# Study Protocol and Statistical Analysis Plan

# Evaluating Benefits of Hearing Aid Microphone Directionality Technologies

V.2

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## Protocol Title

# Evaluating Benefits of Hearing Aid Microphone Directionality Technology

## 1 Background

Paradise hearing instruments (HI) have an adaptive binaural beamformer, known as Stereozoom (SZ) that is activated in speech in loud noise (SiLN) environments. SZ has been proven to provide speech intelligibility (SI) benefits to HI users in noise. In particular, SZ has shown up to a 5.5 dB improvement over an omnidirectional microphone and up to 1.5 dB improvement over Phonak's monaural beamformer, Ultrazoom (UZ), in speech reception threshold (SRT) assessments in noise. A summary of these findings can be found in the "Phonak Compendium Stereozoom Part I: the benefit of wirelessly connected narrow directionality in Phonak hearing aids for speech intelligibility" by Stewart et. al (2019) available on phonakpro.com. SZ achieves these speech intelligibility benefits through mixing the input of each hearing instrument (HI) to create a narrow beam with a variable null that adapts in accordance to the noise source(s).

The effect of this mixing is a narrow beamformer with a high directivity index (DI) that is ideal for listening to single, front-facing speech sources. However, the mixing of HI inputs also results in the loss of spatial perception.
In comparison, the monaural beamformer, Ultrazoom (UZ), does not mix the HI inputs between sides. As such, it retains localization cues and; therefore, creates a spatial release from masking.
Accordingly, there is a tradeoff between Stereozoom and Ultrazoom, wherein SZ provides better directivity and UZ provides better spatial awareness. Good directivity and spatial awareness both contribute to improved speech intelligibility, so it is problematic to have to choose between one or the other.
Therefore, there is an opportunity to balance the advantages of both to optimize the performance of the binaural beamformer. This might be achieved through a change in the binaural beamformer strength. Today, in Paradise devices, the beamformer strength of SZ can be thought of as 70%. As such, the opportunity to change the beamformer strength could mean making the beamformer wider (<70%) or narrower (>70%), and both should be explored. In addition to the binaural beamformer strength, it would also be worthwhile to investigate the transition speed for binaural beamformer activation. The current transition speed for SZ is instantaneous (time constant = 0 sec.), which may be disturbing for some users. Elongating the transition time may result in a more pleasant user experience.

StereoZoom 2.0 is a new parameterization that balances the tradeoff between UZ and SZ. It has not yet been evaluated on human subjects. An evaluation of this feature with human subjects may identify which beamformer strength and transition speed settings strike the best balance between good directivity and spatial awareness while maintaining a pleasant user experience.

# 2 Objectives

The primary objective is to investigate the effect of binaural beamformer strength on spatial perception in speech in noise (SiN) environments through a subjective spatial awareness task comparing three beamformer strengths, including Stereozoom (SZ), with experienced hearing aid users with moderate hearing loss.

List of the secondary objectives:
a. The secondary objective is to investigate the effect of binaural beamformer strength on speech intelligibility in noise through an objective SRT task comparing three beamformer strengths, including SZ, with experienced hearing aid users with moderate hearing loss.

b. The secondary objective is to investigate the perceived benefit(s) of user steering of the binaural beamformer strength for SIN with experienced hearing aid users with moderate hearing loss.

c. The secondary objective is to investigate the perceived benefit(s) of longer transition time (> 0 sec) for activation of the binaural beamformer through a comparison of multiple transition times with one beamformer strength, with experienced hearing aid users with moderate hearing loss.

# 3 Description of the investigational device

This clinical investigation is intended to further development of the StereoZoom 2.0 feature. This feature will be available in future iterations of the Phonak Audeo hearing devices The overall intended purpose of the device is to amplify and transmit sound to the ear and hereby compensate for impaired hearing.

# 4 Design of the clinical investigation

This interventional study will have 2-3 conditions per task for a sample population of 15-20 human subjects. The order of conditions will be counterbalanced and the participants will be blinded to the conditions.

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

There are minimal risks associated with both the investigational device and participating in the clinical investigation. The device used presents non-significant risk per FDA.
The benefits of participating in the investigation include the benefit of personal satisfaction for participating in research to improve hearing instrument technology. Additionally, subjects will also be compensated for their time in participating in this study.

# 6 Endpoints

Primary endpoint: Subjective ratings of the beamformer strength conditions

• Subjective outcome parameters: 1) Perception of beamformer strength via a 100pt scale of 5pt increments from wide to narrow (0 = wide, 100 = narrow) and 2) Preference of beamformer strength via a 100pt scale of 5pt increments from not preferred to preferred (0 = not preferred, 100 = preferred).

Secondary endpoint: Objective and subjective measures
• Matrix Test outcome parameter: SRT 50%

• User steering of beamformer via a slider in a mobile app outcome parameter: subjectively perceived benefits measured via the grouping of the beamformer setting the user chose alongside their response to two questions:

1) Did you notice a change when moving the slider? (No difference, slight difference, clear difference)

2) Are you satisfied with what you could achieve with the slider? (Not satisfied, somewhat satisfied, definitely satisfied)

• Headphone recordings outcome parameter: Noticeability of beamformer transition in A/B comparisons comprised of 4 transition speeds.

