# Clinical Performance Evaluation of 3D Ear Canal Scanning Technology

NCT05000047

April 1, 2021

# Clinical Investigation Plan (CIP)

## [redacted] 3D ear scanner – Workflow timing and preferences compared to traditional silicone earmold impressions

| | |
|---|---|
| Short Title of the clinical investigation (if available) | [redacted] 3D ear scanner – Workflow timing and preferences compared to traditional silicone earmold impressions |
| Sonova StudyID | 371 |
| ID given by Ethics Committee / Investigational Review Board (if already available) | 20201845 (WIRB approval #) |
| ID given by Competent Authority (if already available) | ClinicalTrials.gov Identifier: NCT05000047 |

## Signature Page

The **Study Manager** (Sonova employee representing the Sponsor and taking the practical tasks associated with the Sponsor) has approved the CIP version [2 (dated 04.01.2021), make sure this corresponds to the protocol version and date in the footer], and confirm hereby to conduct the investigation according to the CIP, current version of the World Medical Association Declaration of Helsinki, ISO 14155 norm and the local legally applicable requirements.

| | |
|---|---|
| Name | David Taylor, Au.D. |
| Place, Date | Phonak Audiology Research Center (PARC), 01.04.2021 |
| Signature |  |

Local **Principal Investigator** (PI) at investigation site:
I have read and understood this CIP and agree to conduct the trial as set out in this investigation protocol, the current version of the World Medical Association Declaration of Helsinki, ISO 14155 norm and the local legally applicable requirements.

| | |
|---|---|
| Investigation Site | PARC |
| Name (PI) | Kevin Seitz-Paquette, Au.D. |
| Place, Date | PARC, 01.04.2021 |
| Signature |  |

# Clinical Investigation Plan (CIP)

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# Clinical Investigation Plan (CIP)

## 1 General

### 1.1 Sponsor

| | |
|---|---|
| **Name** | Sonova AG<br>Audiology and Medicalization<br>Audiological Care |
| **Address** | 750 North Commons, Aurora, IL 60504 |

### 1.2 Principal investigator, coordinating investigator and Investigation site(s)

| | |
|---|---|
| **Principal Investigator** | Kevin Seitz-Paquette<br>750 North Commons, Aurora, IL 60504<br>kevin.seitz-paquette@sonova.com<br>(630) 821-5000<br>Director PARC |
| **Coordinating Investigator** of a multi-center investigation (if applicable | N/A |
| **[Investigation Site 1]** | Phonak Audiology Research Center (PARC)<br>750 |
| **[Investigation Site 2]** (if applicable) | N/A |
| **Third party** (if applicable) (e.g. core laboratories, CROs, consultants, biostatisticians, monitoring institution or other contractors) | N/A |
| **Further Staff** | [redacted] (studies coordinator), [redacted] (study monitor), [redacted] (research audiologist), [redacted] (research audiologist) |

## 1.3 Overall synopsis of the clinical investigation

| | |
|---|---|
| **Background and Rationale** | [redacted] claims the [redacted] 3D ear scanning solution to streamline clinical processes. According to [redacted], with the [redacted], you can:<br>• save time and money on handling earmolds and hearing aids<br>• secure digital patient records for easy storage, retrieval and use<br>• ensure a better fit and reduce remakes and returns,<br>• enjoy a cleaner procedure<br>[redacted]<br>Previous research has been done at Sonova HQ to analyze the quality of [redacted] ear scans compared to traditional earmold impressions. However, to fully understand the value drivers, further data is needed exploring efficiency and preferences in comparison to traditional EMI methods. In addition, the department of Audiological Care is interested in finding out if this is a viable piece of equipment for their clinics. The results of previous research regarding quality of the [redacted] has warranted a further look into efficiency and subjective preference. |
| **Investigation Objectives** | The primary objective of this study is to identify any significant differences in the time required for a clinician to complete the workflow of an [redacted] impression compared to traditional earmold impressions. |
| | The secondary objective of this study is to identify any significant preference for both the HCPs and patients when comparing the [redacted] to traditional EMI procedures. |
| **Outcome(s) / Endpoints:** | Time (mm:ss) will be recorded to quantify the duration of each impression procedure.<br>Questionnaires will be administered to assess overall preferences of both the researchers and subjects. |
| **Investigation Design** | ☐ Interventional Study<br>**Investigation Model**: ☐ Single Group ☐ Parallel ☐ Crossover ☐ Factorial ☐ Sequential<br>**Masking**: ☐ single-blided ☐ double-blinded ☐ no masking ☐ other:<br>**Allocation**: ☐ N/A (for single- ☐ Randomized ☐ Nonrandomized |

