Recommended Procedure

Taking an Aural Impression

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General foreword

This document presents a Recommended Procedure by the British Society of Audiology (BSA). This Recommended Procedure represents, to the best knowledge of the BSA, the evidence-base and consensus on good practice, given the stated methodology and scope of the document at the time of publication. Although care has been taken in preparing this information, the BSA does not and cannot guarantee the interpretation and application of it. The BSA cannot be held responsible for any errors or omissions, and the BSA accepts no liability whatsoever for any loss or damage howsoever arising. This document supersedes any previous recommended procedure by the BSA and stands until superseded or withdrawn by the BSA.

This document replaces the BSA document Recommended Procedure Taking an aural impression (2013).

This document will be reviewed by the date given on the front cover. However, should any individual or organisation feel that the content requires immediate update, review or revision, they should contact the BSA using the email bsa@thebsa.org.uk. Please add 'BSA document revision request' in the title. You will be asked to complete a short form with your reasons and this will be passed to the Professional Guidance Group for assessment. Comments on this document are welcomed and should be sent to:

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Shared Decision-Making

It is implied throughout this document that the service user should be involved in shared decision-making when undertaking audiological intervention, receiving subsequent information and understanding how it will impact on the personalisation of care. Individual preferences should be taken into account and the role of the clinician is to enable a person to make a meaningful and informed choice. Audiological interventions bring a variety of information for both the clinician and the subject which can be used for counselling and decision-making regarding technology and anticipated outcomes.

1. Introduction

Aural impressions or digital scans of the ear are required for the manufacture of earmoulds, ear plugs and in-the-ear hearing aids. The purpose of this document is to describe safe and effective techniques for those undertaking the procedure. This document replaces the previous British Society of Audiology (BSA) Recommended Procedure (2013). Refer to the current version of *Taking an aural impression: children under 5 years of age* for a supplement to this, providing additional recommendations specifically for impressions with children aged under 5 years. In some instances, for example when working with those with complex or additional needs it may be appropriate to consider the recommendations made in *Taking an aural impression: children under 5 years of age* for older subjects.

This recommended procedure deals only with the procedure for taking an aural impression and digital ear scanning. It does not cover other associated areas such as training and earmould selection.

2. Aural impression using silicone material

2.1 Infection control, health and safety

Appropriate precautions must be taken throughout the procedure to ensure the safety and well-being of the subject and the clinician. Care must be taken to follow infection control policies and demonstrate good standards of hygiene and cleanliness. Items that come into patient contact during the procedure should be cleaned and disinfected between use. A hard surface disinfection wipe should be used on the otolight, outside of the syringe, and the specula (where single use specula are not used).

Clinicians must consult manufacturers' safety data sheets and ensure, where appropriate, they use personal protective equipment when performing the procedure. For hygiene reasons and to prevent material contamination, kneading by hand is only recommended if wearing non-latex gloves. Alternatively, impression material can be pressed from the measuring spoons onto a mixing block and rapidly kneaded together with a spatula until a uniform colour is obtained.

When performing otoscopy and impression taking the examiner shall work from a stable position. Ideally, this will be seated however in some circumstances this is not possible and an alternative stable posture may be adopted. In all instances the clinician should assess their position and that of the subject to ensure that they are able to perform the procedure correctly and without any risk to themselves or the subject. The subject should not be left unattended during impression taking, particularly if an open-jaw impression is being taken. It is not usually advisable to take impressions on both ears simultaneously, but this might be acceptable in some circumstances with the subject's full consent.

2.2 Subject management

A straightforward explanation should be given to the subject regarding the technique to be employed, along with a warning of the fullness that will be felt in the ear and the possibility of a cough-reflex when the otostop is inserted. Subjects with tinnitus may also notice a temporary enhancement of their tinnitus during the procedure. The subject should be asked about any ear surgery, pain or infection. The subject must not speak whilst the impression material is in the ear, but should keep the mouth in the normal, naturally closed relaxed position unless an open jaw impression is to be taken. The subject can indicate any discomfort by raising a hand or using another suitable non-verbal indication. After explaining the procedure to the subject, informed consent should be obtained and documented appropriately. Subjects should be advised that the impression material cannot be removed until fully set as part of the consent process. The clinician should wash their hands before examining the subject, and ensure all equipment is clean and disinfected where appropriate.

