College of Speech and Hearing Health Professionals of British Columbia

Protocol Category:	Protocol Title:	Protocol #:
Clinical	Ear Impressions	PROT-QA-04
Authorization:	**Date Approved:**	**Last Revised:**
QAPP Committee	August 24, 2015	July 9, 2018

PURPOSE

This protocol ensures:

- quality care to clients (i.e., patients, clients, or long-term care residents) who require an ear impression;
- ear impression taking is of low risk to the client;
- ear impressions taken by registrants (Registered Audiologists (RAUD), Registered Hearing Instrument Practitioners (RHIP), dually-registered RAUD, RHIP, and any support personnel under the supervision of a qualified RAUD) are accurate representations of the external ear and ear canal, and help to identify potential treatment options for a client.

This ear impression protocol is recommended for the majority of cases; however, when exceptional circumstances prevent its use, the protocol may be modified, and the modifications must be clearly documented in the client's record.

SCOPE

All Registered Audiologists (RAUD), Registered Hearing Instrument Practitioners (RHIP), dually-registered RAUD, RHIP, and any support personnel under the supervision of a qualified RAUD providing ear impression-making services for any purpose.

BACKGROUND

Ear impressions are taken to develop end products for the treatment of disorders or for the protection of the auditory system. An ear impression is a physical replica of the ear achieved by injecting an impression material into the ear canal and external ear cavities (concha and helix areas of the ear).

The nature of the ear impression is defined by the presenting concern/condition of the client and the client's ability and willingness to manage the earmold. Registrants must be aware of appropriate intervention options for presenting conditions and discuss those options with the client. The intervention option is selected by the client with guidance from the registrant.

DEFINITIONS

"Impression material" means commercially available impression material, including powder-liquids (ethyl methacrylate) and silicone materials. Powder-liquid impressions are generally less durable, have greater shrinkage and are more prone to distortion and damage. Shrinkage and damage during shipping are generally not a problem for silicone-based impressions. Silicone impression materials vary in both their viscosity and shore values.

"Otoblock with thread" means the appropriate amount of cotton or foam that fills the cross-section of the ear canal to prevent impression material from flowing further into the ear canal than is required. It is also called an impression pad or eardam. Placement of the otoblock allows the impression material to fill the canal completely (allowing the best representation) and assists in protecting the eardrum.

"Pressure release otoblock" means an otoblock that allows for venting (pressure release) when a deep impression is necessary.

"Shore" means measure of the hardness of the impression after it cures. The shore value has no effect on the nature of the impression but relates somewhat to the ability to remove it from the ear, as impression materials with high shore values do not compress easily. In addition, shore affects the manufacturer's ability to modify the impression.

"Viscosity" means the density of the material and the ease with which it flows. Lower viscosity materials flow easily and tend not to expand the ear canal and to model the canal in its least expanded state. Higher viscosity silicones are more difficult to inject and are more prone to expanding the ear canal. The final product tends to fit tighter as a result, which might be may be a desirable feature for high-gain hearing instruments or when better retention within the ear is required in a given device.

APPLICATION PARAMETERS

Individuals prone to ear infections, exposed to excessive noise levels or who present with a hearing loss of any degree may require an ear impression in order to initiate treatment for the presenting concern.

Possible applications of ear impressions may include, but are not limited to:

- preventing water from entering the ear (swim plugs);
- reducing noise exposure or controlling sound input (earplugs/noise plugs);
- coupling assistive listening devices to the ear (e.g., FM systems) and electronic devices;
- coupling behind-the-ear hearing instruments to the ear; and
- making custom hearing instruments.

EQUIPMENT REQUIREMENTS

Ear impression preparation requires, but is not limited to, the following equipment:

- an otoscope with speculum;
- placement tool (e.g., earlight with removable or disposable single-use tip);
- otoblock with thread;
- mixing bowl or wax pad;
- spatula;
- blunt-end tweezers and/or scissors;

- bite-blocks;
- syringe or impression gun; and
- a variety of impression materials.

ASSESSMENT AND/OR DIAGNOSIS OF CONDITION OR DISORDER

Prior to taking an ear impression, registrants must perform an Assessment of Need as well as a Risk Assessment and must assess the most appropriate technique. Risk management procedures must be in place in anticipation of any complications arising from the procedure.

