BRITISH ACADEMY
OF AUDIOLOGY

Uncertainty of Measurement in Audiology

Draft for public consultation

Publication

This document is produced by the British Academy of Audiology (BAA), led by the BAA Service Quality Committee (SQC), and intended for use by audiology services in the UK.

Lead authors: Alan Bryant and Richard Windle

We are grateful for contributions from Gareth Smith and John Fitzgerald and members of the BAA SQC.

Contents

1. Executive Summary

The revised Improving Quality in Physiological Services Accreditation (IQIPS) version 2 standard introduces the concept of "Uncertainty of Measurement" (UoM) into physiological services. Although the terminology might be new to many in the field of Audiology, the basic concepts should be familiar. "Uncertainty" is a quantification of the doubt, variation or dispersion of results that is expected in any measurement.

Implementing UoM into audiology may however introduce some complexity because it is not always easy to accurately establish the inherent variability of measurements used in physiological science. This complexity is reflected in the following ISO statement for pure-tone audiometry, that "due to the complexity of the measurement process, including the personal behaviour of both the test subject and the tester, it is difficult to express the measurement uncertainty in a single generally valid figure" (BS EN ISO 8253-1:2010). As such, it is accepted that the process of integrating UoM into practice may be a gradual development.

The potential for measurement error and sources of variability that are controllable via, for example, robust protocols and training may not be within the definition of UoM (see section 4.2 & A1.6). It is often the case in physiological measurements that potential error or controllable variability is much larger than the remaining random variation assessed as UoM. We therefore propose that UoM should be considered as part of a wider quality management process for measurements. Audiology services should first understand sources of variability in measurements and then seek to control variability through quality management procedures. With this in place, services can subsequently develop their understanding of UoM and move towards a more detailed assessment of UoM, supported by the professional bodies.

This document aims to assist audiology clinical and management leads with their preparation for IQIPS accreditation, specifically incorporating quality management for measurement and UoM principles. It also hopes to provide clinicians with a resource to refresh thinking around the fundamentals of measurement quality and introduce the concept of UoM to a wider audience.

Section 2 details the aims of this document, which is predominantly to provide a basic understanding of UoM principles and to provide support for audiology services by describing the considerations that should be undertaken to meet the current expectations of IQIPS. At this stage, services should be able to define how they will move towards UoM assessment in future and demonstrate that they are working towards this goal. Support for this process is largely addressed within this document. Services with the experience and resources to move further into UoM analysis can of course do so should they feel empowered, if appropriate care is taken with data collection and calculations.

Section 3 gives further background, explaining why UoM has been introduced and why we approach it as one element of broader quality management to improvement measurement.

Section 4 provides a brief introduction to UoM terminology specifically and how it might be applied to audiology, with further details on UoM given in Appendix 1.

Section 5 provides a toolkit for audiology services, which suggests how services can start to identify potential variability in measurements and control it, before developing a strategy and beginning to work towards assessment of UoM in future (or now for those services that might feel empowered to do so). The format of UoM reporting is given in Appendix 2 to set expectations for future IQIPS submissions, although this level of data collection and calculation is not essential for services at this stage

Section 6 summarises our recommendations, also defining the actions for professional bodies to support audiology services, avoiding unnecessary replication of small studies across many departments who do not have the resource to do so at an appropriate level and/or avoid misleading conclusions.

Appendix provides a detailed introduction to the concepts of UoM specifically. It is recommended for any clinician who is new to UoM and wants to develop an increased understanding.

In short, we propose that services should initially focus on identifying and managing any sources of variability in measurements through normal quality management procedures. Services and professional bodies should work together to better define UoM in the context of Audiology moving forward.

Recommendations

1. **Everybody in the audiology profession should recognise the importance of robust quality management procedures**.

   We should understand the role of the assessment of Uncertainty of Measurement (UoM) within quality management.

   We should work together to develop greater understanding of measurement variability, better controls and assessment of UoM to give the highest possible confidence in our measurements.

2. **Audiology services should understand potential sources of variability in measurements and seek to control them.**

   This should be the current aim of audiology services, who can later develop understanding of UoM principles and work towards assessment of UoM in future.

   Objective and behavioural tests on individuals are subject to uncertainty due to human, technical and process factors. The fundamentals of good clinical practice will, if done well, control for much of the variability and uncertainty in our measurements and it is of primary importance that audiology services continue to implement robust quality management processes.

3. **Audiology services should consider the points given in the Audiology Service Toolkit.**

   Services may use Table 1, and this document in general, as guidance in preparation for IQIPS accreditation and review.

4. **Audiology services should be aware UoM principles and future requirements.**

   Services should understand UoM principles and the format of the Uncertainty Budget (Appendix 2) so that a roadmap can be plotted to move towards this in future. Some services may already feel empowered to gather data and develop their Uncertainty Budget further.

   The terminology of UoM may be new to many in audiology but the principles are based on familiar statistical approaches. There may, however, be considerable complexity in defining robust measures of uncertainty for every test undertaken by audiology services across paediatric and adult hearing assessment, patient management and vestibular assessment.

   We do not envisage that many services will be able to undertake local type A evaluations of uncertainty and it is not expected that services do so. Type A evaluations based on small or unrepresentative samples risk producing misleading results and should be undertaken with caution. Type A evaluations are better conducted on the basis of pooled data to form larger samples, or by research groups.

5. **Professional bodies should provide further guidance on UoM.**

It is recognised that robust values for UoM do not exist for every element of tests in audiology and that UoM assessment is an important initiative driven by UKAS. However, in some cases there is a body of literature that should support well-evidenced UoM values for standard procedures.

The professional bodies should seek to support collaborative efforts that define these areas and provide information to audiology services based on larger reviews and meta-analyses that are beyond the means of most audiology services.

Professional bodies should seek to provide information to audiology services and encourage research and collaboration that seeks to undertake type A and B evaluations where there is an agreed need, based on representative samples that provide robust information with sufficient statistical significance.

Areas in which sufficient UoM information cannot be determined should be identified and the professional bodies should seek to support efforts to implement type A evaluation studies, e.g. via collaboration between services or via research teams such as the NIHR biomedical research centres.

Sources of measurement variability and, more specifically, UoM should be considered as part of professional guidelines and recommended practice for specific tests and procedures in future.

6. **Audiology services should collaborate and support professional bodies.**

It is preferable that individual audiology services work with professional bodies to pool data and work to common standards when undertaking type A evaluations. A collaborative, national framework for considering UoM is therefore more appropriate.

2. Aims

Uncertainty of Measurement (UoM) forms part of the IQIPS v2 standards. The professional bodies in physiological sciences were requested by the UK Accreditation Service (UKAS) to introduce UoM to their members working towards IQIPS accreditation, initiating work on this document.