2.3 Examination of the ear

The ear should be examined thoroughly using an otoscope. Any unusual features or abnormalities should be noted and, if necessary, referred for medical advice. Possible contraindications to impression taking and special cases are noted in Section 2.9. The examiner shall take all necessary precautions to minimise the risk of harming the subject, or themself, which is more likely to occur if the examiner is not seated or in a stable position during otoscopy. The examiner shall ensure that appropriate bracing techniques are used while performing otoscopy (see fig. 1).

Figure 1 The picture on the left shows safe otoscopy with the clinician's hand firmly braced against the subject's head, the picture on the right shows dangerous practice with no bracing.

2.4 Preparation

A towel or tissue may be laid over the subject's shoulder to safeguard against the staining or damage to clothing that can be caused by dropped impression material or hands that are greasy from mixing impression material.

Excess hair may be removed from the outer area of the ear canal, if it is essential and with the subject's permission. A clean, disinfected pair of small round-nosed scissors should be used for this. If the stubble is stiff it could be lightly smeared with petroleum jelly or similar to flatten it and to aid subject comfort during removal, however particular care must then be taken when removing the impression as introducing petroleum jelly to the ear canal may result in an air-tight seal leading to an increased risk of barotrauma and damage to the eardrum.

If a large postaural hearing aid is to be fitted or poor pinna structure is observed and the proposed hearing aid may change the shape of the ear, it should be placed in position over the pinna whilst the impression is being taken. Spectacles and earrings should be worn if they are in everyday use. It may be necessary for some piercings, such as tragal piercings to be removed during impression taking as they may impede the impression taking process or get stuck in the setting material. Piercings that impact the area of the product you are making should be marked on the impressions and an explanatory note to the manufacturer should be included with the impression.

2.5 Otostop insertion

Otostops or otoblocks must be used. An otostop is manufactured to a specific diameter from a material that has an inherent resistance to reduction in diameter. The otostop selected should be of a size predicted from otoscopy to be large enough to fill the cross-section of the ear canal, but without causing undue pressure on the ear canal walls. If the otostop has strings, the strings of the otostop should be knotted. As the otostop is placed in an ear, it is compressed by the canal walls. The resistance of the otostop to this compression holds the otostop in place against the force of the impression material. The two types of otostops in common use today are vented and non-vented. With any conventional otostop (foam or cotton), once the impression material has made full contact with the ear canal wall, any air trapped behind the stop is forced to compress against the eardrum. This sensation of ear "fullness" can range from minimal to significant discomfort. A vented ototop allows for the equalisation of air pressure within the ear during the impression making, curing, and removal process, which can significantly reduce discomfort, vented otostops are useful for deep impression taking.

Using a clean otolight, the otostop should be inserted into the ear canal normally to a point just beyond the second bend, i.e. approximately one-half of the way along the canal, although a shorter impression might be acceptable in some circumstances and it is important not to insert the otostop deeper than required as this can cause unnecessary discomfort and possible injury. When using the otolight the clinician's hand must be firmly braced against the subject's head to prevent accidental injury (see Figure 2). The position of the otostop must be checked with an otoscope to ensure there are no gaps between it and the canal walls that could allow impression material to pass. The strings of the otostop should be positioned so they can be firmly secured under the bracing hand to prevent the otostop moving when the impression material is introduced (see Figures 2 and 3).

