# Study Protocol and Statistical Analysis Plan

# Benefits of Roger for speech intelligibility

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# Benefits of Roger for speech intelligibility

## 1 Background

While satisfaction with modern hearing aids is generally high, nearly one third of hearing aid users report that they continue to struggle with following conversations in noise (Picou, 2020). For these listeners, or for particularly noisy listening situations, the use of a Roger device in addition to hearing instruments can further improve speech understanding, thereby mitigating residual difficulty in complex listening environments. For example, Thibodeau (2019) found that the use of a Roger microphone yielded significantly better speech recognition performance on the Hearing-in-Noise Test (HINT), compared with hearing aids alone. Further, the results of this study demonstrated that listeners received a greater benefit from a Roger microphone with multibeam technology (Roger Select) than from one lacking multibeam technology (Roger Pen) in the most difficult listening conditions tested (-5 and -10 dB SNR). This would suggest that Roger technology that incorporates directionality - specifically, multibeam technology - is particularly beneficial for understanding speech in complex listening environments. The Roger On builds upon previous technology, implementing a spatial multibeam strategy. Briefly, the multibeam strategy available in the Roger Select uses three omnidirectional microphones to create six directional beams spaced 60° apart; MultiBeam technology analyzes the signal-to-noise ratio (SNR) of each directional beam and automatically accentuates the signal in the beam with the highest SNR averaged over time (Gigandet et al., 2018). The spatial multibeam function in the Roger On advances this technology by applying head-related transfer function (HRFT) filters to each of the beams, such that the spatial cues are preserved in the amplified signal. The present study will investigate the benefit of the Roger On device as a whole for speech intelligibility, relative to hearing aids alone. It is expected that similar benefit for speech understanding in complex listening environments will be observed for the Roger On, relative to performance without the Roger One device, in the present study.

## 2 Objectives

The primary objective of this study is to demonstrate an improvement in speech intelligibility in noise with the use of a Phonak Roger On remote microphone system compared to the use of hearing aids alone for a group of adults with moderate to severe hearing loss. There is no secondary objective.

## 3 Description of the investigational device

The intended purpose of the investigational device (i.e., Roger On) in the proposed clinical investigation is to pick up the voice of a talker and send it directly to the listener's ears. There are four main use cases for Roger On: (1) table mode, in which the Roger On device is placed on a table to hear the voices of people sitting around the microphone; (2) pointing mode, in which the listener holds the microphone in the direction of the person they want to hear; (3) presenter mode, in which the microphone is hung from a lanyard around the neck of (or clipped to the lapel of) a distant talker; and (4) TV/multimedia mode, in which the microphone is connected to a television or another audio source and the output is streamed directly into the listener's ears. In the proposed clinical investigation, Roger On will be used only in table mode.

The intended purpose of the Audéo P hearing aids (compatible devices to the Roger On) is to amplify and transmit sound to the ear and thereby compensate for impaired hearing. In this clinical investigation, the primary endpoint will be assessed with the compatible devices alone (Audéo P90 alone) and with the investigational device paired with the compatible devices (Audéo P90 + Roger On). When worn alone, the compatible devices amplify inputs

to the hearing aid microphones and transmit sound to the ear and thereby compensate for impaired hearing. When paired with the investigational device, the compatible devices receive the input from the investigational device, combine it with the signal from the hearing aid microphones (using default gain settings and mixing ratio prescribed by Phonak Target software), and transmit this blended signal to the ear.

# 4 Design of the clinical investigation

This clinical investigation is a single-site, interventional study with a confirmatory design. Neither experimenters nor participants are blinded to the intervention (Audéo P90 + Roger On, Audéo P90 alone) as the display on the Roger On device indicates whether it is on or off. Covering the display would prevent the experimenter from confirming that the device is in the appropriate setting for each run. No control group is used for this investigation, as the objective is to quantify the benefit of remote microphone technology over hearing aids alone for individuals with moderate to severe hearing loss. Previous research conducted by Sonova has revealed that, under certain conditions, Phonak Roger technology may yield a benefit for speech understanding in noise and over distance beyond the performance of listeners with normal hearing. Thus, testing a normal-hearing control group would not necessarily indicate what level of performance should be expected.

# 5 Risks and benefits of the investigational device and clinical Investigation

It is unlikely that participants will have any direct benefit from taking part in this study, as the state-of-the-art investigational devices and compatible devices will be used only for a short amount of time during laboratory testing. However, this study has been approved by the study site IRB as a non-significant risk study. Thus, while the likelihood of benefiting from participating in this clinical investigation low, risks associated with study participation are also low.