Many factors influence the quality and consistency of measurements. UoM generally refers to normal variations occurring during valid measurements. Larger variations may occur, such as errors but these are not classified as UoM factors. In forming BAA guidance on this matter, we therefore decided that it was important to first highlight the need to refresh our thinking around broader quality management approaches that aim to ensure high standards of measurement overall. The concepts of UoM should then be introduced as part of this wider approach, but should not be our primary concern until the foundations of quality measurement are addressed first. On this basis, the aims of this document are to:

- Refresh thinking around the importance of controlling for variability and error in our measurements, and promote good practice in measurement quality;
- Help services understand when measurement variability occurs, when it can be relevant to measurements, and how to manage variability and improve consistency;
- Introduce the basic concepts of Uncertainty of Measurement (UoM) and sign-post additional reading for those particularly interested in the area;
- Ensure that audiology services and their clinicians have a basic understanding of UoM in order to meet current IQIPS requirements;

- Provide a toolkit to support audiology services' accreditation to the new IQIPs v2 standard in the short-term;
- Highlight the importance and the need for assessment of UoM as part of broader quality management improvement across the profession;
- Provide a clear statement of long-term expectations and the format of future reporting of UoM (i.e. the "Uncertainty Budget") to enable the profession and individual audiology services to plot a route towards full UoM assessment in the future;
- Assure ourselves and others of the quality of measurements across audiology services;
- Provide the foundation for further supporting documentation from BAA and other professional bodies, as the profession continues to promote high-quality measurements and incorporation of UoM in future.

The considerations and recommendations in this document should be regarded as an initial response that has necessarily been developed quickly to support audiology services with upcoming IQIPS assessments. The document provides non-binding guidance and recommendations that individual services may decide are appropriate for them or not. It is intended that this document will be reviewed and superseded as further work is undertaken.

3. Background

Some degree of uncertainty is inherent to any measurement. For example, there may be small variations in method, equipment accuracy or conditions that fall within acceptable practice, causing the value of the measurement to vary. Consequently any single measurement should be regarded as an estimate of the true value being measured. It can therefore be argued that this estimate is not complete unless it is reported with a statement of the uncertainty in the measurement (UKAS, 2019). As a profession we are keenly aware of the need for accurate diagnostic information and its importance to interpretation and management decisions. The BAA are therefore supportive of the move towards assessment of uncertainty and better measurement quality in general.

Uncertainty of Measurement (UoM) is an important part of quality assurance and a key element of international accreditation standards. For example ISO 15189 sets out requirements for quality management and competence in medical laboratories, including the evaluation of UoM. UKAS IQIPS v2 was developed to be better aligned with international standards and this is, in part, why UoM now has a greater visibility.

Audiology services should be aware of UoM in clinical practice and reflect this understanding in service policy. UKAS understands that UoM is a new notion for physiological sciences and that its incorporation into clinical practice where additional human subject factors are common, may be less clear than for laboratory-based measurements. ISO states, in its method for pure-tone audiometry, that “due to the complexity of the measurement process, including the personal behaviour of both the test subject and the tester, it is difficult to express the measurement uncertainty in a single generally valid figure” (BS EN ISO 8253-1:2010). As such, it is accepted that the process of integrating UoM into practice may be a gradual development.

It is important to remember that UoM is only one element of a broader quality management approach to clinical measurements. In general, we should be aiming to identify and control any aspect of measurement variability that can be minimised, and then express the remaining range of variation as UoM. The overall approach we describe in this document is to suggest actions that all audiology services should be able to undertake in the short term, which builds towards full implementation of UoM assessment in the longer term.

For those services working towards or maintaining IQIPS accreditation, the initial UKAS expectation is that they can demonstrate a basic understanding of UoM, an awareness of the factors causing uncertainty in measurements, and a strategy for controlling variations in measurement as part of an ongoing quality management system. Services should also be able to express a strategy for introducing the assessment of UoM and be working towards this. This document aims to support services where required although it is understood that some services will be empowered to make more local advancements with regard to UoM in particular. Services will not be expected to calculate levels of uncertainty (uncertainty budget) at this stage, unless they feel empowered with the resources and experience to do so. Of note, IQIPS assessors will be looking for assurance that there is a developing awareness of local measurement quality control and UoM across clinical staff members. With this in mind, we hope this document can provide a useful introductory resource for all audiology clinicians.

In the longer term, the BAA aims to produce further guidance as part of an ongoing process of supporting members. As part of this process, the BAA is calling on support from individual members and services to help define approaches and pool measurements where necessary.

4. An Introduction to Uncertainty of Measurement

4.1 Application to Audiology

The focus of this document is on improving overall quality management in audiology, and that assessment of Uncertainty of Measurement (UoM) is one of several elements. Nevertheless, it is important to introduce audiologists to the basic concepts and terminology of UoM before proceeding further. This section therefore provides a "whistle-stop tour" of UoM, with **further details and explanation given in Appendix 1**. Each specific UoM term defined is highlighted in bold. Readers should not be overly concerned by the details of terminology and calculations, but to have a broad appreciation. In the short-term, it is most important to understand what constitutes a likely source of error or uncertainty in any measurement, and how to identify and control these wherever possible.

In laboratory services, governed by ISO 15189, detailed assessment of UoM is important because results, such as pathology tests, may indicate a specific condition or course of treatment. It is therefore important to know whether a numerical result is clearly positive, negative or borderline (where a given criteria may be within the bounds of uncertainty of a single measurement). Many tests in physiological services, such as audiology, are based on humans and this clearly introduces further sources of variability and a broader set of concerns when interpreting results. For example, the result of any one test is likely to be regarded in the context of a test battery and the case history of a patient so, although the UoM might be assessed, it is not always solely indicative of an outcome or management plan and is assessed within the bounds of clinical discretion and, often, based on published clinical norms dependent on various other factors such as age or gender. Care might also need to be taken in reporting variability because of the risk of creating confusion or suggesting inaccuracy to patients. However, in audiology we make measurements every day to form the basis of our diagnosis and management. It is therefore important that we understand the uncertainty surrounding tests and what impact it might have on our decisions.

4.2 Basic Concepts and Terminology (see Appendix 1 for further discussion)

All measurements are prone to some uncertainty and therefore no measurement is complete without an acknowledgement of the level of uncertainty (UKAS, 2019). In simple terms, UoM "is the doubt that exists about the result of any measurement" (Bell, 1999). Note that a "measurement" is something that provides a numerical quantification of a property; a measurement does not include tests that only provide a qualitative outcomes such as pass/fail or yes/no, unless the criteria for a pass/fail is based on a numerical measurement in the background.

Ideally, we would be able to express a measurement as a combination of the result and the uncertainty in the result. For example, rather than stating an audiology measurement as simply "75 dB HL", we should be able to express it in the following format:

75.0 ± 10 dB HL, at a level of confidence of 95%.

