Admin. Note: This document describes the Study Protocol and Statistical Analysis Plan for the study "Wear-Time Trial for Self-Fitting Hearing Aid" (NCT04823494, ID: X-Men)

Laboratory Study and Wear-Time Trial for Self-Fitting Hearing Aid

CLINICAL INVESTIGATION PLAN

TITLE	Laboratory Study and Wear-Time Trial for Self-Fitting Hearing Aid
PROTOCOL/STUDY NO.	0001
VERSION	1
DATE	03AUG2021
INVESTIGATIONAL DEVICE	Jabra Enhance Plus
SPONSOR	**GN Hearing A/S** Lautrupbjerg 7 DK-2750 Ballerup Denmark Registration number: 3005650109 **Contact person:** Lars Hagander **Tel:** +45 4575 1111 **Fax:** +45 4575 1119 **E-mail:** lhagander@gnresound.com
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AUTHORS AND EXPERTS	Larry E. Humes, Ph.D.; Marie Schroeder, M.S.
COMPLIANCE	The Protocol and clinical investigation are performed in accordance with International Standard (ISO) 14155, the Declaration of Helsinki, and local and national law.

CIP PURPOSE **Study Title: Laboratory Study and Wear-Time Trial for Self-Fitting Hearing Aid**; Protocol version 1.3b; Final dated 03-AUG-2021.

This CIP will serve to further clarify and specify details related to the existing contracts and statements of work between Vanderbilt and GN Hearing, Northwestern and GN Hearing, and Sertoma Speech and Hearing Center and GN Hearing. Specifically, it will help ensure that the IRBs, and research protocols across Vanderbilt and Northwestern are consistent with each other and the general protocol developed in collaboration with GN Hearing.

Copies of this protocol will be disseminated to all site-specific research personnel and the IRB protocols will be completely consistent with the detailed protocol described herein.

Since the information in this protocol is confidential, it will not be disclosed to any third parties, other than those involved in approval, supervision, or conduct of the study.

TABLE OF CONTENTS

DOCUMENTATION AND VERSION CONTROL

Pursuant to U.S. 21 CFR 812.140 and ISO 14155 GCP requirements, this section records all changes made to the protocol for a specific study. In the table below, relevant changes to controlled versions of the protocol are recorded.

Revision	Date (DDMMMYYYY)	Revision Author, Organization	Comments/Changes
1.0	04JUL2021	Larry Humes, Consultant	Initial Release
1.1	06JUL2021	Larry Humes, Consultant	Inclusion Criteria revised
1.2	09JUL2021	Larry Humes, Consultant; and site Investigators Ricketts & Dhar	Reconciliation of CIP with protocol and contracts
1.2d	18JUL2021	Larry Humes	Added scales for phone use and music listening
1.2e	21JUL2021	Larry Humes, Carol Sammeth	Adopted Carol's edits and updated device name
1.2f	23JUL2021	Larry Humes, Carol Sammeth, Marie Schroeder	Edits re: addition and use of User's Manual in study; edits of company info
1.3	24JUL2021	Larry Humes, Carol Sammeth, Marie Schroeder	Incorporated edits from CS and MS
1.3a	27JUL2021	Larry Humes	Added minor edits from TV and TR
1.3b	03AUG2021	Larry Humes	Changed from 2 to 3 sites

STUDY SYNOPSIS

Full Study Title:	Laboratory Study and Wear-Time Trial for Self-Fitting Hearing Aid
Classification:	Pre-market clinical investigation
Type of Study:	There are two components to this study. For the first, an in-lab session, a repeated-measures design is used to assess the reliability and validity of the self-fitting method. For the second, a wear-time trial, a cross-over design is used with 10-14 days of wear time for each segment of the field trial.
Device Regulatory Status:	Jabra Enhance Plus is an investigational device
Significant / Nonsignificant Classification:	Non-Significant Risk Study (Abbreviated IDE regulations apply, 21 Code of Federal Regulations Part 812)
Number of Patients:	N=36
Duration of Patient Participation:	20-24 weeks (3-5 weeks per patient)
Patient Population	Adults, 18-75 years, with mild-to-moderate sensorineural hearing loss
Number of Sites:	3
Duration of Study:	Approximately 90 days
Background and Rationale:	Self-fitting hearing aids represent an FDA device classification that was recently created while implementation of the Over the Counter Hearing Aid Act by the FDA is in progress. These devices are designed for adults with perceived mild-to-moderate hearing loss and the fitting is largely driven by the wearer. This trial seeks to establish the reliability and validity of GN Hearing's self-fitting process, as well as the safety and efficacy of the device, for the company's first self-fitting hearing aid, Jabra Enhance Plus.
Purpose:	To establish the reliability, safety and effectiveness of GN Hearing's fitting process and self-fitting hearing aid, Jabra Enhance Plus.