# 6 Endpoints

Speech intelligibility in noise, measured using the AzBio Sentence Test in percent correct is the primary clinical endpoint of this clinical investigation for the comparison of the intervention conditions Audéo P90-R + Roger On vs. Audéo P90-R. This endpoint will be measured in three listening conditions of varying difficulty: -5, 0, and +5 dB SNR.
This clinical endpoint was chosen to obtain clinical data that shows the clinical benefit of the Roger On device. The intended purpose of the investigational device (i.e., Roger On) is to pick up the voice of a talker and send it directly to the listener's ears, in order to improve speech understanding in noise and over distance. The measurement of speech intelligibility in diffuse noise was selected as primary endpoint because this is one of the primary use cases for Roger technology.

# 7 Inclusion and Exclusion Criteria

Inclusion criteria for participant selection:

1. Hearing impaired adults (minimum age: 18 years) who are experienced hearing aid users
2. Hearing loss is symmetric (no more than a 15 dB difference between the right and left ears at three contiguous frequencies) and moderate to severe in degree (N3-N5 standard audiogram)
3. Good written and spoken English language skills
4. Healthy outer ear (confirmed by otoscopy)
5. Informed consent as documented by signature

Exclusion criteria for participant selection:

1. Contraindications to the medical device noted upon otoscopy (e.g., ear canal drainage)
2. Known hypersensitivity or allergy to materials of the investigational device or compatible device
3. Inability to produce reliable test results
4. Known psychological problems
5. Reported symptoms of vertigo and dizziness by participant

# 8 Measurements and procedures

**Pure-tone audiometry**

Pure-tone audiometry is the gold standard measurement for assessing a person's hearing status. This involves measuring the threshold of hearing (i.e., the lowest level of sound that can be detected at least 50% of the time) at the frequencies most important for understanding speech (.25-8kHz) and recording these thresholds on an audiogram. Bone conduction thresholds are measured using a bone oscillator, and provide information about the integrity of the cochlea (organ of permanent hearing) and retrocochlear pathway by bypassing the outer and middle ears. Air conduction thresholds are measured using headphones or insert earphones, and thus assess the entire auditory pathway.
In this investigation, study candidacy will be determined based on potential participants' audiograms from previous clinical appointments within the past one year prior to enrollment.

**Real Ear Measurement (REM)**

Real-Ear Measurement (REM) is a tool used to objectively measure the hearing instrument's frequency response in a participant's ear. In this clinical investigation, on-ear REM will be completed using the Verifit2.
First, the participant's hearing thresholds will be entered into the Verifit2 and the appropriate hearing aid fitting formula (DSL v5, NAL-NL1, NAL-NL2) will be selected. Based on these entries, the software will determine the appropriate amplification targets. In this clinical investigation, the fitting formula that the participant's current hearing aids have been fit to will be selected. For most participants, this is the NAL-NL2 formula, as this is the most common fitting protocol used in a clinical adult population.
Next, a soft silicone probe tube will be placed in the participant's ear canal. The tip of the probe tube is placed in the participant's ear canal, past the end of the hearing aid receiver or sound bore, ideally ~2mm away from the participant's eardrum. The silicone probe tube is attached to a microphone that sits just outside the participant's ear.
The participant will be seated in front of a loudspeaker at a distance of 0.5-1 m. The International Speech Test Signal (ISTS) speech signal will be presented from the loudspeaker at 50 dB, 65 dB and 80 dB. This signal will be recorded with the probe tube placed in the participant's ear, and the microphone just outside the participant's ear. In this way, the measurement is used to validate a hearing aid fitting at the participant's ear since it considers all relevant factors like direct sound, hearing aid output, and the individual anatomy of the participant's ears. This method is also used indicate the quality of the hearing aid fitting i.e. if the hearing aid provides enough amplification in the specific frequencies, based on the targets prescribed by the fitting formula.
Real ear measurement will be completed after hearing aid fitting and before the administration of study tasks.

**Speech Intelligibility in Noise**

Participants will be seated 2 m away from a loudspeaker positioned at 0 azimuth; the Roger On device will be placed on a table in front of the participants, 1 m away from the same loudspeaker.
AzBio sentences will be presented one at a time from the loudspeaker at a level of 65 dBA, measured at the location of the participant's head (i.e., 2 m from the loudspeaker).
Multi-talker babble noise will be presented from two loudspeakers in the front corners of the testing room. Speakers will be rotated away from the center of the room in order to create a background of diffuse noise. The noise will be calibrated at the same location as the speech,

to the appropriate level for the given condition – that is, 60 dBA for the +5 dB SNR condition, 65 dBA for the 0 dB SNR condition, and 70 dBA for the -5 dB SNR condition.
Participants will be instructed to repeat as much of each sentence as they can understand. For each sentence, the investigator will indicate the number of words correctly repeated. Proportion/percent of words correctly repeated for each list of sentences indicates speech intelligibility in noise performance.
Participants will complete this task in each intervention condition (Audéo P90 + Roger On, Audéo P90 alone) and in each listening condition (-5, 0, and +5 dB SNR).
Speech intelligibility in noise will be completed following hearing aid fitting and REM.

