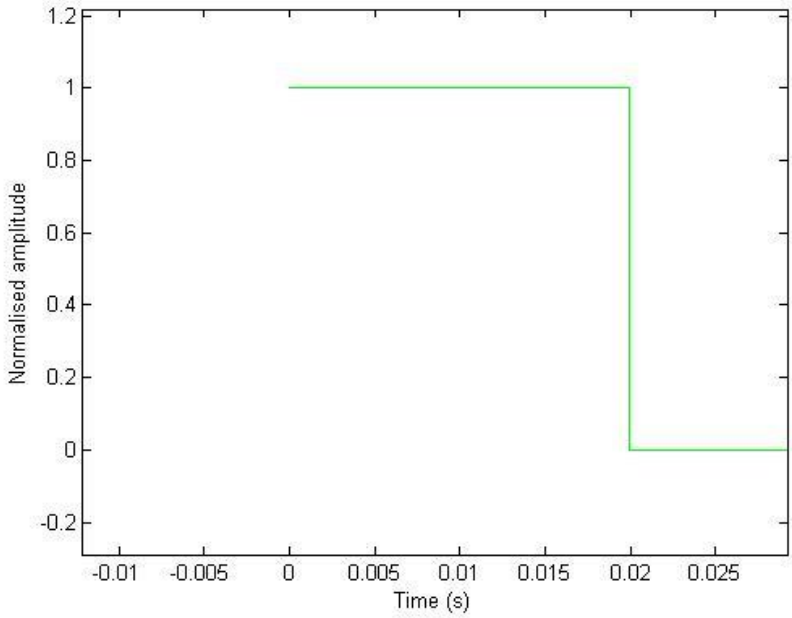

Figure 9. Rectangular signal developed for evaluating the ear simulator

In order to use the full bandwidth of the WS3 receiver microphone, the signal is digitised using a sampling rate of 202 kHz. The measured signal is subject to the deconvolution procedure described earlier. The measured and the deconvolved signals are shown in Figure 10 below.

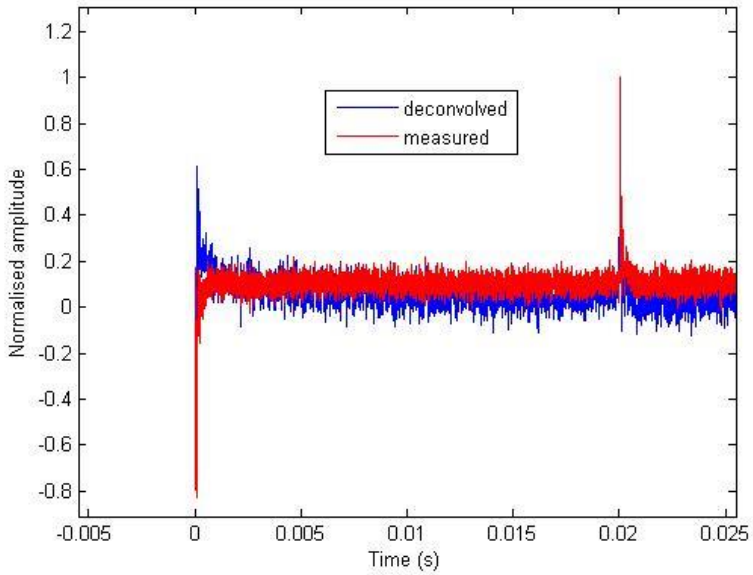

Figure 10. Microphone output signal and result following deconvolution of the microphone transient response.

The rectangular pulse introduces two responses of the system. One at the rising section of the pulse, and another at the falling section. Either part excites the system and the result is the impulse response of the coupler. The rising and falling portions of the output signal is shown in the figure below.

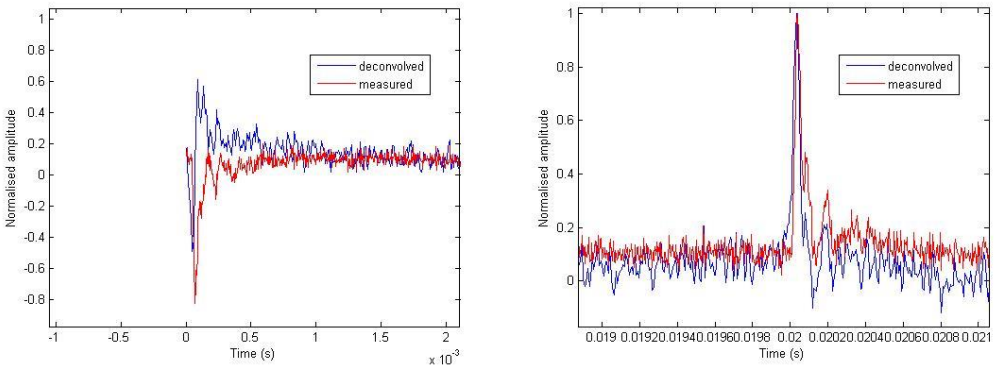

Figure 11. Close-up view of the microphone output signal deconvolution signal

The differences between the rising and falling responses may be due to the fact that the rectangular pulse starts exactly at time zero, and there may be some differences in the response times of the generator and the receiver channels. Therefore, the rising portion may be better measured by introducing a small delay in the designed signal in such a way that it is ensured that the measured signals are sampled integrally.