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| | **Number of Arms:** [2]<br>☑ Observational Study<br>**Investigation Model** / **Time Perspective**<br>☑ Cohort ☐ Ecologic ☐ Retrospective<br>☐ Case-Control ☐ Family-based ☐ Prospective<br>☐ Case-only ☐ other: ☐ Cross-sectional<br>☐ Case-crossover ☐ other:<br>**Number of Groups/ Cohorts:** [1] |
| **Type of design** | ☑ Exploratory ☐ Confirmatory ☐ Observational |
| **Inclusion / Exclusion criteria:** | External auditory canal must be present and medically unremarkable to facilitate impressions. Participants with surgical ears or without external auditory canals must be excluded. |
| **Measurements and procedures:** | Three researchers will be facilitating these appointments to limit variability of researcher skill across the two conditions. Researchers will familiarize themselves with the [redacted] equipment through independent practice prior to a training facilitated by [redacted] (occuring April 22nd) and will follow [redacted] training recommendations (perform scans on 10+ ears following in-person training) prior to data collection. Participants will be seen for one appointment. The researcher will perform both traditional earmold impressions and 3D ear scans on both ears (conditions will be randomized and counterbalanced across participants). An additional researcher will use a stop watch to quantify the time (mm:ss) it takes for each condition, for both ears. At the end of the appointment, participants will also be asked to complete a subjective questionnaire regarding each condition, focusing on their perception of comfort and level of involvement throughout the impression taking. The resulting data will be compiled for all participants and analyzed using a T-test, to identify any significant differences in the time it takes to complete each method of earmold impressions, in addition to any differences in subjective domains. |
| **Intervention:** | [redacted] 3D Ear Scanning Solution |
| **Control Intervention (if applicable):** | Traditional silicone earmold impression material, administered by a cartridge impression gun. |
| **Number of Participants with Rationale:** | N = 30 (10 participants per researcher). Both conditions will be measured for each participant. This sample population will provide an adequately powered study under the assumption that time variance of each condition is within approximately 5 minutes. |

# Clinical Investigation Plan (CIP)

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| **Investigation Duration:** | Approximately 1 month |
| **Investigation Schedule:** | Month/ Year of First-Participant-In (planned): MAY/2021<br>Month/ Year of Last-Participant-Out (planned): JUN/2021 |
| **Statistical Considerations:** | Analysis of procedure time data will take place at the conclusion of the trial. The intended analysis assumes a normally-distributed response variable. As such, procedure times for each methodology will be tested for normality using a Shaprio-Wilk test |
| **Trial registration:** | U.S. National Library of Medicine – clinicaltrials.gov<br>ClinicalTrials.gov Identifier: NCT05000047 |
| **Investigation category and Rationale** | Non-significant Risk Investigation |
| **US FDA regulated Device** (applicable in the US) | ☐ *Yes*<br>☑ No |
| **US FDA IDE** (applicable in the US) | ☐ *Yes* , IDE Number: [xxx]<br>☑ No |
| **Clinical Phase:** | ☐ *Pre-market* [Exploration/ Confirmation]<br>☑ *Post-Market* [Confirmation/ Observational] |
| **Good Clinical Practice (GCP) Statement:** | This investigation will be conducted in compliance with the protocol, the current version of the Declaration of Helsinki, ISO 14155 (as far as applicable) as well as all national legal and regulatory requirements. |

## 2 Identification and description of the investigational device

### 2.1 Description of the investigational device and its intended purpose.

[redacted]

The [redacted] is an alternative approach to traditional impression procedures. By creating a 3D digital scan, [redacted] claims that the [redacted] has potential to reduce shipping and procedural times in a cost effective manner.

## 2.2 Legal manufacturer of the investigational device.

[redacted]

## 2.3 Model/type, including software version and accessories

[redacted] 3D Ear Scanner

SN: [redacted]

## 2.4 Traceability during and after the clinical investigation

Participants will be assigned a non-identifying subject identification number. This number will be used to trace scans and impressions and will correspond to the respective participant.

## 2.5 Intended purpose of the investigational device in the proposed clinical investigation.

The [redacted] is an alternative approach to traditional impression procedures. By creating a 3D digital scan, [redacted] claims that the [redacted] has potential to reduce shipping times and procedural times in a cost effective manner. (See section 2.1)

## 2.6 Populations and Clinical indications

External auditory canals must be present and medically unremarkable to facilitate impressions. Participants with surgical ears or without external auditory canals must be excluded.

## 2.7 Description of the materials used

[redacted] 3D Ear Scanner- The [redacted] is an alternative approach to traditional impression procedures. By creating a 3D digital scan, [redacted] claims that the [redacted] has potential to reduce shipping times and procedural times in a cost effective manner. (See section 2.1)

Traditional silicone earmold impression material- Dreve Otoform A/flex

- Shore Rating = 25 +/- 2 Shore A

*Used with 48ML Impression Gun

## 2.8 Summary of the necessary training and experience

Researchers will familiarize themselves with the [redacted] equipment through independent practice prior to a training facilitated by [redacted] (occuring April 22nd) and will follow [redacted]

training recommendations (perform scans on 20+ ears following in-person training) prior to data collection

### 2.9 Description of the specific medical procedures involved in the use of the investigational device.

The [redacted] 3D ear scanner is used to create a 3D mapping of the ear canal. This digital file is then used to produce an earmold. Traditional earmold impressions require an audiologist or HCP to place a dam to prevent impression material leakage, then fill the external auditory canal with silicone impression material. This material then has to set prior to being removed from the ear canal and then proceeds to production stages.

## 3 Justification for the design of the clinical investigation

### 3.1 Preclinical Evidence

N/A – The [redacted]3D ear scanner is a post market device.