It may or may not be appropriate to use this format in communication with patients and other professionals, but a service should at least understand the degree of uncertainty inherent to any measurement and clinical decisions should be based on this understanding.

The example above introduces a few UoM concepts:

- "± 10 dB HL" is the size of the margin of uncertainty, or "**interval**";
- the "**confidence interval**" is therefore 10 dB either side of 75 dB, i.e. from 65 dB to 85 dB;
- "a level of confidence of 95%" describes the scale of doubt, or "**confidence level**".

In audiology, we're well aware that there is some variability in measurements because of equipment, environmental or human factors. Our understanding of test-retest reliability tells us that all measurements will vary randomly to some extent. The Uncertainty of Measurement approach

enables us to evaluate variability in a standardised manner. It might also be interpreted as simply formalising the terminology for well-understood, basic statistics. Random variation in a measurement can be described by a statistical distribution, often in the form of a "normal distribution" or well-known "bell curve". If this is the case, the interval and confidence level can be determined from the standard deviation of measurements. In the example above, the interval is based on calculating two standard errors (two standard deviations corrected by the number of measurements) which determines a confidence level of approximately 95%. In UoM terminology, the standard error is described as the **standard uncertainty, u**. The number of standard uncertainties used to yield an equivalent level of confidence is called the **coverage factor, k**. In this example, k = 2 to give a confidence level of approximately 95%, so the interval is expressed as 2 x u. The greater the number of standard deviations used to calculate the interval, or the greater the coverage factor, then the higher the level of confidence, so we can be more certain that any measurement we undertake will fall within the bounds of the interval. In other words, the wider the confidence interval, the more likely it is that any one measurement will sit within it. We recommend reading Appendix 1 or the recommended literature to give more clarity to this process.

When evaluating UoM it is important to separate errors and variability factors that do not contribute to UoM (and control where possible) from those factors remaining as inherent variations in a measurement and which therefore do contribute to UoM. Factors that contribute to UoM are those that might directly affect measurements as they are "normally" conducted, for example: variation in equipment performance; normal physical variations between patients; placement of transducers; equipment calibration; calibration drift; operator skill; and environmental factors such as noise or temperature. Factors that are not considered to contribute to uncertainty generally include those outside the scope of a "normal" measurement, for example: human errors and procedures not conforming to guidelines; equipment failures; and individual pathologies that may inhibit responses such as dementia, non-organic behaviour, alcohol intake or ASD (see Appendix 1 for further discussion). Nevertheless, the latter remain important sources of variability and error, so should still be controlled or reported as part of overall measurement quality management. When considering the potential causes of uncertainty in measurements, services should ultimately be able to identify and evaluate them. There are two approaches to evaluating uncertainty. **Type A evaluations** are based on a statistical assessment of measurements; essentially repeating the measurement multiple times and analysing the variation within that measurement (i.e. looking at the variation from the bullseye for an archer who has fired 100 arrows). However, as discussed further in Appendix A1.4, this will depend on a sufficient sample size to be valid. Type A evaluations conducted on small samples, or on subjects that are not representative of the normal patient population, risk providing misleading results that might affect clinical decisions. It is therefore more difficult to conduct rigorous type A evaluations in physiological services, such as audiology, compared to laboratory services. Consequently a **type B evaluation** may often be preferable, which is based on other sources of information such as published literature, manufacturers' information or historical analysis of data. Luckily in audiology, documents such as ISO 325-1:2010 do a lot of the work for us and suggest UoM values based on large studies that we can utilise as long as we follow similar good clinical practice.

Identified causes of uncertainty, their evaluation and the evaluation method with relevant references can be summarised in a table for each of the evaluations undertaken. This table is usually referred to as an **Uncertainty Budget** and a template is provided in Appendix 2. Please be aware that standard uncertainties from various factors cannot be simply added, but should follow the root-sum-square approach (see Appendix 1). It is not expected that individual services define uncertainty in this manner currently, but work towards this approach over the coming years using the resources provided by professional bodies.

5. Audiology Service Toolkit

5.1 Considerations for Audiology Services

This section provides a toolkit for audiology services, given in Table 1. It describes a list of areas that may be currently considered as part of any service's measurement Quality Management and Quality Control procedures. It should also help those services working towards IQIPS accreditation under IQIPS version 2. A number of these controls will already form part of an IQIPS v2 Quality Management System (e.g. evidence of peer review, calibration, measurement protocols).

The toolkit also suggests future actions that may be considered by individual services as they prepare to assess UoM. It should assist the professional bodies in providing better UoM data in the future, in order to better support individual audiology services.

Table 1: current and future considerations for audiology services working towards incorporating UoM assessment within quality management procedures.

Current considerations: implementing Quality Management processes for measurement and understanding UoM	
1	**Understand the importance of Quality Management in measurement** Service managers should recognise the importance of Quality Management, including the identification and control of measurement variability in all of its forms. For services working within the specifications of IQIPS v2, the processes in place to promote good measurement quality (i.e. peer review, calibration) will inherently form part of the services Quality Management System (QMS). The provision of a QMS is also a requirement for v2 accreditation and therefore a service may refer to these QMS processes when assuring assessors with regard to measurement control. Service managers should understand the principles of UoM, based on this document, and how it forms part of improving quality measurement.
2	**Include Measurement Quality Management within the service strategy** Incorporate quality management and UoM principles into the service strategy and overall approach to quality management (reflecting this within the QMS for IQIPS services), making use of the text and information in this document.
3	**Understand the tests carried out in your service** Create a Schedule of Tests that defines all of the measurements conducted within the scope of the service. When a service begins to evaluate UoM it will only have relevance to assessments where a numerical measurement value is recoded.
4	**Manage the tests and equipment in your service** Develop and maintain an Equipment Log (mandated by IQIPS) and identify each variant of equipment used for each of the measurements conducted in the service. For IQIPS services it is worth noting the greater requirements for equipment control, documented in IQIPS v2 standard statements guidance (facilities and resources section).
5	**Equipment Quality Control** Maintain the Equipment Log and a schedule of maintenance and stage C calibration. Maintain calibration logs, manufacturer's instructions and data for the equipment used in the Schedule of Tests. For IQIPS services refer to IQIPS v2 standard statements guidance document (facilities and resources section). Demonstrate that stage A checks are a part of normal operation and are monitored.
6	**Associate the correct procedures with measurements and tests** Identify processes and process documentation associated with each measurement. This may be local or national guidance, SOPs or published literature (some examples are given in Appendix 2). List this against each measurement.
7	**Evaluate sources of measurement variability** Identify potential sources of measurement variability, both error and UoM, in test procedures. These are detailed further in Section 4.2. Begin to differentiate between measurement error and measurement variability that is defined as UoM and others.
8	**Quality Control** Consider how measurement variability can be minimised using normal quality management procedures, audit, training and peer review. As discussed, much of this will form the foundations of a department's QMS for IQIPS services. It is suggested that services should initially focus on general good practice, assessing for wider variability and looking for controls that improve quality and consistency.

