Study Protocol and Statistical Analysis Plan

Clinical Study of Released Unitron RIC and
BTE Hearing Aid Models – ID# 515

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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

This clinical study intends to show that compared to the unaided condition, the released Unitron RIC and BTE hearing aid models provide amplification that will improve speech intelligibility when programmed for individual hearing losses. The study (and the resulting clinical data) will support the clinical benefit claim: “improved speech understanding” necessary to update the CER which is necessary for the CE submission. The claim will not be use externally or in any marketing material.

1.2 Primary and Secondary Objectives

The primary objective of this study is to confirm the improvement in the speech understanding with the released Unitron RIC and BTE hearing aid models in 20-25 participants with mild to severe hearing loss in a sound room/lab setting; testing will be performed with a standardized speech discrimination test – HINT in noise and the data will be collected during one-time visit.

2 Design of the clinical investigation

2.1 General

2.1.1 Design Type

This is a confirmatory study using a single group, unblinded in a single site. The data will be collected during one-time visit and results for each form factor will not be compared against each other but only against the unaided condition.

2.2 Procedures

2.2.1 Investigation-related Procedure

Participants will be selected from the existing database and based on their hearing loss; inclusion/exclusion criteria will be discussed. If necessary, an updated hearing test will be conducted prior to the start of data collection. Participants will be contacted via email and/or call to set up a time for the one-time visit. During the visit, participants will sign the consent form, they will be fit with the released Unitron RIC and BTE hearing aid models, and perform the HINT test in the sound room for the three study conditions: unaided, aided with RIC, and aided with BTE.

3 Statistical design and analysis

3.1 Determination of Sample Size

Although we have no prior data showing an estimated mean difference between unaided and aided conditions, we looked at the literature to estimate aided vs unaided benefit.

Valente & Mispagel (2008) investigated unaided and aided (Omni and Directional) HINT performance in adults with a sloping normal to moderately-severe SNHL. Results had shown that aided-directional HINT performance was significantly better than both unaided or aided-omni

conditions. The mean difference (1.7 dB) and SD (2.4) between unaided and aided-directional performance were used for the power analysis and ultimately calculating sample size.

Power Analysis was done using the G*Power Software (Faul et al., 2007). Power analysis was done for a one-tailed dependent t-test between two means. The table below list the input parameters used to calculate sample size.

Input parameters	Output parameters
• Mean of differences: 1.7 • SD of differences: 2.4 • Effect size dz: 0.708 • Alpha=0.05 • Power=0.95	• Non centrality parameter: 3.40 • Critical t: 1.72 • Actual power: 0.95 • Df: 22 • **Total sample size: 23**

Based on the above calculations, it was determined that a minimum of 23 participants will be required based on a power analysis using arms-length data.

3.2 Statistical criteria of termination of trial

There is no statistical criteria that would cause termination of the trial.

3.3 Planned Analysis

The data analysis will be done upon completion of data collection. A one-tailed t-test will be done as part of the analysis.

3.3.1 Datasets to be analyzed, analysis population

- Analysis population: 20-25 participants
- Data sets:
    - Unaided vs. aided with RIC.
    - Unaided vs. aided with BTE.

3.3.2 Primary Endpoint Analysis

The data will be entered in a Microsoft Excel spreadsheet for analysis. The statistician assigned will analyze the data to determine statistical significance between conditions if present.

3.3.3 Secondary Endpoint Analysis

Non applicable.

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 forms will be stored in a secured cabinet only accessible by the researchers.