### 3.2 Clinical Evidence to date

Previous research has shown comparable quality of impression between [redacted] 3D ear scanner and traditional earmold impression procedures. However, it is unknown how [redacted] claims of increased efficiency applies to the workflow of Sonova's retail facilities. In particular, Audiological Care has the need for supportive data in deciding whether or not the [redacted] 3D ear scanner adds value to their businesses. These value drivers of interest include procedural time, and subjective comfort and overall preference for patients and providers.

### 3.3 Description of clinical development stages

Post Market – Observational

- Registry
- Post Market Clinical Investigation

## 4 Risks and benefits of the investigational device and clinical investigation

### 4.1 Anticipated clinical benefits

Better understanding of the value drivers behind [redacted] 3D Ear Scanners. This data will support the decision making process for incorporating these products into Audiological Care clinics.

### 4.2 Anticipated adverse device effects

The devices used in this investigation are post-market devices, and are to be used as recommended by the manufacturers. For these reasons, there are no anticipated adverse device effects.

### 4.3 Risks associated with participation in the clinical investigation

The investigatory procedure and comparator procedure both carry risks typical to the standard of care of earmold impression procedures. When placing an object in the auditory canal, there is risk of discomfort to the participant. In addition, when equipment is placed too deep into the

auditory canal, there is risk for damage or perforation of the tympanic membrane. There are risks of skin sensitivity to material of the devices inserted into the auditory canal, as well as risk for abrasions or irritation while placing these devices during the procedure.

### 4.4 Possible interactions with concomitant medical treatments as considered under the risk analysis

Exclusion criteria of this investigation removes the possibility of interactions with concomitant medical treatments.

### 4.5 Steps that will be taken to control or mitigate the risks

Researchers will be trained in accordance with the manufacturer's [redacted] recommendations specific to this product prior to data collection. The control condition (Silicone earmold impression procedure) is within the scope of practice of the research audiologists. The research audiologists are licensed by the state of Illinois and the procedures performed are within their scope of practice as defined by the licensing body.

*Table 1: Summary of all controls taken to mitigate the risks of the product related residual risks.*

| Polarion Risk-ID –Auditory Canal Discomfort | |
|---|---|
| Risk Control | Researchers are trained in both procedures to limit this risk as much as possible. This training has been provided by the manufacturers of equipment. Performing this procedure complies with the scope of practice of their licensing body. |
| Polarion Risk-ID – Tympanic Membrane Perforation | |
| Risk Control | Researchers are trained in both procedures to limit this risk as much as possible. This training has been provided by the manufacturers of equipment. Performing this procedure complies with the scope of practice of their licensing body. |
| Polarion Risk-ID – Skin Sensitivity | |
| Risk Control | Researchers are trained in both procedures to perform them as safely and efficiently as possible. This allows the time of contact with equipment to be as limited as possible for participants, minimizing the risk of skin sensitivity occurances. |
| Polarion Risk-ID – Skin Abrasions and Irritation | |
| Risk Control | Researchers are trained in both procedures to limit this risk as much as possible. This training has been provided by the manufacturers of equipment. Performing this procedure complies with the scope of practice of their licensing body. |

### 4.6 Risk/benefit rationale and justification of the selection of clinical endpoint(s).

The risks of this study are minimal as the procedures are within the scope of practice of the research audiologists, and manufacturer training recommendations are to be followed for the [redacted] 3D ear scanner. These limited risks are accompanied by the benefit of understanding whether or not the [redacted] 3D ear scanner will be beneficial to Audiological Care Clinics,

particularly in terms of procedural timing and preferences for both patients and providers. To satisfy the primary objective, the entirety of the procedural workflow will be captured using a stop watch (mm:ss) for both conditions, in order to have a direct measure of the timing component of the investigation. To satisfy the secondary objective, subjective questionnaires will be administered to answer questions relevant to incorporating this product into clinics. Question domains will include, but are not limited to, patient comfort, patient's perceived level of involvement, researcher's ease of use, and both patient/provider confidence in the scan/impression producing an appropriate earmold.

# 5 Objectives and hypotheses of the clinical investigation

## 5.1 Purpose of the clinical investigation claims for clinical performance, effectiveness or safety of the investigational device that are to be verified

The purpose of this study is to better understand the value drivers behind the [redacted]. The study intends to find any significant difference in the time it takes to complete the workflow of the [redacted] 3D ear scanner impressions, compared to a traditional silicone earmold impression (EMI). A secondary purpose of this study is to identify preferences between the [redacted] and traditional methods, for both patients and providers. This information will allow us to find out whether this is a viable piece of equipment for Audiological Care clinics.

## 5.2 Primary and Secondary Objectives

The Primary objective is to identify any significant differences in the time required for a provider to complete the workflow of an [redacted] 3D ear scanner, compared to traditional silicone earmold impression procedures. The secondary objective is to identify any significant preferences for both providers and patients.

## 5.3 Scientific justification and clinical relevance for effect sizes, non-inferiority margins or equivalence limits

This is an exploratory trial, and as such, no specific effect size, non-inferiority margin, or equivalence limit is applicable.

## 5.4 Safety Objectives

There are no risks or anticipated adverse device effects to be assessed for this investigation.

## 5.5 Hypothesis

The study is exploratory in nature and will be used to further develop further hypotheses. The purpose of this study is to better understand the value drivers behind the [redacted]. The study intends to find any significant difference in the time it takes to complete the workflow of the [redacted] 3D ear scanner impressions, compared to a traditional silicone earmold impression (EMI). A secondary purpose of this study is to identify preferences between the [redacted] and traditional methods, for both patients and providers. This information will allow us to find out whether this is a viable piece of equipment for Audiological Care clinics.