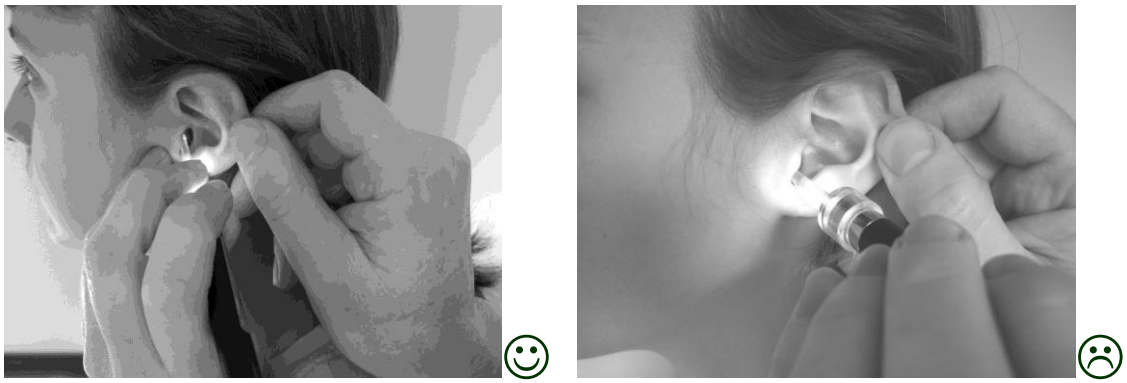

Figure 2 *The picture on the left shows safe otostop insertion, with the clinician's hand braced firmly against the subject's head. The technique shown on the right is dangerous as there is no such bracing.*

2.6 Taking the impression

There are currently two main types of impression material in common use. Condensation silicone consists of a small amount of hardener added to a larger quantity of putty. Addition silicone consists of two component materials mixed in equal parts. Addition silicones are often preferred due to their easier mixing, better flow properties and long-term stability.

2.6.1 Syringe technique

Prior to taking an impression the expiration date on the impression material should be checked. The in-date impression material should be mixed in accordance with the manufacturer's instructions. The consistency of the material must be such that it will flow out of the syringe without undue pressure on the

plunger being required and clinicians should be aware that different materials exhibit different viscosities and that external factors such as room temperature may influence the curing time. The diameter of the syringe nozzle will also affect the ease with which the material can be injected. The material should be placed into the syringe without any trapped air bubbles. It is important to check that the material is properly mixed before introducing it to the subject's ear. This can be done by dispensing a small amount on to a tissue and checking for a uniform colour.

The nozzle should be inserted into the ear canal to a point approaching the otostop, and the plunger then pressed firmly and steadily. Excessive pressure must not be used to inject the material as this may cause discomfort, move the otostop or force material beyond the otostop. As the material flows back around the end of the nozzle the syringe should be slowly withdrawn, care being taken to maintain steady pressure on the plunger and to keep the end of the nozzle buried in the already expelled material. This prevents bubbles or folds being formed. The concha areas (cavum concha and cymba concha) should be filled but not over-filled as the weight of excess material may distort the shape of the ear. Throughout the syringing process it is essential to brace between the syringe and the subject's head to avoid accidental injury, and to prevent the otostop moving (Figure 3). The completed impression must not be touched prior to removal, other than to check if it has set.

Figure 3 *The picture on the left shows safe syringing technique with firm bracing against the subject's head and the otostop strings being held. The picture on the right shows unsafe practice with no bracing.*

2.6.2 Gun technique

These devices mix the impression material automatically and allow the use of very low viscosity materials. There are two types of impression guns: manual and electric. Manual guns require the squeezing of a trigger to dispense the impression material. Electric guns have electrically powered buttons and are available with a mains cord or as a cordless rechargeable unit. Appropriate positioning of the subject whilst using corded guns is advised to ensure safe impression-taking. For users of cordless electric guns, it is important to check

there is sufficient battery power before starting the procedure. It is expected that clinicians follow manufacturer's instructions for safe impression-taking using impression guns.