9	**Report variability of measurements appropriately** Agree procedures and terminology for reporting measurement variability and uncertainty to professionals and patients. Use appropriate wording for indicating the degree of accuracy in tests. (For example, it may be better to describe some test outcomes in words rather than misleadingly definitive numerical values, e.g. with non-standard stimuli such as live speech or music.)
10	**Revise protocols appropriately** Consider revising local guidelines and SOPs where appropriate to ensure that measurement variability is included and considered as part of clinical decision-making.
11	**Consider Measurement Non-Conformity** For IQIPS services, measurement quality might be considered when developing a service's non-conformity reporting process (see IQIPS v2 standard statements guidance for information on IQIPS stance on non-conformity reporting).
12	**Foster staff awareness** Ensure staff are trained and peer reviewed to ensure compliance with guidelines. Ensure staff are aware of the principles of quality management processes, measurement variability, UoM and appropriate reporting of measurements. For IQIPS services, a developing awareness of measurement control and UoM, amongst clinical staff, will be an expectation of assessors. This document may provide a useful resource for fostering awareness.
'Working towards UoM'considerations: Preparing for UoM assessment	
12	**Plan for UoM assessment** Describe a process (or actions) for determining sources of UoM in future. It is likely that individual services will use further iterations of this BAA document for support and guidance, and it should be acceptable to refer to this document as a definition of future actions as long as understanding can be demonstrated.
13	**Prioritise measurements for assessment** Prioritise measurements for detailed consideration of variability. Those measurement procedures that require priority attention include high volume measurements (such as those used in standard hearing assessments), those determining a high risk clinical outcome, or those that might be indicative of outcomes in isolation. Tests that are used as part of a specialist test battery in combination with specialist clinical discretion (e.g. vestibular assessment) should be considered in the same way, to minimise controllable variability, but might be considered lower priority for working towards full UoM assessment at this stage.
14	**Define sources of Uncertainty of Measurement (UoM)** Start with the prioritised measurements/tests. Sources of UoM will likely be the remaining sources of potential variability inherent to "normal" measurements (i.e. those that conform to protocols) that cannot be controlled by error-reduction or with clinical protocols. It may be useful to services to begin pooling uncertainty levels for equipment and calibration (liaising with manufacturers and calibration providers) so this information is available for future consideration of uncertainty budgets.

15	**Work with other services and professional bodies** If services undertake significant work to define Uncertainty of Measurement, either type A evaluations or detailed type B evaluations, such a literature reviews and meta-analyses, these should be communicated to the BAA (nominate email address and/or person/committee) in order to pool data and develop a UK understanding of UOM Pooled data can be used in further iterations of this BAA document and to support other services. Services willing to take part in multi-site studies that will pool data to better determine UoM in specific tests in future should also contact …….

Note:
This toolkit has been developed to support services. It is not intended to be mandatory and services may feel there are other ways to assess and assure for measurement quality and UoM. Recommendations are based on the foundations of good clinical practice, but it is understood that services are likely to be working towards comprehensive quality management and control documentation. It is therefore not expected that every service will be able to complete every element of the toolkit, but should be explicit about actions to complete the process in future.

5.2 Sources of Variability in Measurements

Services should determine the sources of potential variability for each of their measurements. Some of these sources will be general, influencing many or all measurements, others will be more specific to a particular measurement type. Fig.1 summarises potential sources of variability in any measurement. Variability includes all factors that can affect a measurement: including error, poor processes, some human factors that may not be considered part of UoM, and random factors that may affect a "valid" measurement that will be considered as part of UoM. There may already be controls in place to reduce variability (e.g. calibration, protocols and peer review). However it must be recognised that quality management and quality control will be ongoing processes, such that the key element of service culture should be to continually assess for gaps and areas of improvement. Examples of controls and associated documentation for each of the sources of variability is given in Table 2. This is applied to an example, given in Table 3, of potential sources of variability in PTA and REMs. Considering Table 3, it should be clear that **UoM is sometimes a much less significant source of potential measurement variability than other factors**, which is why it is important that all sources of variability should be identified and controlled prior to detailed assessment of UoM.

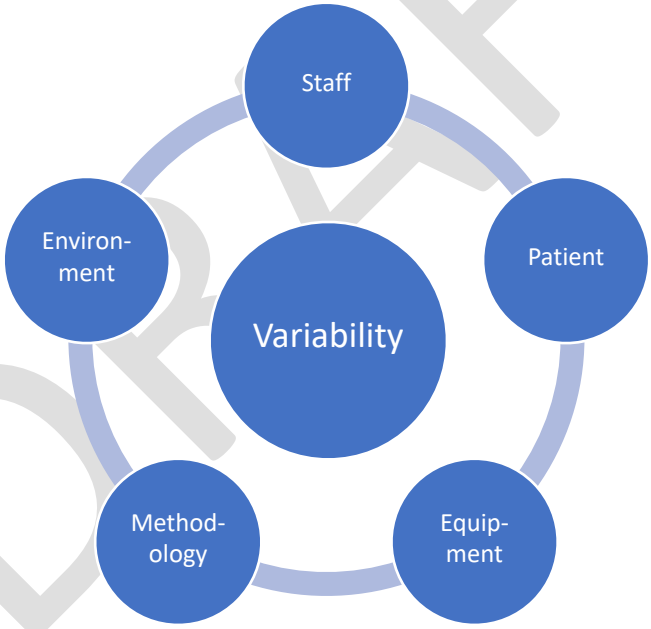

Figure 1: general sources of variability in measurements.

Table 2: common controls for measurement variability.