# 6 Design of the clinical investigation

## 6.1 General

### 6.1.1 Design Type

This observational study will have two conditions ([redacted] 3D ear scanner and a control condition - traditional silicone impression procedure) across a sample population of 30 human subjects. The order of conditions will be counterbalanced and blinding is not applicable.

### 6.1.2 Measures for minimizing bias

Conditions will be counterbalanced across participants. In addition, three research audiologists will be involved in data collection in order to better represent the skill level of an average provider.

### 6.1.3 Endpoints with rationale for their selection and measurement

To satisfy the primary objective, the entirety of the procedural workflow will be captured using a stop watch (mm:ss) for both conditions, in order to have a direct measure of the timing component of the investigation. To satisfy the secondary objective, subjective questionnaires will be administered to answer questions relevant to incorporating this product into clinics. Question domains will include, but are not limited to, patient comfort, patient's perceived level of involvement, researcher's ease of use, and both patient/provider confidence in the scan/impression producing an appropriate earmold.

### 6.1.4 Methods and timing for assessing, recording, and analyzing variables

To satisfy the primary objective, the entirety of the procedural workflow will be captured using a stop watch (mm:ss) for both conditions, in order to have a direct measure of the timing component of the investigation. To satisfy the secondary objective, subjective questionnaires will be administered to answer questions relevant to incorporating this product into clinics. Question domains will include, but are not limited to, patient comfort, patient's perceived level of involvement, researcher's ease of use, and both patient/provider confidence in the scan/impression producing an appropriate earmold.

### 6.1.5 Equipment to be used for assessing the clinical investigation variables and arrangements for monitoring maintenance and calibration.

To satisfy the primary objective, the entirety of the procedural workflow will be captured using a stop watch (mm:ss) for both conditions, in order to have a direct measure of the timing component of the investigation. To satisfy the secondary objective, subjective questionnaires will be administered to answer questions relevant to incorporating this product into clinics. Question domains will include, but are not limited to, patient comfort, patient's perceived level of involvement, researcher's ease of use, and both patient/provider confidence in the scan/impression producing an appropriate earmold.

### 6.1.6 Any procedures for the replacement of participants (not applicable to randomized clinical investigations

In the event of attrition, a rolling recruitment approach may take place in order to maintain adequate power of the investigation.

### 6.1.7 Clinical investigation sites

PARC, 750 North Commons Drive, Aurora, IL 60504

### 6.1.8 Definition of completion of the clinical investigation

The clinical investigation is considered complete when the study report has been reviewed and approved by the appropriate authorities.

## 6.2 Investigational device(s) and comparator(s)

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|---|---|
| Description of the exposure to the investigational device(s) | For each subject, the investigational device ([redacted] 3D ear scanner) will have an exposure time of approximately 15 minutes, or the length of time it takes to complete a 3D ear scan in its entirety. |
| Description of the exposure to the comparator(s), if used. | For each subject, the comparator (silicone earmold impression procedure) will occur for approximately 15 minutes, or the length of time it takes to complete a traditional silicone earmold impression. |
| List of any other medical device to be used during the clinical investigation (if applicable) | N/A |
| Number of investigational devices to be used, and justification | 1 – The investigational device can be reused and sanitized between subjects in accordance with the manufacturer recommendations. |

## 6.3 Participants

| | |
|---|---|
| Inclusion criteria for participant selection | Adult aged (18+ years) and any degree of hearing loss. |
| Exclusion criteria for participant selection | External auditory canal must be present and medically unremarkable to facilitate impressions. Participants with surgical ears or without external auditory canals must be excluded. |
| Criteria and procedures for participant withdrawal or lost to follow up | During the consent process, participants agree to their involvement being completely voluntary and they may withdraw at any time. A participant is immediately withdrawn if requested to be removed from the investigation. In addition, in the event of an adverse event, the investigation will be paused until the event is reviewed and it is deemed safe to continue the investigation. |
| | Attrition will be documented in an excel spreadsheet containing all collected data. |
| | In the event of attrition, a rolling recruitment may take place in order to maintain adequate statistical power of the investigation. |
| Point of enrollment | Following the manufacturer recommended training protocol for the investigatory device for all researcher involved in data collection. |
| Point of randomization (if applicable). | N/A, conditions will be counterbalanced during enrollment. |
| Total expected duration of the clinical investigation | Approximately 1 month |

| | |
|---|---|
| Expected duration of each participant's participation | Approximately 30 minutes |
| Number of participants required to be included in the clinical investigation, and where needed anticipated distribution of enrolment among the participating clinical sites. | 30 subjects seen at PARC |
| Estimated time needed to select this number (i.e. enrolment period). | Approximately 2 weeks |
| Relationship of investigation population to target population | Investigation population will contain a variety of external auditory canal sizes and shapes, relatable to the average patient without any external auditory canal anomalies. |
| Information on vulnerable, pregnant and breastfeeding population, if applicable. | N/A |