In most respects the techniques and precautions when using a gun are the same as when using a syringe. It is important to check that the material has been mixed before use, by squirting a short length onto a tissue before introducing it into the ear. Bracing the gun safely against the head can be more difficult than with a conventional syringe due to the length of the device (Figure 4) and clinicians who are unable to handle a gun with adequate bracing are advised against its use. It is possible to use shorter cannula tips and spacers to limit the reach of the gun trigger. Clinicians that are finding the size of the gun difficult to use safely should contact the gun manufacturer and impression material manufacturer to discuss options.

Figure 4 *The picture on the left shows bracing against the subject's head. The picture on the right shows a lack of bracing, which is potentially dangerous.*

2.7 Removing the impression

The impression material should be allowed to set as outlined in the manufacturer's specification. A fingernail can be lightly pressed against the impression material and if this action leaves no mark on the material, the impression has set satisfactorily. Prior to removal of the ear impression clinicians should be aware of the possibility of handling cerumen or blood and may like to wear gloves. The impression should then be slowly and carefully eased out of the ear, taking care to break the air-tight seal that will have developed around the impression before pulling it from the ear. It may help removal if the subject moves their jaw a little from side to side during this process. The impression should be checked for completeness and repeated if it is inadequate. The impression must not be replaced in the ear for any reason. Following the removal of an impression, the clinician must wipe the impression, taking care to clear away any debris and cerumen.

The impression should not be trimmed before dispatch to the manufacturing laboratory. The laboratory makes use of the full length of the impression to determine the best position for the sound bore in the earmould, especially to avoid placing the exit of the sound bore into the wall of the ear canal at one of the bends. It is therefore advisable to mark the desired length of the earmould on the impression, and to advise "cut to mark" on the packaging. Clinicians should follow their manufacturer's recommendation regarding the removal of the otoblocks from the impression.

If the material has left a slight film of grease or moisture in the ear, the ear should be dried with a tissue or cloth. The ear must then be examined again with the otoscope in order to ensure that all of the impression material and otostop have been removed. Some redness of the ear canal and drum may be seen after an impression has been taken however any soreness or injury must be referred for medical attention.

2.8 Open jaw impression technique

In some cases it may be appropriate for an impression to be taken with the jaw open, as this will affect the shape of the ear canal. For this process a dental mouth prop or bite-block should be placed between the subject's side or rear teeth, after the otostop is inserted, as shown in Figure 5 below.

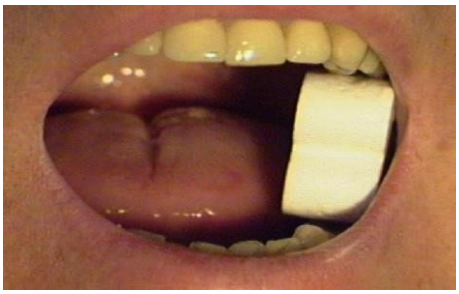

Figure 5

The correct position of a mouth prop for an open jaw impression. (Reproduced with permission of Starkey Laboratories)

A new and clean mouth prop should be used for each subject. The position of the otostop should be checked carefully using an otoscope when the mouth prop is in place to ensure there are no gaps between the otostop and the canal walls.

The subject should be given a tissue to deal with any dribbling when the mouth prop is in place.

Once the impression is set the mouth prop should be removed first. As the impression is likely to be a tight fit, extra care is required to ensure it is removed safely. With an open jaw it is particularly helpful if the subject moves their jaw gently from side to side during its removal.

2.9 Special cases and possible contraindications to impression taking

2.9.1 Post-operative ears

Impression taking should be avoided in the immediate post-operative period, until the ear and especially the canal and pinna have fully healed. In many post-operative ears the eardrum will be weakened and extra care must be taken when removing the impression to avoid barotrauma. When there is a mastoid cavity it is essential not to allow any impression material to enter this space. The cavity can be packed with additional otostops and very careful otoscopy must follow otostop insertion to ensure the cavity is closed to impression material. Extra care must also be taken when injecting the material to hold the strings of the otostops to prevent their movement.