Primary Effectiveness Objectives/Endpoints:	- *For the effectiveness component of the immediate in-lab session comparisons*, Real-Ear Aided Gain (REAG) will be measured using both an audiology-best-practices hearing aid fitting (PRO-FIT) and a self-fitting method (SELF-FIT).
	  ○ Success criterion is defined as SELF-FIT REAG is equivalent to PRO-FIT NAL-NL2 prescription REAG targets based on the average real-ear aided gain at 500, 1000, 2000 and 4000 Hz.
	- *For the reliability component of the immediate in-lab session comparisons*, Real-Ear Aided Gain (REAG) will be measured twice (A, B) using the SELF-FIT method.
	  ○ Success criterion is four-frequency average REAG for SELF-FIT B is equivalent to the REAG for SELF-FIT A
	- *For the effectiveness of the wear-time crossover field trial*, the Abbreviated Profile of Hearing Aid Benefit (APHAB) will be measured

	following both an audiology best-practices hearing aid fitting (PRO-FIT) and a self-fitting method (SELF-FIT). o Success criterion is defined as SELF-FIT APHAB global score is non-inferior to PRO-FIT APHAB global scores following completion of the wear-time field trial.
Secondary Effectiveness Objectives/Endpoints:	- *For the effectiveness component of the immediate in-lab session comparison*, aided Quick Speech-in-Noise test (QuickSIN) performance will be compared between SELF-FIT and PRO-FIT. o Success criterion is the SELF-FIT QuickSIN speech-recognition threshold in noise (signal-to-noise ratio, SNR) is equivalent to that of PRO-FIT. - *For the reliability component of the immediate in-lab session comparison*, QuickSIN performance will be measured twice (A, B) using the SELF-FIT method to assess test-retest reliability. o Success criterion is QuickSIN thresholds are equivalent for SELF-FIT A and B. - *For the effectiveness of the wear-time crossover field trial*, QuickSIN performance will be compared between SELF-FIT and PRO-FIT. o Success criterion is defined as SELF-FIT QuickSIN SNR is equivalent to PRO-FIT QuickSIN SNR following completion of the wear-time field trial.
Primary Safety Objectives/Endpoints:	Tabulations of Adverse Events (AEs) and Serious Adverse Events (SAEs). o Success criterion is no recorded device-related AEs or SAEs.
Inclusion Criteria:	An initial telephone or internet screening of interested persons will take place. • During this remote screening, prospective subjects will provide their age (subject to verification at Visit 1) and answer a Yes/No question as to whether they have trouble hearing in noise. Those answering "No" will not be considered further for enrollment. • Those answering "Yes" will then be asked to describe their perceived hearing loss on a 4-point scale (no trouble, a little trouble, a lot of trouble, and cannot hear). Prospects answering at the two extremes will not be considered further for this study. • Those answering "a little trouble" or "a lot of trouble" will be invited to the in-person Screen that immediately precedes hearing aid fittings in Visit 1. To be eligible to participate in this study, an individual must meet all of the following criteria:

	• Mild-to-moderate bilateral sensorineural hearing loss (thresholds from 250 – 8000 Hz with at least one threshold greater than 20 dB HL and thresholds at 500, 1000, 2000 and 4000 Hz less than or equal to 55, 65, 70, and 80 dB HL, respectively) • Mix of male and female subjects (aiming for a representative balance) • Mix of prior hearing-aid use (aiming for 70-80% persons with no prior hearing aid use) • 18-75 years old (aiming for primarily 50-70 years old, with avg. age ~65 years) • Able to read and comprehend English • Patient willing to provide informed consent
Exclusion Criteria:	An individual who meets any of the following criteria will be excluded from participation in this study: • Hearing outside of limits noted above • Self-reported ear-related pathology (including chronic severe dizziness or chronic severe tinnitus)
Sampling Frame:	The proposed sample size of n=36 subjects will be sufficient to rule out a null hypothesis of non-equivalence of SELF-FITSs A and B (reliability) or SELF-FIT A and PRO-FIT (validity) with about 80% power with 0.05 significance level. In addition, distributions of deviations from the standard-of-care measures will be generated for the primary and secondary measure and for the reliability and validity components of the study.
Statistical Considerations:	A statistical test of hypothesis of whether the primary effectiveness endpoint is equivalent to the standards observed in professional fits for both the reliability and validity components of the study. The mean absolute values of the differences between test-retest for the SELF-FITs and between the SELF-FIT and PRO-FIT will be reported by visit.