A sample flow chart that outlines the order of steps to take can be found in the College of Audiologists and Speech-Language Pathologists of Ontario's (CASLPO) *Preferred Practice Guideline for Ear Impressions.*

COMPETENCIES

Registrants making ear impressions must be able to:

- explain the anatomy of the external ear, ear canal and tympanic membrane;
- discuss conditions of the external ear, ear canal and tympanic membrane that would preclude making an ear impression;
- identify conditions of the external ear, ear canal and tympanic membrane that would prevent an ear impression from being taken safely, including:
  - identifying conditions and circumstances that would require medical clearance to safely proceed;
  - managing cerumen and referring client to an appropriately regulated health professional; and
  - providing referral sources.
- examine the external ear and ear canal using an otoscope with proper bracing technique;
- obtain a relevant case history from the client with particular attention paid to conditions and medical/surgical procedures involving the outer and middle ear;
- prepare the otoblock (including size and placement of the otoblock) and accurately check the placement after insertion;
- demonstrate current ear impression techniques using consistent, proper bracing techniques and explain criteria for using different techniques;
- explain the effect of ear canal shape on the removal of the impression;
- explain the impact of different impression materials on the client and on the resulting impression;
- place an otoblock with placement tool using proper bracing;
- mix impression material using the correct procedure;
- apply appropriate pressure when syringing ear impression materials into the ear canal;
- safely remove impression material to preserve the integrity of the impression;
- perform a repeat otoscopy, using proper bracing, after removal of impression material;

- demonstrate knowledge of:
  - the impact of the manufacturing process on the nature of the impression, including:
    - impact of shape and size of the ear impression;
    - effects of retention and acoustic properties of the earmold;
  - the interaction of the earmold and the end-product, including:
    - acoustic properties required of end-product;
    - retention requirements; and
    - techniques to modify the earmold to meet requirements of end-product.

INTERVENTION

Proper ear impressions involve the following stages to ensure that the most appropriate method is employed:

- assessment of need;
- informed consent;
- risk management assessment;
- selection of impression technique

A. Assessment of Need

The registrant must:

- obtain a relevant case history from the client that includes:
  - the reason for the ear impression;
  - conditions of the outer and middle ear or past medical/surgical procedures of the outer and/or middle ear.
- examine the external ear and ear canal with an otoscope, which, in conjunction with the case history and assessment results, will assist in determining:
  - if an ear impression is necessary;
  - if an ear impression can be taken safely;
  - which technique would be most suitable.

B. Informed Consent

The client must be:

- fully informed of each step of the ear impression procedure and the outcomes, benefits and risks associated with the process;

- told the nature of the treatment, the expected benefits, any probable or serious risks and side effects of the treatment, alternative courses of action, and the likely consequences of not having the treatment;

See Appendix A, which outlines a checklist of possible topics for discussion with the client.

C. Risk Management Assessment

Improper ear impressions can result in physical harm and/or mental harm to the client. It is important that the registrant establish a risk management program that:

- identifies and analyzes risks in terms of probable negative end results;
- outlines risk control procedures.

D. Contraindications for Ear Impressions

Ear impressions are contraindicated when:

- impacted or excessive cerumen is present in the ear canal;
- a foreign body is present in the ear canal;
- fresh blood is present in the ear.

Ear impressions may also be contraindicated due to:

- history of ear surgery (including tympanostomy tubes);
- an infection of the external or middle ear with active drainage;
- a perforated tympanic membrane;
- dizziness;
- use of blood thinning medication (e.g., Coumadin, Heparin, high-dose Aspirin);
- pathological conditions of the pinna, ear canal or tympanic membrane;
- presence of a skin disorder;
- unusual texture of the ear;
- client age;
- other conditions identified at the examination.

See Appendix B for a checklist of possible risks and contraindications to discuss with the client.

Clinical judgment is extremely important in reviewing the possible contraindications for the ear impression procedure. For ear impressions in infants and young children, registrants should refer to the current BC Early Hearing Program Guidelines, *Hearing Equipment Training and Resource Manual* for information on ear impression procedures. For adult procedures, registrants can refer to Taylor and Mueller (2011).

E. Possible Complications When Taking an Ear Impression

The registrant should be aware that the pressure that can be exerted during syringing with normal viscosity earmold materials is sufficient to rupture the tympanic membrane if the material flows past the canal block or if the block is pushed down to the tympanic membrane.

Complications can include:

- cerumen impaction;
- hematoma of the ear canal or tympanic membrane;
- perforation of the tympanic membrane;
- traumatic perforation with perilymph fistula;
- impact on existing or previous surgical procedures;
- exacerbation of certain conditions (e.g., Meniere's disease, skin irritations or conditions within the external ear or canal);
- filling the middle ear with impression material;
- vasovagal response.

F. Implementation of Risk Mitigation Strategies for Clients

Registrants must have a risk management plan in place to manage any complications that may arise or, if necessary, refer the client to a physician. In certain instances (e.g., impression material in the middle ear, dislodged tympanostomy tube, Vasovagal response), this could require immediate medical intervention. Registrants must counsel the client and significant others about negative consequences that might occur as a result of the ear impression process.