## 6.4 Procedures

### 6.4.1 Investigation-related Procedure

Three researchers will be facilitating these appointments to limit variability of researcher skill across the two conditions. Researchers will familiarize themselves with the [redacted] equipment through independent practice prior to a training facilitated by [redacted] (occuring April 23rd) and the researchers will follow [redacted] training recommendations (perform scans on 20+ ears following in-person training) prior to data collection. Participants will be seen for one appointment. REUR/REUG, RECD, tympanometry, and reflex thresholds will be collected. The researcher will perform both traditional earmold impressions and 3D ear scans on both ears (conditions will be randomized and counterbalanced across participants). An additional researcher will use a stop watch to quantify the time (mm:ss) it takes for each condition, for both ears. After each procedure, participants and the clinician will also be asked to complete a questionnaire regarding each condition, focusing on their perception of comfort and level of involvement throughout the impression taking. In the event that a clinician feels as though a silicone impression needs to be remade, this will be recorded on the clinician questionnaire. Timing will be recorded for all attempts, but only the time recorded for the final impressions will be used in the data analysis. The resulting data will be compiled for all participants and analyzed using a T-test, to identify any significant differences in the time it takes to complete each method of earmold impressions, in addition to any differences in perceptual comfort.

**The step by step processes for each procedure and corresponding time recording are as follows:**

## TIMING DETAILS

**Silicone EMI**

- Introduction – “I will be taking some impressions of your ear canals. I will place this foam block in each ear, before filling your canals with the silicone impression material. It will take a few minutes to harden before I remove them. Due to the nature of this study, I am going to ask you to hold any questions until after the procedure is done, but do not hesitate to let me know if you are experiencing any discomfort throughout the procedure.”
- Have materials out and ready to go (impression cartridge in impression gun, box folded together, but do not put a tip on the impression gun)
- Otoscopy
- Cerumen management if needed
- Start timer
- Tie off otoblocks
- Place otoblocks bilaterally
- Confirm otoblock placement with otoscopy
- Put tip on impression gun
- Administer impression material bilaterally
- Check hardness of silicone every 30 seconds
- Remove impressions when set
- Inspect impressions for landmarks
- Perform otoscopy
- Put impressions in box
- End timer
- Administer questionnaires

[redacted]

- Introduction – “I will be using this camera to take some scans of your ear canals. I will place a headset on you and this probe will be inserted into your canal. You will be able to view the procedure on the TV in front of you. Due to the nature of this study, I am going to ask you to hold any questions until after the procedure is done, but do not hesitate to let me know if you are experiencing any discomfort throughout the procedure.”
- Otoscopy
- Start timer
- Sanitize [redacted] tip and headset
- Enter patient info
- Hair management
- Headset placement
- Perform scans bilaterally
- Inspect scans for landmarks
- Press power button on screen to save scans
- End timer
- Administer questionnaires

**IN THE EVENT THAT A CLINICIAN FEELS AS THOUGH THE IMPRESSION/SCAN IS UNSATISFACTORY TO SEND IN FOR A CUSTOM PRODUCT, THE PROCEDURE WILL BE REPEATED. THE TIMING OF ALL PROCEDURES WILL BE RECORDED ON THE TIMING**

**RECORDS, AND REASON FOR REPEAT WILL BE CAPTURED IN THE CLINICIAN QUESTIONNAIRE.**

These timing details do not include setting up equipment (removing from drawers/cabinets, etc.), sending a silicone impression order through the eStore, or sending [redacted] scans to a manufacturer. One researcher (David) will take a one-time time recording of these processes and others that may be of interest, separate from data collection.

### 6.4.2 Sponsor activities

N/A

### 6.4.3 Outcome comprising factors

Inclusion/exclusion criteria, limiting bias with multiple researchers, uncertainty of how HL may influence subjective preferences, etc.

Exclusion criteria has been designed to limit comprising factors due to participant anatomy. Multiple researchers will be administering appointments to limit researcher bias.

## 6.5 Monitoring plan

The extent and nature of monitoring appropriate for the clinical investigation including the strategy for source data verification (SDV) are based on considerations such as the objective, design, complexity, size critical data points and endpoints of the clinical investigation. A detailed plan for monitoring arrangements is provided separately from this CIP (TPL-160).

# 7 Statistical design and analysis

The description of and justification for the statistical design and analysis of this clinical inves-tigation is in line with Chapters 5 and 6.

## 7.1 Determination of Sample Size

A priori sample size estimation was not performed for this investigation, as the investigation is exploratory and does not aim to confirm any effect with statistical significance and power.

## 7.2 Statistical criteria of termination of trial

This is an exploratory trial and will not have statistical criteria for termination.

## 7.3 Planned Analyses

The statistical analysis plan includes the methods and types of the analysis, the variables the data sets and the timeframe when the (interim) analysis is planned.

### 7.3.1 Datasets to be analyzed, analysis population

Total procedure time will be recorded in seconds. Each procedure time will be recorded along with the audiologist, the anonymous participant ID, the procedure methodology (i.e., scanning or traditional silicone impressions), and the ordinal number of the procedure for the given methodology by the respective audiologist. Qualitative data will be collected as a question, response, methodology, and anonymous participant ID.

### 7.3.2 Primary Analysis

Analysis of procedure time data will take place at the conclusion of the trial. The intended analysis assumes a normally-distributed response variable. As such, procedure times for

each methodology will be tested for normality using a Shaprio-Wilk test. If the data are normally distributed, additional analysis will proceed immediately. If data are not normally distributed, transformation(s) may be performed on the data, as appropriate, to achieve an approximately normal distribution of the response data for further analysis.