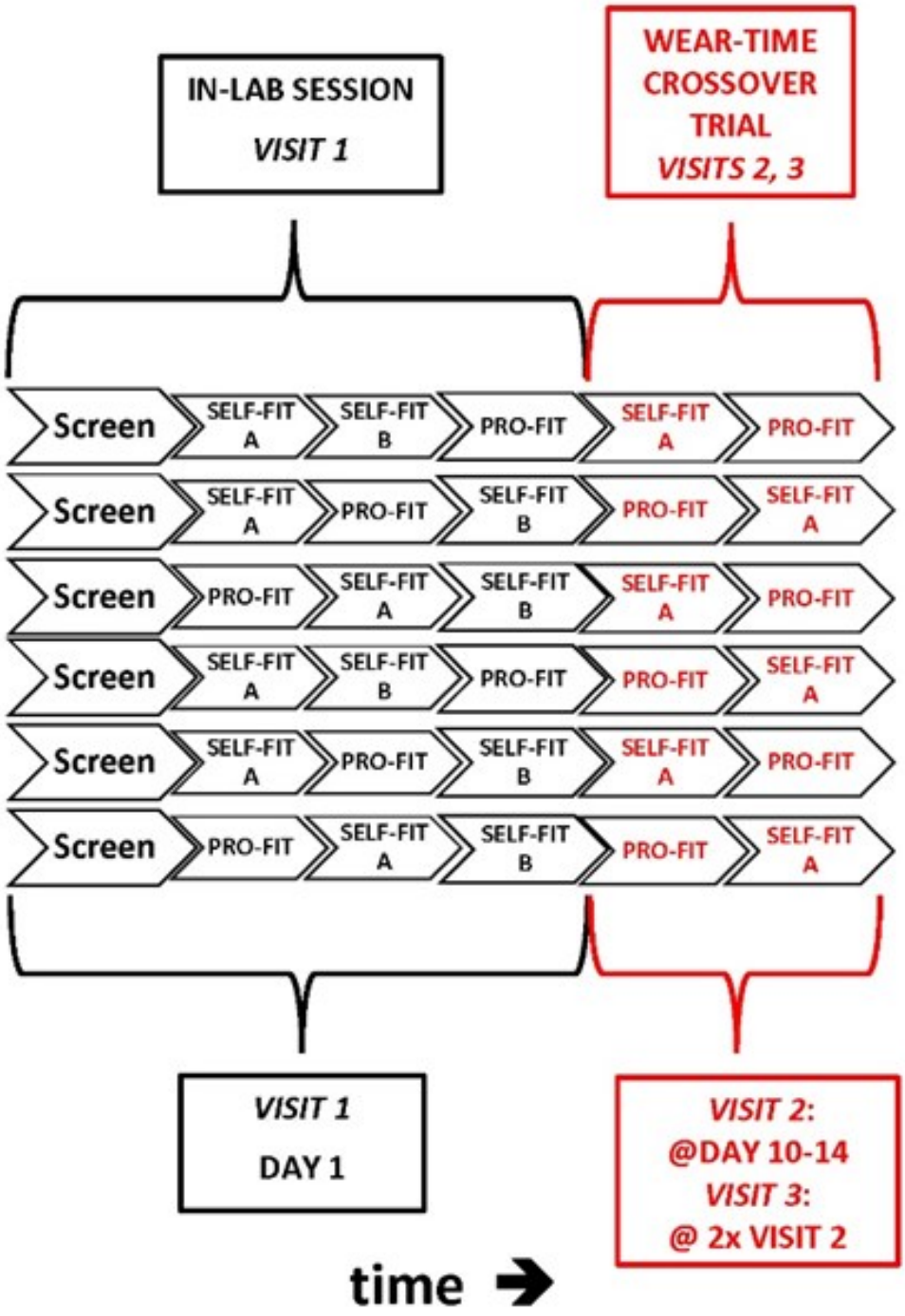


Figure 1. Study Flow

1.0 PRELIMINARY INVESTIGATION AND JUSTIFICATION

1.1 Introduction

The objective of this pivotal study is to establish the reliability and validity of the fitting process to be used for GN Hearing's Jabra Enhance Plus device. The Jabra Enhance Plus is a prototype self-fitting hearing aid. The study will also evaluate safety and effectiveness of the Jabra Enhance Plus device using acoustical measures of gain and output, behavioral measures of benefit, and other measures of device safety which are standard in the hearing-aid industry.

1.2 Background

Self-fitting hearing aids are designed for adults with perceived mild-to-moderate hearing loss and the fitting is largely driven by the wearer. This trial seeks to establish the reliability and validity of GN Hearing's fitting process for the company's first self-fitting hearing aid, Jabra Enhance Plus, and the safety and efficacy of the device.