Source of Variability	Examples of documentation and controls
Equipment	• Equipment and consumables should be appropriate for diagnostic procedures including regular maintenance, calibration and servicing. • Faulty equipment should not be used. • Services should be aware of level of UoM attributed by the manufacturer to the measurement values obtained from their equipment when good practice is used (an example of Type B UoM evaluation). • It may be necessary to prioritise equipment to gather this data, as discussed in Table 1 (point 13). • There should be appropriate quality control (QC) processes in place to ensure equipment is reading reliably (e.g. stage A tests). • There should be a programme in place to ensure Stage C calibration is completed in a timely manner. This will include internal physical calibration and verification, by an accredited calibration service. There should be a documented process for equipment management and a comprehensive equipment log. IQIPS services can consult IQIPS standards statements guidance document for details including a mention on traceability. • There will be a value of UoM for the calibration process itself and this should be available in the calibration certification. • Services should be aware of variations due to placement of equipment, e.g. transducers such as headphones, that may cause further measurement variability (e.g. variation in higher frequency air conduction thresholds) or error (e.g. due to collapsed auditory meatus or folded tragus).
Methodology	• Services should have accessible, up-to-date, evidence-based standard operating policies (SOP) that all staff follow. • The service should consider and utilise national and international guidance where available. • Where national guidance is not available, or where a service moves away from national guidance, local guidance documents should be provided based on evidence or documented consensus of expert opinion. • Appropriate audit processes should be in place to capture systematic errors and make appropriate corrections to procedure, maintenance or training.
Environment	• The environment should be conducive to making high-quality measurements. • This should include a suitable ambient noise strategy and avoidance of any other distraction or discomfort to test subjects. • Services should be aware of equipment tolerances and ensure that equipment is used within suitable environments.

Staff	• Staff should be properly trained and assessed in the use of equipment and regular checks (e.g. stage A). • Staff should be trained and aware of procedures guidance • Staff should also be aware and of how measurement variability, control and UoM influence their work and the service. • Maintenance of CPD records can help assure a learning and quality-driven culture. • Peer review process can help assure services that staff are following good measurement practice and guidelines. • A programme of spot checks and audit can help assure services that staff are following guidelines and interpreting measurements in line with local or national best practice.
Patient	• Normal physical variation between patients may introduce variability in testing, e.g. size of head and tightness of transducers, skull thickness and transmission of bone conduction. • Clear guidance should be given to patients in performing as test subjects. The ability to understand or conform to test instructions may vary between patients. • Any physical, mental or behavioural condition that may impair the performance of a subject should be noted and measurement results considered in that context. • A patient's level of tiredness, stress, anxiety, cognitive ability or attentiveness may affect tests involving their responsiveness. • Environmental factors may inhibit a patient's ability to perform or may be a distraction. • Medications and motivational factors may also mediate responsiveness.
IQIPS Specific Considerations	• A Quality Management System (QMS) will be in place for all IQIPS services and areas within the QMS will often relate to good measurement quality (i.e. ambient noise, measurement protocols) • The Annual Management Review will also likely reference areas related to measurement quality and is a requirement of v2 • A non-conformity log will reference areas important to measurement quality (i.e. equipment faults, trends in measurement spot checks &/or audit) • IQIPS v2 mentions root cause analysis and trend analysis as tools for improving service quality. This is likely to extend to areas of measurement quality. • See IQIPS standard v2 and IQIPS v2 statements guidance for details

Table 3: examples of potential sources of variability and possible control mechanisms for PTA and REMs. (N.B. this is an example of an assessment for variability and quality control that might benefit local protocols in the future.)

Test	Sources of Variability	Assessment / Action
Pure tone audiometry (PTA)	• Individual clinician error in testing or interpretation • Tester bias • Non-auditory cues	• Sources of error or controllable variability • Control through clear protocols, training, peer review and audit
	• Calibration	• Imported uncertainty; assess as UoM
	• Equipment variation	• Some controllable variability; controlled via checks and maintenance • Some remaining random variation in normal operation; assess as UoM
	• Equipment malfunction	• Controllable error • Control via checks and maintenance
	• Physical patient factors (e.g. head size, bone density, ear canal volume) • Placement of headphones and BC	• Some controllable variability; controlled via training, protocols, use of appropriate equipment and placement • Some remaining random variation in normal operation; assess as UoM
	• Collapsed meatus or occluding tragus	• Controllable error • Control via protocols, training, availability of appropriate equipment (i.e. inserts)
	• Patient responsiveness (e.g. related to attention, tiredness)	• Controllable variability; controlled via protocols, training, environment • Some remaining random variation; assess as UoM
	• Background noise	• Controllable variability; control via protocols, audit measurements, acoustic treatments, training and clinician awareness
	• Patient-generated noise (e.g. breathing, blood, tinnitus)	• Some controllable variability; controlled via training, protocols, e.g. use of warble tones • Mainly remaining random variation; assess as UoM
	• Distractions (e.g. visual)	• Controllable variability; control via appropriate facilities and clinician awareness
	• Patient comorbidities (response speed, dexterity, medications and conditions affecting responsiveness such as dementia, ASD, ADHD, non-organic behaviour)	• Some controllable variability; controlled via training, protocols, clinician awareness, test modifications • Not counted as measurement uncertainty • The effect on any test should be reported with appropriate caveats
	• Understanding of test instructions (due to cognitive issues or poor English)	• Controllable error • Control via protocols and training, e.g. clear test instructions, test modifications, re-test

	• Variations in tymps, prior noise exposure (e.g. including microsuction), colds and flu, ear wax	• These are <u>not</u> measurement variability but factors causing actual variability in hearing
Real Ear Measurements (REMs)	• Individual clinician testing error in technique • Incorrect acoustic parameters/verification parameters	• Sources of error or controllable variability • Control through clear protocols, training, peer review and audit
	• Loudspeaker output	• Controllable variability • Controlled via protocol (loudspeaker calibration process)
	• Microphone variability	• It should be noted that REMs are based on comparative measurements (e.g. sound levels measured by the same mic before and after hearing aids) such that variability should be cancelled
	• Probe tube placement	• Source of error or controllable variability • Control through clear protocols, training, clinician awareness, peer review and audit
	• Patient movement	• Largely controllable variability • Controlled via protocols and training (clinician observation and awareness) • Some random error, which may be assessed as UoM
	• Background noise	• Controllable error • Noise may alter or interrupt the procedure, so should be controlled primarily by environmental corrections • Transient noise control is dependent on training (clinician awareness)
	• Uncertainty of measurement factors (UoM)	• REMs are not a diagnostic procedure but a process of setting hearing aid gain (first fit) which is checked by subsequent validation with the patient. Microphone measurements are largely comparative and no diagnostic measurement value is reported. It is not thought appropriate to apply UoM vales to this procedure.

7. References

Bell, S. (1999), “A Beginner’s Guide to Uncertainty of Measurement”; Measurement Good Practice Guide No. 11 (Issue 2), National Physical Laboratory, publ. HMSO, London. Available at: https://www.npl.co.uk/special-pages/guides/gpg11_uncertainty.

UKAS (2019), “M3003 The Expression of Uncertainty and Confidence in Measurement”; Edition 4, United Kingdom Accreditation Service, Oct 2019. Available at: https://www.ukas.com/wp-content/uploads/filebase/publications/publications-relating-to-laboratory-accreditation/M3003-Expression-of-Uncertainty-and-Confidence-in-Measurement-Edition-4-October-2019.pdf.

ISO (2008), ISO/IEC GUIDE 98-3:2008, “Uncertainty of Measurement — Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)”.