# 9 Statistical design and analysis

### Determination of Sample Size

In a previous investigation of Roger technology (Thibodeau, 2019), significant benefit of Roger, compared to hearing aids alone, was observed for speech intelligibility performance in a cohort of 10 adults. Thus, 10 adults will be recruited to participate in this clinical investigation. Additional participants may be recruited if preliminary results of speech intelligibility reveal higher intersubject variability than observed in previous studies, or if participants withdraw or must be excluded.

### Statistical criteria of termination of trial

No *a priori* statistical criteria will be used to determine the termination of the trial. However, the trial may be terminated prior to the completion of all planned data collection if a statistically significant effect of the intervention is observed and no additional participants are able to be recruited.

### 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.

### Datasets to be analyzed, analysis population

Speech intelligibility in noise performance will be recorded in proportion of words correctly repeated within each intervention condition (Audéo P90 + Roger On, Audéo P90 alone) in each listening condition (-5, 0, +5 dB SNR) for each anonymized participant.

### Primary Endpoint Analysis

Primary analysis of study data will be completed at the conclusion of the data collection period by a representative of the sponsor (study manager). The results of the speech intelligibility task will be subjected to multivariate analyses of variance (MANOVA) to examine main and interaction effects of intervention.

### Secondary Endpoint Analysis

If main or interaction effects are observed on MANOVA, post hoc tests will be used to examine differences in mean speech intelligibility performance across intervention for each listening condition. These post hoc tests will be completed at the conclusion of the data collection period by a representative of the sponsor (study manager).

### Interim Analysis

Interim analysis (MANOVA) will be completed on a rolling basis by a representative of the sponsor (study manager). This will be done to monitor study results as participants are enrolled and tested to determine whether inclusion criteria should be adjusted to include more participants to ensure an adequately powered study.

### Safety Analysis

All safety related events will be constantly monitored by the investigators and will immediately reported to the Principle Investigator and representative of the study sponsor (study manager). Evaluation of any SAE, SADE, or UADE will be conducted promptly by the study manager using Sonova's standard medical device referral protocol. Confirmed UADEs will be reported to the IRB within 10 days after receiving notice of the event. If it is determined that an event or effect presents an unreasonable risk to subjects, this study, or those parts of the study presenting that risk, will be terminated no later than 5 working days after the determination is made and no later than 15 working days after Sonova USA first received notice of the event.

A safety analysis of the relevant data will be completed at the conclusion of the data collection period.

### 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.

### Handling of missing data and drop-outs

Should participants withdraw from the study or be lost to follow up prior to completion of all study tasks and/or conditions, no effort will made to compute what their performance would have been in the incomplete tasks/conditions. Rather, this will be treated as missing data. Drop-outs will not be replaced, however, additional participants may be recruited/enrolled, depending on availability of volunteers.

## 10 Investigation Duration

Total expected duration of the clinical investigation: 2 months

Expected duration of each participant's participation: ≤ 2 hours

## 11 Data Handling and Management

### Case Report Forms (CRF)

Clinical investigation data will be recorded both with paper Case Report From (pCRF) and electronic Case Report Form (eCRF). A CRF will be maintained for each enrolled clinical investigation participant. All CRFs will be kept current to reflect the participant's status at each phase during the course of this clinical investigation. Participants will be identified in the CRF by an appropriate coded identification (participant ID). All clinical investigation team members are authorized for the CRF entries and it will be assured that any authorized person can be identified both for pCRFs and eCRFs. If pCRFs will be used, the investigator's identifier as well as the participant ID will be filled in and data are entered into an electronic file for analysis by the respective investigator. Data will be monitored by the assigned monitor. Participants are allowed to self-correct. Investigators do not make any corrections without documentation (i.e., from electronic records from software output).

### Specifications of source documents

Source data are available at the investigation site to document the existence of the clinical investigation participants. The source data are documented in the following source documents:

- Participant information including Informed Consent Form
- Audiometric data (electronic document on password-protected clinical database)
- Lateralization and spatial hearing task results
- Subjective comments regarding investigational device (if any)
- Compensation Record Form
- Adverse Event and Device Deficiency Form

Source data which are collected on paper CRFs are transferred to eCRFs by the respective investigator. The pCRFs source documents are stored in the investigator site file (ISF).

