

Study Protocol and Statistical Analysis Plan

AutoFocus360 Sound Quality Preference and Claims Study (AF360)

February 18, 2026

NCT07224919

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 purpose of this study is to produce evidence for claims substantiation for the feature called AutoFocus 360.

1.2 Primary and Secondary Objectives

The primary objective is to determine if participants with hearing loss prefer AutoFocus 360 (AF360 - intervention) over Fixed Wide Directional (FWD - control) in terms of sound quality for the attribute “noise disturbance” for speech in competing noise coming from multiple directions relative to the listener during a 2-hour study session.

The secondary objective is the same as the primary objective, except that preferences will be assessed for the sound quality attribute “speech clarity”.

2 Design of the clinical investigation

2.1 General

2.1.1 Design Type

This is a randomized, double-blinded in-person study. AF360 will serve as the investigational condition and FWD will serve as the comparator condition.

2.1.2 Measures for minimizing bias

Bias will be minimized by double-blinding and counter balancing sound quality attribute order between participants.

2.1.3 Endpoints with rationale for their selection and measurement

Sound quality preferences will be gathered using A-B paired comparisons. In this task, participants are asked to perform pairwise comparisons between two (A and B) stimuli. In each pair, participants listen to A and B and indicate whether they prefer A or B in terms of noise disturbance (primary endpoint) and speech clarity (secondary endpoint).

Paired comparisons are considered most sensitive to subtle differences over other sound quality assessment methods (Amlani & Schafer, 2009), which is of particular importance for the conditions under test due to their subtle acoustic differences.

Noise disturbance is considered the primary objective because differences in noise levels tend to be the most apparent difference between AF360 and FWD conditions based on pilot and bench testing. Speech clarity is considered the secondary objective because speech clarity may change due to changes in SNR on account of differences in noise levels. While differences in noise levels will produce changes in SNR, the magnitude of SNR changes may not produce perceptible differences in speech clarity. Therefore, there is a higher likelihood of observing differences in noise disturbance, hence the probability of preference in terms of noise disturbance is assigned as the primary endpoint, while the probability of preference in terms of speech clarity is the secondary endpoint.

2.2 Procedures

2.2.1 Investigation-related Procedure

Session 1:

During session 1, participants' health information will be updated if it has been more than one year since their last assessment. Their information will be updated by reassessing their case history, otoscopy, air conduction thresholds, bone conduction thresholds, and tympanometry.

Between sessions:

In between study sessions, the researcher will record study samples. Samples will be recorded using this procedure:

- 1) Calibration of recording set-up
- 2) Fitting of hearing aids to individual audiogram
- 3) Creating two programs; each with AF360 or FWD enabled
- 4) Placing hearing aids on KEMAR mannequin
- 5) Recording of study samples
- 6) Uploading samples to unique SoundSurvey link for the respective participant.

Session 2:

During session 2, participants will conduct A-B paired comparisons between AF360 and FWD for all combinations of the other factors. Given talker location (x4) and noise type (x2), there are 8 unique combinations by which to compare AF360 and FWD.

Participants will listen to each unique comparison twice – once while rating the “noise disturbance” sound quality attribute (primary endpoint) and again while rating the “speech clarity” sound quality attribute (secondary endpoint), for a total of 16 unique combinations if considering sound quality attributes.

Finally, accounting for down-time and breaks (up to 30 minutes), there may be up to 90 minutes of testing time. Estimating 30 seconds per comparison allows for a total of 180 sound quality comparisons. A total of 16 unique combinations allow for 11 repetitions of each unique combination in a 90-minute session. One of those repetitions will be used for training whereas the remaining 10 repetitions will be used as official study data.

2.2.2 Sponsor activities

The study sponsor is responsible for the following:

- participant recruitment
- provision of study equipment, assessment
- data collection, analysis, reporting and monitoring
- Training to all investigators on the investigative devices and associated accessories or software.
- Training to all investigators on the protocol (CIP), CRFs, Adverse Event/ Device Deficiency Forms and other required documents necessary for the maintenance of the TMF and ISF.
- Categorization of Adverse Events regarding causality and seriousness.