Improving Quality in Physiological Services (IQIPS) (ukas.com)

- IQIPS v2 Standards
- IQIPS v2 Standard Statements Guidance

Appendix 1:

The Principles of Uncertainty of Measurement

A1.1 Definition

In simple terms, "Uncertainty of Measurement is the doubt that exists about the result of any measurement" (Bell, 1999). A measurement provides a numerical quantification of a property; a measurement does not include tests which provide a qualitative outcomes such as pass/fail or yes/ no unless there is a measurement value behind that pass/fail.

All measurements are prone to some uncertainty and therefore no measurement is complete without an acknowledgement of the level of uncertainty (UKAS, 2019). There will be a variety of factors that combine to form the total level of uncertainty. A critical part of the UoM process is therefore to define these factors which may be due to normal variations in process, normal physiological variations in the test subject, environmental conditions and test equipment. Box 1 gives an example of uncertainty in a temperature measurement. Note that UoM includes variation in normal conditions, but does not include error, defined as a difference between a measurement and the true value (Bell, 1999). Errors that not part of UoM include mistakes, bad practice, poor interpretation, although it is obviously important that these factors are controlled to support good measurement quality.

UoM should be considered in any interpretation of measurement, especially when defining normality or abnormality. If a measurement value is clearly within a normal range, the UoM may not be a determining factor. However, if a measurement value is close to a lower or upper range of normality, within the degree of uncertainty, then the UoM will affect interpretation. In audiology we make measurements every day to form the basis of our diagnosis and management. It is therefore important that we understand the uncertainty surrounding tests and what impact it might have on our decisions.

Box 1: uncertainty in temperature measurement (UKAS, 2019)

If we use a thermometer to measure the temperature of the room, how certain can we be of that measurement and with what degree of confidence? The following factors may cause variation in individual measurements:

- the location of the thermometer in the room,
- the humidity of the room,
- the way the thermometer is held, possibly warmed by the hand,
- the resolution (i.e. scale increments of the thermometer),
- how the operator reads the measurement,
- the calibration of the thermometer.

A1.2 Quantifying Confidence in Measurements

A key feature of UoM is the confidence (or certainty) one has in a measurement statement. For example, we often use the words “about” or “approximately” in daily life to express some element of uncertainty. In a scientific domain, a better-defined statement is required and this has two features (Bell, 1999):

- The size of the margin of uncertainty, or “interval”;
- The scale of doubt, or “confidence level”.

If we consider the statistical notions of random variability, spread or distribution, mean average, standard deviation and confidence intervals, the concepts behind UoM become more familiar. It should be noted that terms such as “standard deviation” refer to an assumption of normal distribution, and it should be remembered that this may not always be the case. Nevertheless, assuming a normal distribution, consider an example of reporting a measurement as “75.0 dB HL”. Taking into account an uncertainty interval and a level of confidence, we should report the measurement fully in the format of:

75.0 ± 10 dB HL, at a level of confidence of 95%.

We know that there is some variability in measurement because of equipment, environmental or human factors. With a knowledge of basic statistics, we can work out two standards errors (based on two standard deviations, with approximately 95% confidence) of normal variation in the measurement. If we increase the confidence level (above 95%) we will need to increase the number of standard deviations used and the interval (± 10 dB HL) will become larger, but we will be more certain that the true measurement value is within that interval. Thus the basics of UoM should be considered as fairly straightforward. However introducing the principles of UoM into all audiological tests can quickly become complex because it is not always a straightforward process to determine the interval by sampling measurements; this is discussed in more detail in Section A1.4.

This document provides a basic introduction to UoM and assumes a basic knowledge of statistics. A broader introduction to UoM and associated statistical principles can be found in the document produced by the National Physical Laboratory (Bell, 1999). A more detailed guide to UoM is provided by UKAS (2019).

It’s important to note that in many cases, the management of uncertainty is already defined within published procedures. For example, variation in behavioural responses in Pure Tone Audiometry (PTA) is managed sufficiently by following BSA procedures that measure the threshold after repeated measurements to tones of ascending volume. In fact, some ISO standards such as that for PTA (BS EN ISO 8253-1:2010) have sections already defining UoM for the procedure, if you follow best ISO/BSA practice.

A1.3 Random and Systematic Uncertainty

The total UoM is a combination of both random effects and any imperfect correction for systematic effects (Bell, 1999).

Random uncertainty will, by definition, occur differently each time a measurement is made and, in general, cannot be eliminated from measurements. Consequently the more measurements are made and averaged, the better the estimate of the true value. This is well-defined in many electrophysiological measures, such as the auditory brainstem response (ABR), where a certain number of averaged measurements are required to overcome noise due to physical and electromagnetic factors. In standard audiology tests, other factors can introduce random variability between patients and for repeated measurements on the same individuals, for example: the size of an ear canal affects the sound level inside an individual’s ear; bone density, muscle tone and fat affect transmission of bone conducted vibration; background noise varies by time of day; individual

behavioural responses vary with wakefulness and attentiveness; transducers such as headphones and bone conductors can impart different input stimuli depending on their placement.

Systematic uncertainty arises when the same factor occurs in the same way each time a measurement is performed. In this case, repeated measures will be of no value because the systematic error occurs each time and to the same degree. Examples of systematic errors include wear-and-tear on equipment or equipment failures that deviate from calibrated levels, variation in procedure between centres or testers, calibration error, or calculation procedures. Systematic uncertainty may be assessed by regular checks, such as stage A checks in audiology and audits, or by comparison to reference measurements. Systematic uncertainty can be corrected using correction factors (if the systematic error is known), process change, ceasing to use specific equipment or recalibration.

Note that both types of uncertainty will cause a different spread, or distribution, of measurement values. In physiological sciences undertaking measurements on people, we often assume a random, or “normal”, distribution characterised by the well-known “bell curve”. However, it should be remembered that this distribution is not always valid, so any evaluation of UoM should assess the nature of the distribution as the first part of any analysis (Bell, 1999; UKAS, 2019).

A1.4 Type A and Type B Evaluations of Uncertainty

The degree of uncertainty of any measurement can be estimated by one of two methods:

- Type A evaluation – based on a statistical assessment of measurements;
- Type B evaluation – based on other sources of information.

Type A and B should not be equated to evaluations of random or systematic uncertainty respectively. Both approaches can be used in either case to determine the distribution, spread or standard deviation of measurements, although type A evaluation is more typically used to quantify random error.