Data (raw or transformed, per above) will then be subjected to analysis via linear mixed effects modeling. The model will be constructed to regress (raw or transformed) procedure time on a dummy variable of methodology (fixed effect), with a random effect of audiologist. This model will allow the investigators to evaluate the relative difference in procedure time between the methodologies, while removing and separately evaluating the variance contributed by the audiologist undertaking the procedure.

### 7.3.3 Secondary Analysis

Qualitative data acquired via questionnaires will not be statically analyzed. A cursory (i.e., visual) analysis of the “learning curve” for each audiologist may also be performed, but will not be included as a statistical analysis.

### 7.3.4 Interim Analysis

No interim analysis is planned during this trial.

### 7.3.5 Safety Analysis

No safety analysis is necessary as the procedures performed are within the scope of practice of the researchers and utilize publicly available equipment.

### 7.3.6 Deviation(s) from the original statistical plan

Deviations to the statistical plan will be captured and reported in an update to this document, with justification.

## 7.4 Handling of missing data and drop-outs

Participants with missing procedure time data for either or both methodologies will be excluded from statistical analysis entirely. Missing qualitative data will not impact statistical analysis (as no statistical analysis is planned for qualitative data). Drop-outs will not be replaced during this study. Achieved statistical power will be calculated and documented if the planned sample size is not achieved.

# 8 Quality Assurance and Control

## 8.1 Data Handling and record keeping/ archiving

Study data is recorded both with paper and with electronic Case Report Forms (p/eCRF). For each enrolled study participant a CRF is maintained. All CRFs are kept current to reflect the subject’s status at each phase during the course of study. Participants cannot be identified in the CRF by name or initials and birth date but an appropriate coded identification is used. All study team members are authorized for the CRF entries and it is assured that any authorized person can be identified both for pCRFs and eCRFs. If pCRFs are used, the investigator’s acronym as well as the subject ID is filled in and data are entered into an electronic file for analysis by the respective investigator and data get monitored by the assigned monitor. In case of a self-evident corrections, either the subject does it by himself or the investigator undertakes the correction by crossing out the word/sentence with a single horizontal line and by adding the correction including his personal identifier and the date.

### 8.1.1 Specifications of source documents
Timing measures will be recorded for both procedures and any additional attempts. Data from questionnaires will be compiled, but not statistically analyzed. Other data includes source intake form and Noah packages containing tympanometry and reflex thresholds, RECD, and REUR data.

### 8.1.2 Record keeping/ archiving
All paper data will be stored in a locked filing cabinet at the Phonak Audiology Research Center (PARC). All electronic data files will be encrypted and stored on secure research computers. All identifying data will be stored at PARC. De-identified data will be shared with production to cross-check the quality of scans/impressions, and with partners at Sonova Switzerland.

## 8.2 Data management

### 8.2.1 Procedures data review, database cleaning, queries
During data collection of the investigation, physical copies of the data will be compiled and digitized by the study manager on a daily basis. Data will be reviewed for mis-entries or inaccuracies as each data set is entered.

The extent and nature of monitoring appropriate for the clinical investigation including the strategy for source data verification (SDV) are based on considerations such as the objective, design, complexity, size critical data points and endpoints of the clinical investigation. A detailed plan for monitoring arrangements is provided separately from this CIP (TPL-160).

### 8.2.2 Procedures for verification, validation and securing of EDC system
Not applicable for this investigation.

### 8.2.3 Procedures to maintain and protect participant privacy.
The identifiable data kept at PARC will be destroyed as soon as the final analyses have been completed. The de-identified data will be kept for seven years after the publication of results. When the data are destroyed, paper records will be shredded by services provided at PARC. Electronic data will be encrypted as de-identified NOAH packages, where applicable, to be shared with Sonova Switzerland.

### 8.2.4 Procedures for data retention.
Digital records of anonymized data will be stored on company network drive.

### 8.2.5 Specified retention period.
Digital records will be archived for 7 years from date of acquisition.

### 8.2.6 Other aspects of clinical quality assurance, as appropriate.
Refer to LoESD for licensure, insurance status, and appropriate qualifications of researchers.

# 9 Amendments to the CIP

Amendments to the CIP, if necessary, will be updated with justification in this document.

# 10 Deviations from clinical investigation plan

Deviations from the CIP to protect the rights, safety and well-being of human participants under emergency circumstances may proceed without prior approval of the sponsor and the EC

– such deviations will be documented and reported to the sponsor representative (Investigation Manager) and the EC as soon as possible. Apart from that the investigator is not allowed to deviate from this CIP unless that deviation does not influence the investigation data.

### 10.1 Procedures for recording, reporting and analyzing CIP deviations

Each deviation from the CIP will be documented including date of protocol deviation, name of investigator, participant ID, affected visit (if applicable), reason for deviation and anticipated influence on investigation data.