- Assessment of Device Deficiencies regarding their potential to lead to a Serious Adverse Device Effect.
- Registration of study in ClinicalTrials.gov and input of results at conclusion of study.

2.2.3 Outcome comprising factors

Participants need to meet the hearing loss criteria to listen to the recorded samples. If participants cannot tolerate the loudness of the stimulus presentations, they may be unable to complete the study task and will be withdrawn from the study.

3 Statistical design and analysis

3.1 Determination of Sample Size

The sample size calculation is based on the primary endpoint which is the probability of preference in terms of noise disturbance for speech in competing noise coming from multiple directions relative to the listener. The probability of preference will be evaluated using a generalized linear mixed effect model (GLMM) with a logit link function. The model will include fixed effects for the microphone mode (AutoFocus 360, Fixed Wide Directional), noise type (speech-shaped, cafeteria) and talker location (front, left, rear, right), as well as random effects for participants to account for within-subject correlation. The effect size of interest is estimated from a pilot study conducted with normal hearing participants, which showed a log-odds ratio of 5.08 for the preference of AutoFocus 360 over Fixed Wide Directional in terms of noise disturbance.

To estimate the approximate statistical power for a given sample size, monte carlo simulations have been run based on the model from the pilot data. The resulting statistical power is calculated as the percentage of significant tests out of the total number of successful runs. Therefore, 15 participants are needed to achieve statistical power over 90% even if the effect size is reduced to 50% and the variation between subjects is increased to 2 times.

3.2 Statistical criteria of termination of trial

No apriori statistical criteria will be used to determine the termination of the trial.

3.3 Planned Analyses

3.3.1 Datasets to be analyzed, analysis population

All participants are exposed to the same intervention. As such, all participants will be treated as single cohort for analysis.

Intent-To-Treat set (ITT)

All enrolled participants will be included in the ITT analysis for the primary, secondary and exploratory endpoints.

3.3.2 Primary Endpoint Analysis

The probability of preference in terms of noise disturbance is defined as the primary endpoint for this study. Generalized linear mixed effect model will be used to evaluate the difference between AutoFocus 360 and Fixed Wide Directional. The model will include fixed effects for the microphone mode, noise type and talker location, as well as random effects for participants to account for within-subject correlation. The efficacy will be claimed when there is a significant difference between AutoFocus 360 and Fixed Wide Directional with significance level of 0.05 and AutoFocus 360 is preferred to Fixed Wide Directional.

3.3.3 Secondary Endpoint Analysis

The probability of preference in terms of speech clarity is defined as the secondary endpoint for this study. The secondary endpoint will be analyzed only if there is significance in primary

endpoint. Generalized linear mixed effect model will be used to evaluate the difference between AutoFocus 360 and Fixed Wide Directional. The model will include fixed effects for the microphone mode, noise type and talker location, as well as random effects for participants to account for within-subject correlation. The efficacy will be claimed when there is a significant difference between AutoFocus 360 and Fixed Wide Directional with significance level of 0.05 and AutoFocus 360 is preferred to Fixed Wide Directional.

3.3.4 Interim Analysis

There is no interim analysis planned for this study.

3.3.5 Safety Analysis

Adverse events and serious adverse events will be reported in the clinical investigation report.

3.3.6 Deviation(s) from the original statistical plan

The description of all deviations from the original statistical plan will be provided in the clinical investigation report including proper justification.

3.4 Handling of missing data and drop-outs

No statistical techniques will be used to impute missing data. If a subject's data is missing for any reason, that subject will not be included in that portion of the analysis. The number of subjects included in the analysis will be reported so that the impact of missing data can be assessed.

4 Informed consent process

4.1 Process for obtaining informed consent

Participants are required to sign a consent form prior to participating in the study. The consent form with the name and signature of the person obtaining consent will be provided to participants upon arrival to their first session. Participants are asked to review the entirety of the form and ask questions about the content in the form, if any. Participants consent to participate in the study by signing the form.