Type A evaluation generally involves conducting repeated measurements in order to determine a statistical distribution. To do so requires measurement of a sample population for which a number of factors should be considered:

- The population should be representative, i.e. subjects of the same characteristics as those who are normally tested. Unless producing local normative data, the use of a small number of young staff or students with good hearing and no medical conditions will be unlikely to represent the population of audiology patients who are largely older adults with various impairments. So when collating type A data this should be a consideration.
- The sample (number of measurements undertaken on individuals) should be of adequate size to determine intervals with sufficient statistical significance. Small sample sizes risk being unduly affected by chance outliers.
- Potential bias should be avoided, e.g. due to a single tester conducting normative studies ignoring normal tester variance, because this is a component of UoM.
- The comparison may need to be conducted longitudinally, i.e. include repeated measures or test-retest reliability, as well as between-subject measures.
- Methodology should comply with standard procedures that allow comparison of results with other studies in other centres.
- It is preferable that methodology, results and analysis are peer reviewed or externally validated.
- Undertaking any procedure, including measurements, on any patient who has no clinical need can raise ethical issues. Services should be aware that any study of UoM or normative data

based on patients may need NHS Research Ethics Committee (REC) approval, so services should assure themselves that appropriate approval has been given.

It should be apparent that type A evaluations can introduce complexity to the process of determining UoM. Measuring small sample groups or using unrepresentative subjects may lead to misleading results and a variation in the interpretation of results between centres. It is therefore recommended that care be taken if individual audiology services are to undertake type A evaluations, because it requires a thorough approach and adequate resource. It is likely that most Type A evaluations, when considered necessary, will be more practical and powerful if undertaken collaboratively by multiple services, professional bodies and research groups.

Type B evaluations may take place where there is more scarce information, or where type A evaluations are difficult to achieve or not appropriate. Although type B evaluation can sometimes be thought of as more qualitative, proper approaches may also be quantitative. Type B evaluation can take many forms, for example:

- Assessment of peer-reviewed published literature for measurement variation or a full meta-analysis;
- Published normative data undertaken on large population samples;
- Published guidance and recommended procedures;
- Combining data from multiple non-peer reviewed sources and exercising clinical judgement;
- Use of manufacturers' measurement specifications;
- Regular calibration measurements and calibration certificates;
- Historical analysis of local measurement data;
- Careful application of data for similar procedures where no specific data exists for measurements undertaken.

In some cases, particularly in audiology as we have discussed, type B evaluation may be preferable to locally-originated type A evaluation, e.g. where there are published norms and variances based on a large, representative sample for a calibrated measurement which follows a standard procedure. In other cases, clinical judgement may need to be employed in interpreting data. It is also clear that some activity, e.g. a review of published literature, may be better conducted at national scale or as a collaboration to avoid replication of work between individual departments.

A1.5 Factors That Contribute to UoM

Variations and uncertainty in measurements come from various sources. It is important to remember that factors that contribute to uncertainty are those which might directly affect measurements as they are "normally" conducted; they do not include errors and mistakes that should not be part of the measurement process. Sources of uncertainty in measurement include (Bell, 1999):

- **The measurement instrument:** e.g. variation in transducer performance, ageing equipment, calibration drift, electrical interference.
- **The item or trait measured:** e.g. physical differences between patients, including size and shape of ear canal, affecting the resonances at different frequencies; size of skull, density of bone, muscle and fat affecting bone conduction; physiological and neurological variations affecting the amplitude of electrophysiological responses; variability in response based on normal daily changes in mood, attentiveness or wakefulness of a subject.
- **The measurement process:** e.g. the variability in placement of transducers such as headphones, inserts and bone conductors; placement of electrodes; patient compliance.

- **Imported uncertainty:** e.g. the calibration uncertainty for a piece of equipment, which should be provided by the manufacturer or calibrator.
- **Operator skill:** the degree of skill or experience will vary between operators. This can affect both the process of undertaking a measurement and interpretation of results. There may also be physical variations in operators, e.g. strength (which may affect a head thrust, for example) or reaction time.
- **The environment:** (e.g. temperature, noise, humidity) may impact a measurement instrument and the response of a patient.

A1.6 Factors That Do Not Contribute to UoM

As discussed above, uncertainty refers to the doubt in measurements as they are usually conducted. It does not refer to various other factors that well-designed procedures should aim to exclude from the measurements (Bell, 1999). In particular, operator mistakes are not considered as part of uncertainty. Obvious mistakes may include incorrect left-right placement of transducers, or poor probe tube placement during REMs, or may be errors of procedure or interpretation. The overall quality management system (including published procedures, compliance audits, training, peer review and management) is the appropriate means with which to minimise error, and is not considered part of UoM.

Tolerances should not be considered as an uncertainty, but a limit of acceptance for a measurement or item of equipment when they are tested or calibrated. These should not be used as UoM data.

In physiological services such as audiology, there can be a range of human factors that contribute to uncertainty, such as normal physical variations between patients. However other patient factors should not be considered factors of uncertainty, for example: those causing genuine alterations of response (e.g. recent noise exposure or drug use), increased artefact in measurement (e.g. eye makeup for VNG, extreme intake of caffeine for electrophysiology) or variable results due to motivation (e.g. non-organic behaviour, social communication delay). These should be excluded or noted on results, but are not inherent factors contributing to uncertainty.

As previously mentioned, processes for controlling sources of variability and error is at the core of good clinical practice and will promote good quality, consistent measurement and interpretation (see Appendix 1).

A1.7 Calculating and Reporting UoM

In the preceding sections we have discussed the principles of UoM in relation to well-known, basic statistics. This section briefly discusses specifically how UoM should be calculated and reported where this work is undertaken.

The “standard uncertainty”, ***u***, is the same statistic that was traditionally known as a “standard error”. It is based on the estimated standard deviation of a sample, ***s***, corrected by the number of measurements in the sample, ***n***:

$$u = \frac{s}{\sqrt{n}}$$

The standard uncertainty, ***u***, is based on one standard deviation and has a confidence of approximately 68%, based on a normal distribution. Likewise, a 95% confidence level is achieved by approximately two standard deviations, i.e. 2 x ***u***; 99% confidences equate to 2.58 x ***u***; and 99.7% confidence equates to 3 x ***u***. The multiplier for ***u*** (i.e. 1, 2, 2.58 and 3) is referred to as the “coverage factor”, ***k***, in UoM terminology. Be aware that this equation and confidence levels only apply to evaluations where there is a normal distribution.

Where information is scarce and a type B evaluation is conducted based on only the upper and lower limit of uncertainty, standard uncertainty can be calculated based on the half-width, ***a*** (i.e. half the distance between the upper and lower values) from:

$$u = \frac{a}{\sqrt{3}}$$

This equation may be used where a calibration certificate provides an upper limit of variability. For example, if a calibration certificate gave a variability range of 3-5 dB, take the upper limit of 5 dB and divide by $\sqrt{3}$, giving ***u*** = 5 /$\sqrt{3}$ = 2.9 dB. Other approaches and distributions may require less simple equations and reference in these cases should be made to Bell (1999) and UKAS (2019).