G. Precautions for Those Making and Receiving the Ear Impression

Registrants must always ensure that precautions are taken to prevent risk of harm to themselves. Consideration should be given to using non-latex gloves when handling impression material because of the possibility of health consequences resulting from repeated absorption of impression chemical through the skin; registrants are advised to refer to material data safety sheets. In the event the end product (e.g., earmold or hearing aids) requires modification, it is recommended that the registrant wear eye protection and a mask to protect against hazardous airborne particles. Precautionary measures for blood and fluid-borne pathogens should be taken at all times.

Registrants must notify the manufacturer receiving the impression when it may have been contaminated with blood, body fluids and/or discharge from an active ear infection.

Registrants must be familiar with the CSHBC adopted clinical practice guideline, *Infection Prevention and Control Guidelines for Audiology* (ACPG-04).

H. Selection of Impression Technique

The results of the Assessment of Need and Risk Management Assessment will assist the registrant in determining the most effective technique to be utilized to minimize risk of harm and result in the best possible outcome for the ear impression. Registrants must have competencies in a variety of procedures to accommodate the range of client presentations. The following factors need to be considered when choosing the procedure for making an ear impression:

- status of ear tissue (intact versus. non-intact);
- type of end product needed (e.g., completely-in-the-canal (CIC) hearing aid, behind-the-ear (BTE) hearing aid or a deep versus shallow impression);

- open versus closed-jaw impression, considering mandibular movement and requirements of high-gain instruments;
- type of impression material to be used, considering the shore, viscosity, size and texture of ear canal (soft, normal, hard) and mastoid cavity; and
- comfort and fit of end-product, taking into account the need to minimize feedback and the ability of the client to handle the earmold.

CLIENT EDUCATION AND DISCHARGE INFORMATION

The registrant must assess the earmold prior to the client's discharge. Factors to consider in assessing the earmold include:

- Retention;
- comfortable fit;
- interaction of final product with the earmold; and
- ability of client to use the earmold.

Clients should be counselled about any potential reactions they may have and what they should do if this occurs. This includes but is not limited to irritation that may be a precursor to infection.

If the earmold does not meet the specific criteria defined by the client or the function of the final product, the registrant must determine the required course of action, which might include: counselling the client, making modifications to the earmold or taking a new ear impression. If a new ear impression is required, a reassessment of the technique utilized to make the ear impression would be necessary to ensure an appropriate final product.

DOCUMENTATION

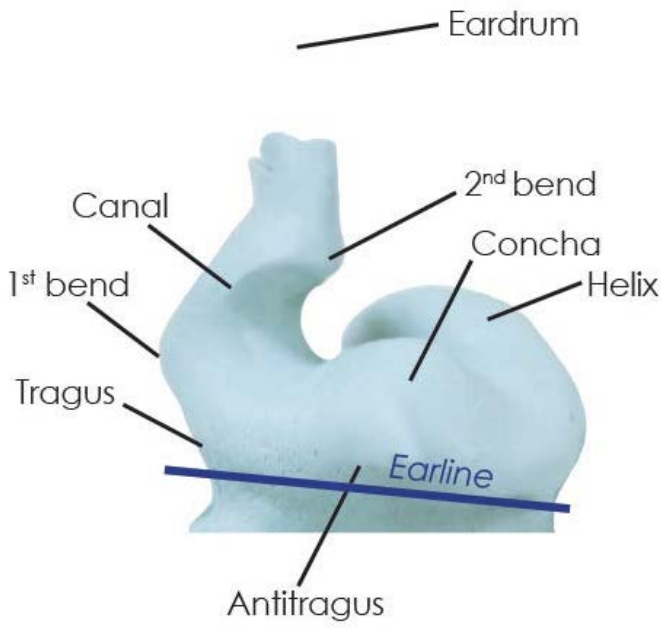
Registrants should refer to the guideline *Documentation and Record Management* (CPG-04) and the standard of practice *Client Consent* (SOP-PRAC-06) for further details on documentation and consent.

CLINICAL OUTCOMES

The intended clinical outcome includes preparing an ear impression with low risk to the client, which results in an earmold that is usable for the client's purpose(s). The ear impression service is concluded when the resulting earmold serves its intended function.

See Figures 1, 2 and 3, which illustrate a labelled ear impression diagram, a good ear impression example and an incomplete ear impression example, respectively.