2.9.2 Perforated eardrums

It is usually safe to take an impression when the drum is perforated, as long as there is no active infection in the outer or middle ear. Care is required when removing the impression to minimise the risk of injury to the middle ear structures (such as the round window) through barotrauma.

2.9.3 Stenosis

Many ear canals have an abnormally narrow section, called stenosis, usually in the outer part. In these cases there is a potential hazard from the impression material going beyond the stenosis and the impression being difficult to remove, causing discomfort. There is also risk of the impression breaking off in the ear on removal, due to the narrow section. A stenosis may dictate that the impression is not as long as usual. The otostop should be inserted to a position at or just beyond the narrowing to prevent impression material going too deep.

2.9.4 Deep impressions

Some deep-seated ear plugs for noise protection and invisible in canal or completely in canal hearing instruments (CIC or IIC) require a particularly deep impression that reaches some distance beyond the second bend and into the bony part of the canal. Many clinicians routinely use open jaw impressions for deep fitting instruments as described above. If the canal is very narrow or contains a sharp bend, then it may not be possible or safe to take a particularly deep impression. If you are in any doubt of the suitability of the ear for a deep impression, or your skill and experience in taking these please seek support from a clinician with appropriate experience to further your skills and knowledge in this technique.

2.9.5 Impressions on small children

It is strongly recommended that anyone undertaking impressions on small children has received additional training in this area.

2.9.6 Infections

It is safer not to take an impression if there is an active ear infection in the outer ear, or discharge from the middle ear. If this is unavoidable advice should be sought from an infection control expert, as well as earmould manufacturers on appropriate precautions such as the use of gloves, face masks and aprons, and the correct disposal of equipment afterwards.

The impression will need to be disinfected before it is sent to the manufacturer. For subjects with possible infectious or communicable diseases (such as HIV or Hepatitis) it is recommended that the impression box is enclosed in a sealed plastic bag within another sealed plastic bag, with clear indication of the nature of the infection and any decontamination process that might have been carried out prior to dispatch. The impression must be packaged for postal services separately (and not with other impression boxes). The parcel should be clearly marked on the outside to ensure the receiving person is aware of the contamination status. Where possible, the manufacturer should be contacted to ensure the receiver is prepared in accordance with their decontamination of bio-hazardous substance procedure and have adequate PPE before opening and processing the parcel.

2.9.7 Excessive wax or foreign object in the canal

Excessive wax or foreign objects should be removed from the ear prior to impression taking. If not, these may be pushed further into the ear by the otostop, or the impression may not be a true representation of the shape of the canal due to their presence.

2.9.8 Others

In any unusual situation, where the clinician has limited experience or concerns about how to proceed safely, it is strongly recommended that advice and supervision are sought from someone suitably competent.

3. Three-Dimensional digital ear scanning

3.1 Introduction

Three-dimensional (3D) ear scanning devices are used to create a digital model of the desired ear mould fitting surface without the use of otoblocks and silicone material. The digital scan is submitted electronically to manufacturers or earmould laboratories. Currently, digital ear scanning is recommended for adults aged 18 and above. This section shall inform clinicians on considerations when performing digital scans (such as contra-indications, subject preparation and performing the procedure). It is not intended to specify the details of the scanning procedure or on the components for this type of equipment. It is therefore expected

that clinicians adhere to equipment manufacturer's instructions, local health and safety, infection control and information governance policies, as well as have the relevant training required to competently perform this procedure.

Figure 6: *Digital Ear Scan taking place using a hand-held scanner and headset, image supplied by Natus UK*

3.2 Preparation

3.2.1 Otoscopy

Perform full otoscopic examination of the ear canal and pinna to determine that it is safe to carry out the scanning procedure and there are no contraindications present. A small amount of wax which does not change the shape of the surface of the canal may not interfere with the scanning procedure. Oil and wax must not be transferred onto the probe as it can distort the 3D image.