It should also be noted that the total UoM cannot simply be calculated by adding together standard uncertainty for each factor. In this case, total UoM is calculated from the root-sum-square (RSS) values of individual factors, sometimes called “summation in quadrature”. In other words, add the square of each ***u*** together and then take the square root of the total.

Uncertainty, once calculated, should be reported in an appropriate manner that reflects the needs of colleagues in medical professions and patients. For example, medical colleagues need to understand when a measurement is clearly within normal or abnormal range, or whether the degree of uncertainty makes the result unclear. Patients may not wish to see a UoM statement on every result because this can undermine confidence or cast doubt on findings, causing unnecessary anxiety. Services should therefore use terminology that is appropriate to the recipient such that exact statements of UoM may, in some cases, be reserved for detailed reports or evaluation services such as IQIPs. The format in which uncertainty is documented and reported, or not reported, will be a local decision.

Appendix 2:

Example Template of an Uncertainty Budget

N.B. This is an example of a partially-completed Uncertainty Budget. It is provided in order to set expectations for the format that the profession can work towards in future. The BAA and other professional bodies will aim to provide further support with this process in the coming 24 months, where possible using published literature such at the ISO for PTA. Services are not expected to complete Uncertainty Budgets at this stage.

Uncertainty Budget

Introduction

The service recognises the importance of identifying and minimising sources of variability in measurements. In particular, we understand the principles of Uncertainty of Measurement and commit to identifying and evaluating potential causes of uncertainty in measurements following the procedures described in the British Academy of Audiology (BAA) document "Uncertainty of Measurement in Audiology" (2021), based on the ISO guide 98-3:2008, "Uncertainty of Measurement – Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)". This Uncertainty Budget is based on the template provided in the BAA (2021) document. The following sections evaluate the uncertainty for each of the measurements undertaken in the service. The standard uncertainty, u, is evaluated and a coverage factor of k =2 is applied to establish a level of confidence of approximately 95%. The overall Uncertainty of Measurement is rounded to the nearest decibel.

Evaluations assume that our quality management procedures have been applied, i.e. that the following has occurred: equipment has been calibrated, staff have been trained and follow local and national procedures, staff have been peer reviewed, stage A checks have been conducted, and environmental conditions (e.g. background noise) are within specified limits.

Pure Tone Audiometry (PTA), Air Conduction (AC) Measurements

Audiometry is conducted following the British Society of Audiology (BSA) document "Recommended Procedure: Pure-tone air-conduction and bone conduction threshold audiometry with and without masking" (2018).

Clinical audiometers are calibrated to ISO standards, so a separate calculation was not undertaken for each audiometer used in the service.

Uncertainty factor	Evaluation type	Standard uncertainty, u	Sources
General form of uncertainty for hearing threshold level determinations at frequencies below 4kHz without masking	B	4.9 dB	[1]
Combined standard uncertainty, u		4.9 dB	-
Expanded Uncertainty of Measurement for 95% coverage, U		**10 dB**	-

[1] BS EN ISO 8253-1:2010, "Acoustics — Audiometric test methods Part 1: Pure-tone air and bone conduction audiometry".

Pure Tone Audiometry (PTA), Bone Conduction (BC) Measurements

It is known that BC measurements are inherently more variable [2-4] with standard deviations of 8 dB for BC quoted in one paper [4] compared to 5dB for AC, although standard uncertainty was not given. ISO [1] gave the equivalent standard uncertainty in BC measurements as 6.0 dB.

Audiometry is conducted following the British Society of Audiology (BSA) document "Recommended Procedure: Pure-tone air-conduction and bone conduction threshold audiometry with and without masking" (2018).

Clinical audiometers are calibrated to ISO standards, so a separate calculation was not undertaken for each audiometer used in the service.

Uncertainty factor	Evaluation type	Standard uncertainty, u	Sources
General form of uncertainty for hearing threshold level determinations at frequencies below 4kHz without masking	B	6.0 dB	[1]
Combined standard uncertainty, u		6.0 dB	-
Expanded Uncertainty of Measurement for 95% coverage, U		**12 dB**	**-**

[1] BS EN ISO 8253-1:2010, "Acoustics — Audiometric test methods Part 1: Pure-tone air and bone conduction audiometry".

[2] Coles RRA, Lutman ME and Robinson DW (1991), "The limited accuracy of bone-conduction audiometry: its significance in medicolegal assessments"; The Journal of Laryngology & Otology 105 (7), p.518-521.

[3] Lundgren H (2010), "Bone Conduction Transducers and Output Variability - Lumped-parameter modelling of state variables"; MSc Thesis, Chalmers University of Technology, Göteborg, Sweden.

[4] Robinson DW, Shipton MS (1982), "A standard determination of paired air- and bone-conduction thresholds under different masking noise conditions"; Audiology 21(1), p.61-82.

Soundfield Audiometry

….

Uncertainty factor	Evaluation type	Standard uncertainty, u	Sources
Test-retest reliability	B	1.0 dB	Expert consensus [1]
Audiometer and loudspeaker calibration	B		Locally determined [2]
Loudspeaker placement	B		Locally determined [3]
Patient position	B		Locally determined [4]
Ambient noise	B		Locally determined [5]
Experience of tester	B	0 dB	[6]
Subject cooperation	B	0 dB	[7]
Combined standard uncertainty, u			[8]
Expanded Uncertainty of Measurement for 95% coverage, U			[9]

[1] Measurements undertaken on adults at … and … suggested a standard uncertainty of 1.0 and … dB respectively.

[2] Local calibration certificates should provide variability in output sound levels. Standard uncertainty should be calculated as described in Section A1.7.

[3] Loudspeakers may be adjustable to head height, so u = 0 dB in this case. Otherwise measurements should be undertaken to estimate sound level variation due to head height and standard uncertainty calculated as described in Section A1.7.

[4] Sound level measurements should be taken 0.5m around the measurement position and standard uncertainty calculated as described in Section A1.7.

[5] The service should review ambient noise levels or management of it. If sufficient acoustic treatments can be employed to reduce noise below those deemed sufficient (in ISO 8253-1:2010) then u = 0 dB. Alternatively, if testing can be restricted to a miniUoMm dB HL level with acceptable ambient noise, then u = 0 dB.

[6] ISO 8253-1:2010 specifies this factor to be 0 dB for PTA, so the same can be assumed here.

[7] If a subject is uncooperative the uncertainty will be significantly increased. However, this should be highlighted in the clinical journal and report, with an appropriate interpretation of the measurements undertaken.

[8] Calculated as the square root of the sum of squared uncertainty factors as described in Section A1.7.

[9] 95% coverage implies that two standard uncertainties are required, U = 2 u.