# 7 Inclusion and Exclusion Criteria

Subjects fulfilling all of the following inclusion criteria are eligible for the investigation:
• 18-90 years of age
• Moderate to moderately severe (N3-N4) bilateral sensorineural hearing loss
• Fluent in English; ability to read and write in English
• Willing and able to provide informed consent
• Participants must be experienced hearing aid users with symmetrical hearing loss defined as a difference of ≤ 10 dB between ears an air bone gaps ≤ 10 dB.
• Must be able to use app and smart phone.
The presence of any one of the following exclusion criteria will lead to the exclusion of the subject:
• Self-reported ear-related pathology (otorrhea w/in 90 days, dizziness, sudden hearing loss or worsening of hearing w/in 90 days, otalgia)
• Visible deformity of the ear
• Chronic, severe tinnitus
• Unilateral hearing loss
• Cognitive impairment
•Asymmetrical hearing loss
•Other diagnoses that may cause fluctuations in hearing (i.e. Meniere's)
•Unable to tolerate the physical fit of a RIC device
•Visual impairment that prevents the participant from seeing the adjustment slider in the mobile app
•Inability to be seen for 3 lab visits

# 8 Measurements and procedures

All home-trial data is locally stored on the participant's phone and will be manually extracted via a wired connection during their lab visits after each two week home trial. The extracted data is then saved in a company network drive.

All lab data is collected digitally. There are no paper questionnaires or result sheets in this investigation. The data files are saved in a company network drive after task completion.

All analysis of the results will occur at the conclusion of the study.

# 9 Statistical design and analysis

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.

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

Speech recognition thresholds will be recorded in dB SPL. SRT results will be recorded along with the anonymous participant ID, and task condition. Qualitative data will be collected as a question, response, and anonymous participant ID.

Analysis of the qualitative data will take place at the conclusion of the trial. Data (raw or trans-formed, per above) will be subjected to analysis via linear mixed effects modeling. The model will be constructed to regress (raw or transformed) subjective rating on a dummy variable of condition (fixed effect). This model will allow the investigators to evaluate the relative difference in subjective ratings between the beamformer strengths.

Analysis of the SRT data and qualitative data related to the secondary objectives will take place at the conclusion of the trial, using similar methodology at described above.

# 10 Investigation Duration

Expected duration of each participant's participation is 4-5 weeks.

# 11 Data Handling and Management

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.

Source documents for this investigation include, audiograms, Target fitting files, appointment checklists, data packages extracted from the app, and digital results packages exported from software used to collect data from lab tasks.

Any paper-based data will be stored in a locked filing cabinet at the investigation site. All electronic data will be stored on an access-restricted server owned, operated, and maintained by Sonova USA. Servers used to store data in this investigation are physically located in the US. Permission to access data will be limited to study manager, monitor, PI, and essential research staff, as designated by the principal investigator.

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 misentries 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 de-tailed plan for monitoring arrangements is provided separately from this CIP.

# 12 Amendments to the CIP

If it is necessary to make an amendment to this CIP, the changes to the CIP will be clearly identified with the date the change was made, and the version number will be incremented. Non-substantial amendments (e.g., correcting a typographical error) will be recorded as a mi-

nor version incrementation, whereas substantial amendments (e.g., a change to the study procedure or statistical plan) will be recorded as a major version incrementation. In an emergency situation, this CIP will be amended and updated only after participant health and safety have been assured and FDA/WIRB have been notified (as applicable).

# 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

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

# 15 Informed consent process

Informed consent will be obtained from participants prior to any study participation in accordance with the IRB guidelines. The participants will be granted sufficient time to read through the consent in full and ask any questions they have before signing. After the participant signs the consent form, the researcher will sign and provide a copy to the participant. This process will take place in a private office located in the Phonak Audiology Research Center (PARC). Participants will be incentivized with a monetary stipend of 30 USD per hour spent at the investigation site, plus mileage reimbursement for round-trip travel between the investigation site and their home address. Mileage reimbursement will be calculated based on the shortest driving distance in miles multiplied by the Internal Revenue Service's (IRS) standard mileage rate at the time the study concludes.

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 con-sent until the last protocol-specific procedure, including a safety follow-up period (ISO-14155, 2020). Documentation includes dates of event, treatment, resolution, assessment of serious-ness 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).
The investigator(s) will follow-up on a biweekly basis with any participant experiencing an AE until either a) the participant reports resolution of the AE or b) 8 weeks have passed since the participant's final visit. If, however, the participant's condition worsens throughout the 8

week follow-up period, the investigator will continue to follow-up biweekly until the AE is resolved or the participant's condition stabilizes over an 8 week period.

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

This investigation will not include any vulnerable populations.

# 18 Suspension or premature termination of the clinical investigation

The study will be terminated if the majority of the participants are not able to wear the devices for the study visit.
The study will be terminated if the participants or researchers are exposed to safety risks other than those outlined in this document.

The study may be terminated in the event natural disasters, widespread outbreak of illness, compromised structure of the investigation site, etc. that would make continuation of the study impossible or impractical. The study will be suspended within 5 days of determination that the study or device put participants at an unreasonable risk.

If a participant is suspended, terminated, or withdraws from the study, their data can be traced with their unique study identification number.

According to the FDA, follow-up is required for participants who experience Serious Adverse Events. Follow up will be conducted by the study manager and/or the PI 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 U.S. regulations.
The results of the clinical investigation will be published on clinicaltrials.gov no later than one calendar year following the final participant appointment.
An internal report of the results of this investigation will be completed and uploaded to eQMS.