Figure 1: Labelled Ear Impression Diagram



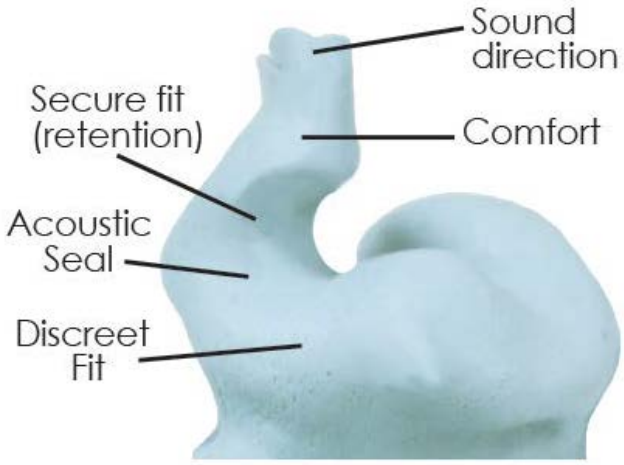
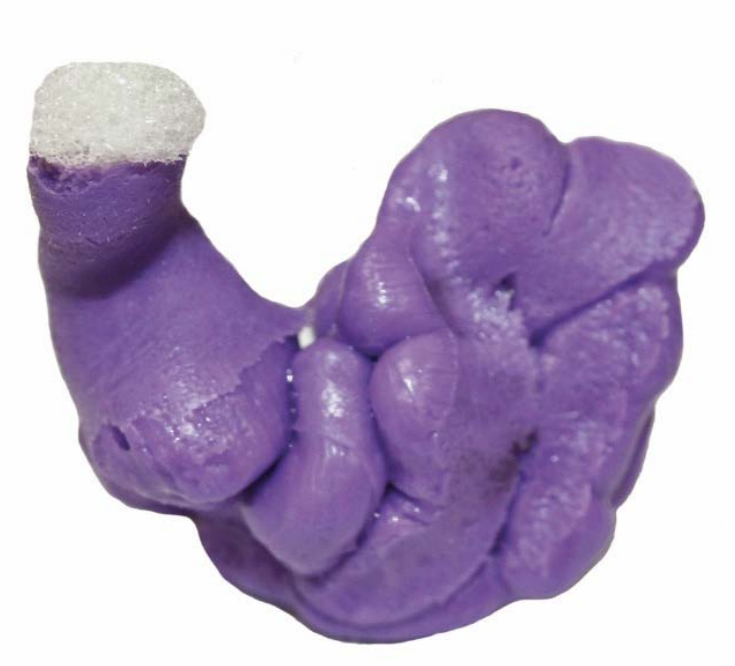


Figure 2: Good Ear Impression Example

Figure 3: Incomplete Ear Impression Example



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CSHBC RELATED DOCUMENTS

Documentation and Record Management (SOP-PRAC-01)

Documentation and Record Management (CPG-04)

Ear Impressions (POL-QA-08)

Infection Prevention and Control Guidelines for Audiologists (ACPG-04)

APPENDIX A: CLIENT DISCUSSION CHECKLIST FOR ALLOWING AN EAR IMPRESSION TO BE TAKEN

The client understands that:

- ☐ to provide hearing/ear health care intervention, the registrant must take an impression of my ear;
- ☐ he or she must give consent;
- ☐ every precaution possible will be undertaken to avoid discomfort or adverse results;
- ☐ taking an impression will entail introducing material into my ear and removing it to get a physical representation of my ear canal;
- ☐ risks associated with taking an ear impression might include:
  - ☐ cerumen impaction (firmly wedged ear wax);
  - ☐ hematoma (bleeding) of the ear canal or tympanic membrane (eardrum);
  - ☐ perforation of the tympanic membrane (hole in the eardrum);
  - ☐ traumatic perforation with perilymph fistula;
  - ☐ impact on existing or previous surgical procedures;
  - ☐ worsening of certain conditions such as Ménière's disease, skin irritations or conditions;
  - ☐ within the external ear or canal;
  - ☐ filling the middle ear with impression material.

APPENDIX B: CONTRAINDICATIONS AND RISK FACTORS CHECKLIST FOR EAR IMPRESSIONS

The registrant has identified for the client any conditions that:

☐ contraindicate an ear impression, including:

- ☐ presence of a foreign body in the ear canal;
- ☐ presence of fresh blood in the ear;
- ☐ impacted or excessive cerumen.

☐ might contraindicate an ear impression, including:

- ☐ history of ear surgery (including tympanostomy tubes);
- ☐ an infection of the external or middles ear with active drainage;
- ☐ a perforated tympanic membrane;
- ☐ dizziness;
- ☐ use of blood thinning medication (e.g., Coumadin, Heparin, high-dose Aspirin);
- ☐ pathological conditions of the pinna, ear canal or tympanic membrane;
- ☐ presence of a skin disorder;
- ☐ unusual texture of the ear;
- ☐ client age;
- ☐ other conditions identified at the examination.