Study Protocol and Statistical Analysis Plan

Speech Locator In-car Performance Evaluation– ID# SRF-459

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1 Objectives and hypotheses of the clinical investigation

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

The insight on general and individual preferences between the investigational feature and comparator features will be used to determine if and when the investigational feature should be included in an upcoming platform release. The initial clinical evaluation of the development of this feature has been requested by Research & Development.

1.2 Primary and Secondary Objectives

The primary objective of this study is to measure the subjective impression of the investigational feature (using overall impression and listening effort ratings) in 20 experienced hearing aid users with mild to severe hearing loss.

The second objective is to determine if there are any audible artifacts while implementing the feature, and if there are, measure how bothersome they are to the listener.

2 Design of the clinical investigation

2.1 General

2.1.1 Design Type

This is a randomized, double-blinded in-person study with participants serving as self-controls.

2.1.2 Measures for minimizing bias

Bias will be minimized by (1) randomizing stimuli presentation and (2) double-blinding of stimuli through automated playback.

2.1.3 Endpoints with rationale for their selection and measurement

Ratings are expected to be different among different test conditions. An internal evaluation has been completed with normal hearing employees, who reported audible differences for all selected sound dimensions. Rationales for the specific rating dimensions are as the following:

Speech clarity ratings: Participants will be instructed to “Please rate the clarity of speech”. Speech clarity ratings will be measured on a 100-point continuous slider from worst to best (0-Very unclear, 25-Unclear, 50-Slightly clear, 75-Clear, 100-Very clear). Speech clarity ratings are expected to be impacted by how intelligible the speech is. Participants will rate and compare speech clarity between the investigational and comparator features.

Noise annoyance ratings: Participants will be instructed to “Please rate how annoying the noise is”. Noise annoyance ratings will be measured on a 100-point continuous slider from worst to best (0-Extremely annoying, 25-Very annoying, 50-Moderately annoying, 75-Slightly annoying, 100-Not at all annoying). Noise annoyance ratings are expected to be impacted by how bothersome the background

noise in the recordings is. Participants will rate and compare noise annoyance between the investigational and comparator features.

Spatialization ratings: Participants will be instructed to "Please rate your confidence that the talker is in [a location]", with the local being either passenger of rear left. Spatialization ratings will be measured on a 100-point continuous slider from worst to best (0-I don't know where the talker is, 25-The talker might be to my [location], 50-The talker is probably to my [location], 75-The talker is to my [location], 100-The talker is definitely to my [location]). Spatialization ratings are expected to be impacted by how well the recordings preserve spatial perception. Participants will rate and compare spatialization between the investigational and comparator features.

Overall impression ratings: Participants will be instructed to "All things considered, please rate overall preferences". Overall preferences ratings will be measured on a 100-point continuous slider from worst to best (0-Bad, 25-Poor, 50-Fair, 75-Good, 100-Excellent). Overall impression ratings are expected to be impacted by participants' overall preferences for the different stimuli. Participants will rate and compare overall impression between the investigational and comparator features.

Transition annoyance ratings: Participants will be instructed to "Please rate how annoying the transitions are". Transitions annoyance ratings will be measured on a 100-point continuous slider from worst to best (0-Extremely annoying, 25-Very annoying, 50-Moderately annoying, 75-Slightly annoying, 100-Not at all annoying). Transition annoyance ratings are expected to be influenced by presence of unexpected sounds or transitions that occur in different microphone modes and different listening situations. Participants will rate and compare transition annoyance between the investigational and comparator features.

2.2 Procedures

2.2.1 Investigation-related Procedure

Participant eligibility is determined based on case history on file. The case history consists of audiograms, etiology of hearing loss, other medical information, and personal details like age, gender, contact information, occupation, hobbies, etc. Case history information is gathered prior to the study and as a part of database management, which is a separate process from this investigation.

Participants will be screened for the study using an outreach email and/or call. After successful completion of screening, participants will sign the consent form and complete the demographic questionnaire upon arrival for their first session.

2.2.2 Sponsor activities

Study sponsor is responsible for participant recruitment, assessment, data collection, analysis and monitoring.

2.2.3 Outcome comprising factors

Participants need to meet the hearing loss criteria in order to judge the differences in the recordings for the targeted hearing loss group. If participants cannot tolerate the loudness of the output, they could miss these differences. Therefore, we will recruit only experienced hearing aid wearers.

Participants need to be tech-savvy to the extent that they are comfortable operating the subjective HPP tool using a touchscreen interface, keyboard and/or mice. We will ask for their ability to do so during the screening call. If problems arise during the study session and support cannot solve the issue, the participant will be withdrawn from the study.

Subjective ratings often are not as sensitive as objective outcome measures because participants need to pay attention to small differences. The sound samples have been selected with regards to representation of scenes in which the hearing aid processing produces audible differences. Questions will be formulated in a way that draws participants' attention to the anticipated area of focus (i.e. speech, talker location, microphone mode)

3 Statistical design and analysis

3.1 Determination of Sample Size

We will recruit up to 25 participants, including up to 5 pilot participants. Previous research with subjective ratings has repeatedly shown that data collected with 15-25 participants can yield significant results.

3.2 Statistical criteria of termination of trial

If the results are significant after 15 participants have completing the protocol, we will consider terminating the data collection.

3.3 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. Recall that participants will be completing three repetitions of each stimulus. Repetitions will be averaged within each participant prior to analysis. Reliability within each participant will also be assessed to determine if that participant's data should be included the analysis.

- Repeated-measures analysis of variance (RM-ANOVA) to detect significant effects
- Post-hoc pairwise comparisons to locate the source of significant effects

3.3.1 Datasets to be analyzed, analysis population

- Analysis population: 15-25 participants
- Evaluation group: rating per setting
- Data sets: subjective ratings
- Additional analyses:
    - Individual preferences and their potential dependences, such as hearing loss,

3.3.2 Primary Analysis

The study manager will analyze the collected data set in R Statistics after the data collection is completed. Microsoft Excel and MATLAB may be used for arranging data and plotting data sets.

3.3.3 Secondary Analysis

The study manager will analyze the collected data set in R Statistics after the data collection completed.

3.3.4 Interim Analysis

The study manager will analyze the collected data set in R Statistics in real time as the data collection is completed. Microsoft Excel and MATLAB may be used for arranging data and plotting data sets.

4 Informed consent process

4.1 Process for obtaining informed consent

Participants are required to sign a consent form prior to participation in the study. The consent form will be provided at the time of their first appointment and relevant tick boxes for this particular study will be noted. Participants will consent by writing their names and signature and will include the name of the researcher obtaining consent. The document will be converted into a PDF and will be uploaded into the database. The paper form will be stored in a secured cabinet only accessible by the researchers.