3.2.2 Instruction

The subject must be instructed to remain still during the scan. Although slight movements should not affect the scan, excessive movements can cause errors in the scanning process. The subject should be made aware that it is important that the headset does not shift from the original position, and they should not talk or yawn during the scan. If the scanning equipment has a pause function, the subject should be notified of this and instructed on how to indicate to the clinician to pause the procedure (for example by raising their hand).

3.2.3 Placing the headset

Some current ear scanning technologies require the use of a head set that serves as a reference point for the scanner. The headset must be placed correctly on the subject's head according to the manufacturer's guidance and training. Once the scan has started the headset must not be moved. Clinicians should refer to the manufacturer's safety data specifications for use of the headset with implantable medical devices.

3.2.4 Positioning the subject

It is important to position equipment in a workspace environment where there are no obstacles when using the scanner, as well as considering the positioning of any cables. Ensure the subject's shoulder is not obstructing the scanner and its cable. If necessary, the subject's head can be tilted towards the opposite shoulder.

3.3 Scanning Procedure

3.3.1 Bracing technique

To ensure safety, effective bracing must be used throughout the scanning procedure. It is essential to brace between the scanner and the subject's head to avoid accidental injury throughout the procedure. The scanner manufacturers will guide you on effective bracing technique for their scanner, as this will vary between devices. Clinicians who are unable to handle the scanner without adequate bracing are advised against its use.

3.3.2 Performing the scan

The clinician should perform the scan as described by the scanner manufacturer, including abiding by listed contraindications and electromagnetic compatibility. The 3D image should be reviewed to ensure that it is complete and of a suitable quality for the ear mould manufacturing process.

3.4 Special cases and possible contraindications to ear scanning

3.4.1 Post-operative ears

Ear scanning should be used with caution in post-operative ears. While the scanning process is unlikely to have an adverse effect on the ear, the clinician should consider whether the scan, and therefore the resulting ear mould, will be fit for purpose.

3.4.2 Ear scanning for small children

It is strongly recommended that anyone undertaking ear scanning for small children has received additional training related to working with this population.

3.4.3 Ear Infection

Ear scanning should be considered with caution where the subject has an active ear infection. The clinician should make a judgement based on factors including risk of exacerbating the infection, risk of cross-infection (taking into account manufacturer guidance on disinfection) and whether the scan, and therefore the resulting earmould, will be fit for purpose.

3.4.4 Excessive wax or foreign object in the ear canal

The presence of excessive wax or a foreign body will be evident in the ear scan and therefore any subsequent ear mould manufactured from it. Excessive wax or foreign bodies should be removed from the ear prior to scanning.

3.4.5 If the subject is uncooperative or withdraws consent

Unlike impression taking, a 3D ear scan can be safely aborted mid-process. If the subject is uncooperative or chooses to withdraw consent mid-scan, the clinician should respect the subject's wishes and abort the process.

3.4.6 Sensitivity to strobing light

If the subject or the practitioner is sensitive to strobing light it may be appropriate to consider taking ear impressions using the procedure described earlier in this document.

3.4.7 Others

In any unusual situation, where the clinician has limited experience or concerns about how to proceed safely, it is strongly recommended that advice and supervision are sought from someone suitably competent.

3.5 Cleaning, maintenance and calibration check

Clinicians must ensure the probe tip and headsets have been effectively cleaned immediately after use. The scanner must be cleaned before being placed on a cradle. Follow the manufacturer's instructions on cleaning agents for individual scanner components.

It is recommended to schedule an annual calibration check of the scanner with the equipment manufacturer.

4. References

British Society of Audiology (2018) Guidelines on minimum training standards for otoscopy and impression taking. Reading: British Society of Audiology.

British Society of Audiology (2016) Recommended Procedure. Ear examination. Reading: British Society of Audiology.

British Society of Audiology (2013) Recommended Procedure. Taking an aural impression: children under 5 years of age. Reading: British Society of Audiology.