### 10.2 Notification requirements and time frames

Each deviation needs to be reported to the Sponsor (= Study Manager) and depending on the severity, also to the IRB

For locations under WCG IRB approval (Canada/US): For protocol deviations, reporting to WCG IRBs (including WIRB) is **required only** for deviations that harmed a subject or placed subject at risk of harm or a deviation made without prior IRB approval to eliminate an immediate hazard to a subject **within 5 days.**

(Source: WCG IRB Investigator Guidance: Prompt Reporting Requirements (HRP-071))

### 10.3 Corrective and preventive actions and principal investigator disqualification criteria

The Sponsor may disqualify a clinical investigator if the clinical investigator has repeatedly or deliberately failed to comply with applicable regulatory requirements or the clinical investigator has repeatedly or deliberately submitted false information to the sponsor or, if applicable, to the Ethics Review Board or Competent Authority, in any required report.

## 11 Device accountability

### 11.1 Accountability for investigational device

The PI or authorized designee keep records documenting the following in a written process:

- Names of participants who received, used, returned, or disposed of device
- Date of receipt, identification, and quantity of each investigational device (batch/serial number or unique code)
- Expiry date (if applicable)
- Date(s) of use
- Participant identification

### 11.2 Return of investigational device

The PI or authorized designee keep records documenting the following in a written process:

- Date on which the device was returned (if applicable)
- Date of return of unused, expired, or malfunctioning investigational devices (if applicable)

- Date and documentation of disposal of devices as per sponsor instructions (if applicable)

## 12 Statements of compliance

The clinical investigation will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki (Declaration of Helsinki, 2018).

The Clinical investigation will be in compliance with the ISO 14155 (ISO_14155, 2020) and the following national and regional (if applicable) regulations: N/A

The clinical investigation will not begin until the required approval/ favorable opinion from the EC and regulatory authority (if applicable) have been obtained, (To be checked, if appropriate).

Any additional requirements imposed by the EC or regulatory authority will be followed. (To be checked, if appropriate).

- This clinical investigation is covered with the following insurance: [redacted]
- Professional liability insurance from HPSO
  - [redacted]

This investigation is solely financed by Sonova AG and will be conducted internally.

## 13 Informed consent process

### 13.1 Process for obtaining informed consent

At the beginning of the first appointment, investigators will hand the consent form to the participant in a private setting and grant sufficient time to read the whole form. The consent form contains detailed information about incentives and reimbursement. Any questions will be answered and the participant will be given sufficient time to decide whether or not they want to participate in the study. After the participant signed two copies of the consent form, the researcher will sign both copies as well and provide one copy to the participant.

In case of changes to the procedures described in the consent form, the participant will be informed at the beginning of an appointment.

### 13.2 Process for obtaining informed consent in emergency situations

This Chapter is not applicable for this investigation. Informed Consent will only be obtained by investigation participants who can provide informed consent themselves before enrollment.

## 14 Adverse events, adverse device effects and device deficiencies

Device deficiencies and all **adverse events (AE)** including all **serious adverse events (SAE)** are collected, fully investigated and documented in the source document and appropriate case report form (CRF) during the entire investigation period, i.e. from participant's informed consent until the last protocol-specific procedure, including a safety follow-up period (ISO_14155,

2020). Documentation includes dates of event, treatment, resolution, assessment of seriousness and causal relationship to device and/or investigation procedure.

Information on AEs is systematically collected during the regular investigation visits, and phone calls (if applicable).

## 14.1 Definition and Assessment of Adverse Events and other safety related events

### 14.1.1 Adverse Events (Definition)

An adverse event is an untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device (ISO_14155, 2020)

- Note1: this definition includes events related to the investigational medical device or the comparator.
- Note2: This definition includes events related to the procedures involved.
- Note3: For users or other persons, this definition is restricted to events related to the use of investigational medical device

### 14.1.2 Serious Adverse Event

A SAE is an AE that led to any of the following

a) death

b) serious deterioration in the health of the subject, users or other persons as defined by one or more of the following

- life-threatening illness or injury, or
- permanent impairment to a body structure or a body function including chronic diseases, or
- in-patient hospitalization or prolongation hospitalization, or
- medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function

c) foetal distress, foetal death or a congenital abnormality or birth defect

Note: Planned hospitalization for a pre-existing condition, or a procedure required by the Clinical Investigation Plan, without serious deterioration health, is not considered a serious adverse event (ISO_14155, 2020)

### 14.1.3 Adverse Device Effect

An adverse device effect, is an adverse event related to the use of an investigational medical device (ISO_14155, 2020)

- Note: This definition includes AEs resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or preparation, or any malfunction of the investigational medical device.
- Note: This definition includes any event resulting from use error or from intentional misuse of the investigational medical device

### 14.1.4 Health hazards

Health hazards are findings in the trial that may affect the safety of investigation participants and, which require preventive or corrective measures intended to protect the health and safety of investigation participants SAE

### 14.1.5 Device Deficiencies (Definition)

A Device Deficiency is an inadequacy of a medical device with respect to its identity, quality, durability, reliability, usability, safety or performance (ISO_14155, 2020)

- Note: Device deficiency include malfunctions, use errors, and inadequacy in the information supplied by the manufacturer including labelling
- Note: This definition includes device deficiencies related to the investigational medical device or the comparator

### 14.1.6 Causal relationship of SAE

A causal relationship towards the medical device or investigation procedure should be rated as follows:

**Not related:** The relationship to the device or procedures can be excluded.

**Unlikely:** The relationship with the use of the device seems not relevant and/or the event can be reasonably explained by another cause, but additional information may be obtained.