### Record keeping/ archiving

Any hard copies of the source documentation will be stored in a locked cabinet and kept for a minimum of 3 years after regular or premature termination of the clinical investigation. Electronic data files will reside on a network drive or secure server that is accessible to the clinical investigation team. Servers are located in US. Hence, only encoded data will be stored on servers, which will not include personal data in any means. No third party will be able to trace back the encoded data to personal information of the participants. All identifying data will be stored at the study site.

**Procedures to maintain and protect participant privacy.**
The Sponsor and Principal investigator affirm and uphold the principle of the participant's right to privacy and that they shall comply with applicable privacy laws. Especially, anonymity of the participants shall be guaranteed when presenting the data at scientific meetings or publishing them in scientific journals. Individual participant medical information obtained as a result of this clinical investigation is considered confidential and disclosure to third parties is prohibited. Participant confidentiality will be further ensured by utilizing participant identification code numbers to correspond to treatment data in the computer files as below described further. For data verification purposes, authorized representatives of the Sponsor or the study site Institutional Review Board (IRB) may require direct access to parts of the data records relevant to the investigation.
Actions taken to guarantee participant privacy:

- In general, Sonova follows the requirements from General Data Protection Regulation (GDPR).
- Participant names and details, accessible by the study monitor, appropriate investigators and Principle Investigator, are documented in the Participant Identification Log.

There is no disclosure of personal information to anyone else aside from the investigation team.

- Participant paper-based files will be locked in cabinets at the study site; keys to the cabinet are placed in a location to which only the investigators have access.
- Electronical data is uploaded in project files on SharePoint; access is permitted to monitor, principal investigator, and investigators only.

## 12 Amendments to the CIP

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

## 13 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 (Study 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.

## 14 Device accountability

As there is no home trial component to the study, investigational devices and compatible devices will be kept at the investigation site for the duration of the study and will be returned to the sponsor upon conclusion of the study. Tracking information will be shared between the study site and sponsor.
However, compatible device serial numbers will be saved in the fitting software, allowing for traceability during lab testing sessions (i.e., which devices were worn by each participant during each session).
If an investigational device must be replaced due to a device deficiency, record of the new serial number, device identifier, date of receiving the replacement, date of return of the defect investigational device, etc. will be maintained by the Study Manager.
Representatives of the sponsor (Study Manager) will maintain records of shipment/receipt of investigational devices and related study supplies between the sponsor and study site, including the return of devices to the sponsor once the clinical investigation has been finalized.

## 15 Informed consent process

The investigators will explain to each participant the nature of the study, its purpose, and the

procedures, involving the expected duration, the potential risks and benefits and any discomfort it may entail. Each participant will be informed that the participation in the study is voluntary and that they may withdraw from the study at any time, and that withdrawal of consent will not lead to consequences for the participant. The participant must be informed that their medical records may be examined by authorized individuals.
The formal consent of a participant, using the approved consent form, must be obtained before the participant is submitted to any clinical investigation procedure. The participant should be given the opportunity to read and consider the statement before signing and dating the informed consent form and should be offered a copy of the signed document. The consent form must also be signed and dated by the investigator (or their designee) and it will be retained as part of the study records.

Informed Consent will only be obtained by investigation participants who can provide informed consent themselves before enrollment.

# 16 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.

The causality assessment of the SAE will be conducted according to MDCG 2020-10/1 Safety Reporting in Clinical Investigations of Medical Devices under Regulation (EU) 2017/745.

The reporting of Serious Adverse Events and Device Deficiencies follows the Regulation (EU) 2017/745 and the MDCG 2020-10/1 Safety Reporting in Clinical Investigations of Medical Devices under Regulation (EU) 2017/745.

# 17 Vulnerable Populations

Not applicable; this clinical investigation does not involve any vulnerable populations.

# 18 Suspension or premature termination of the clinical investigation

The clinical investigation will be suspended or prematurely terminated if the feature and/or investigative device malfunctions or 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. The trial will be suspended within 5 days of determination that the study or device puts subjects at an unreasonable risk (per 21 CFR 812).

**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, because the clinical investigation does not involve a blinding/masking technique.

**Requirements for participant follow-up.**

According to the FDA, follow-up is required for participants who experience serious adverse events. Follow-up will be conducted by the study manager until the nature of the event is resolved.

# 19 Publication policy

The clinical investigation will be registered in clinicaltrials.gov, a publicly accessible database, as required by US law.
The results of the clinical investigation will be documented internally in a study report, authored by the study manager.