**Possible:** The relationship with the use of the investigational device is weak but cannot be ruled out completely. Alternative causes are also possible.

**Probable:** The relationship with the use of the investigational device seems relevant and/or the event cannot be reasonably explained by another cause.

**Causal relationship:** The serious event is associated with the investigational device or with procedures beyond reasonable doubt.

Device deficiencies that might have led to an SAE are always related to the medical device.

## 14.2 Foreseeable adverse events and anticipated adverse device effect

*Table 2: List of foreseeable adverse events and anticipated adverse device effects*

| Polarion [Risk ID] | Foreseeable AE | Anticipated ADE | Likely incidence | Mitigation or treatment |
|---|---|---|---|---|
| N/A | Patient Discomfort | N/A | Likeliness is limited | Training |
| N/A | Tympanic Membrane Perforation | N/A | Unlikely | Training, within scope of practice of researchers |
| N/A | Skin Sensitivity | N/A | Unlikely | Training to limit time of contact with equipment |
| N/A | Skin Abrasion and Irritation | N/A | Unlikely | Training, within scope of practice of researchers |

No serious adverse event that could be related to the investigational device or investigation procedures are expected during this clinical investigation.

### 14.3 Non-reportable adverse events

*Table 3: List of all non-reportable AEs including rational*

| Non-reportable AEs | Rationale |
|---|---|
| N/A | The investigation is a one time appointment lasting approximately an hour. An event that happens during this investigation would not be reported if it is deemed unrelated. If in event does occur, it is likely unrelated due to the short timeframe of the investigation. |

### 14.4 Reporting of Adverse Events and Device Deficiencies

#### 14.4.1 Reporting time frame

*Table 4: Overview of time period in which the PI reports AEs and Device Deficiencies to Investigation Manager, Ethics Commission and Competent Authority*

| | Investigation Manager | Ethics Commission | Competent Authority |
|---|---|---|---|
| **Adverse Events** | 1-2 Days | 5 Days | N/A |
| **Serious Adverse Events** | 1-2 Days | 5 Days | N/A |
| **Health hazards that require measures** | 1-2 Days | 5 Days | N/A |
| **Device Deficiencies** | 1-2 Days | 5 Days | N/A |

#### 14.4.2 Reporting Procedure

In the event of an adverse event, the investigation manager will make contact with the principal investigator within 24 hours to align on reporting procedures, as outlines above in 14.4.1, and to evaluate the relationship of the investigational device and the related procedure.

In the event of a serious adverse event, this will be reported to the FDA using Reporting Form FDA 3500, or by telephone at 1-800-FDA-1088.

### 14.5 Follow up of (Serious) Adverse Events

The investigation manager will follow up as recommended by the FDA.

## 15 Vulnerable population (if applicable)

### 15.1 Description of the vulnerable population to be included in the clinical investigation.

The investigation does not include any vulnerable populations.

### 15.2 Description of the specific informed consent process.

Not applicable, as this investigation does not include any vulnerable populations.

### 15.3 Description of the EC's specific responsibility.

Not applicable, as this investigation does not include any vulnerable populations.

### 15.4 Description of what medical care, if any, will be provided for participants after the clinical investigation has been completed.

Not applicable, as this investigation does not include any vulnerable populations.

## 16 Suspension or premature termination of the clinical investigation

### 16.1 Criteria and arrangements for suspension or premature termination of the whole clinical investigation or of the clinical investigation in one or more investigation sites.

The clinical investigation will be suspended or prematurely terminated if the participants or researchers are exposed to safety risks other than those outlined in this document. These events may include but are not limited to – natural disaster, widespread outbreak of illness, compromised structure of the investigation site, etc.

### 16.2 Criteria for access to and breaking the blinding/masking code in the case of suspension or premature termination of the clinical investigation, if the clinical investigation involves a blinding/masking technique.

Not applicable to this investigation, as there is no blinding/masking code.

### 16.3 Requirements for participant follow-up.

Due to the short nature of this investigation, there are no requirements for participant follow-up.

## 17 Publication policy

The clinical investigation will be registered in clinicaltrials.gov, a publicly accessible database, as required by United States national law.

The results of the clinical investigation will be published internally in the format of a study report.

The investigation will be published June 2021 by David Taylor, Au.D.

## 18 Bibliography

*Declaration of Helsinki*. (2018, July 9). Retrieved September 17, 2020, from www.wma.net: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-participants/

ISO_14155. (2020, 07). ISO 14155 Clinical Investigation of medical devices for human participants -Good clinical practice. *ISO 14155 Clinical Investigation of medical devices for human participants -Good clinical practice*. International Organization for Standardization.

[redacted]

# 19 Tables

## 19.1 Table of Tables



## 19.2 Table of Figures

**No table of figures entries found.**

## 19.3 Abbreviations

| | |
|---|---|
| CIP | Clinical Investigation Plan |
| e.g. | Example given |
| EMI | Earmold Impression |
| FDA | Food and Drug Association |
| GCP | Good Clinical Practice |
| ISO | International Organization for Standardization |
| N/A | Not applicable |
| PARC | Phonak Audiology Research Center |
| PI | Principal Investigator |
| TPL | Template |
| US | United States |