1.3 Non-Clinical Testing

Non-clinical software verification and validation testing was conducted for the Jabra Enhance Plus device, which evaluated the device software elements. All elements passed the verification and validation testing regarding the test method, expected result, and actual result. No bugs were detected that were associated with either safety or effectiveness of the system.

1.4 Previous Clinical Experience

No prior clinical studies were performed for the Jabra Enhance Plus device. GN Hearing, however, has extensive experience conducting clinical investigations of the effectiveness and safety of conventional hearing aids and other ear-worn audio devices.

1.5 Device Risk Analysis

1.5.1 Anticipated Clinical Benefits

The Jabra Enhance Plus device will provide measurable acoustic gain and, therefore, is expected to improve the auditory function of the wearer as measured behaviorally using a combination of speech-in-noise measures and self-report benefit measures. The individual participant will experience these benefits personally, but there is also a greater general benefit to all adults with mild-to-moderate hearing loss by establishing the effectiveness and safety of the Jabra Enhance Plus device. The purchase price and access to the device are envisioned to be much less burdensome than conventional hearing aids currently available to adults with mild-to-moderate hearing loss.

1.5.2 Anticipated Adverse Effects

1.5.2.1 Potential risks related to using Jabra Enhance Plus as a treatment vs. standard of care

Compared to the standard-of-care fitting, the only anticipated risks involve the improper self-selection of device settings such that either too little or too much gain will be selected. The maximum possible gain, however, has been limited to minimize the risk to hearing from device use.

1.5.2.2 Potential risks associated with patient population

Because the app used to fit and control the device requires some familiarity with such apps, the user may experience some frustration when initially learning how to fit and control the device.

1.5.2.3 Possible interactions and concomitant treatments

Because both new and experienced hearing aid users are to be included, experienced user may be frustrated with the differences between the Jabra Enhance Plus device and their own hearing aids, including differences in sound quality and adjustment.

1.5.3 Risk/Benefit Rationale

The risks of the Jabra Enhance Plus device are based on data collected in an early feasibility clinical study conducted by GN and are considered minimal. During that feasibility study, no device-related adverse events were observed.

The potential benefits of the Jabra Enhance Plus device far outweigh the possible risks. Hearing aids are the treatment of choice for adults with mild to moderate hearing loss, yet most estimates indicate that only 20-30% of those who could benefit from hearing aids actually purchase them. The primary limitations to purchase pertain to the high cost and low accessibility of conventional hearing aids. Self-fitting hearing aids provide a more affordable and accessible path to good hearing healthcare for millions of adults with mild to moderate hearing loss. These claims are also based on data collected in the early feasibility studies using a previous device version. The benefits of the device include: i) lower device cost to the end user; ii) greater sense of self-control of treatment options through the self-fitting process; iii) no cost of changes to hearing aid settings or fitting.

1.5.3.1 Clinical Relevance of Endpoints

For the in-lab session, the primary effectiveness endpoint will be assessed by the differences in acoustical real-ear aided gain (REAG), a gold-standard measure for the acoustical function of hearing devices for the study population. This endpoint will be used to assess mean absolute-value differences between two replications of the SELF-FIT method (reliability) and between the SELF-FIT and PRO-FIT methods (validity or effectiveness).

For the wear-time trial, the primary outcome measure is a widely used clinical self-report measure of benefit (Abbreviated Profile of Hearing Aid Benefit, APHAB). The APHAB is also a gold-standard, validated assessment of hearing aid benefit relevant for the study population.

Secondary effectiveness endpoints for both the laboratory and field-trial components will be assessed by a standardized measure of speech communication in noise, the QuickSIN. This is a widely used clinical measure of an adult's ability to understand speech in noise and is closely tied to the wearer's primary complaint of difficulty communicating in noise.

Overall study success will be defined by meeting all primary endpoints for the reliability, effectiveness, and safety of the devices and the self-fitting process in the laboratory and field-trial components of this study. Effectiveness outcomes from the SELF-FIT process should be

equivalent to those of the PRO-FIT method in the in-lab session and non-inferior to PRO-FIT in the wear-time trial for the study to be considered successful.

2.0 INVESTIGATIONAL DEVICE DESCRIPTION

2.1 Identification and Description of the Investigational Device

The Jabra Enhance Plus (also called simply the “Earbuds”) is designed to compensate users perceived mild to moderate hearing loss without the aid of a hearing care professional in the fitting of the device. The Earbuds are provided with a dedicated smartphone application, also named Jabra Enhance, and dedicated Charger.

Using the dedicated smartphone application, the Earbud settings are customized based on an initial self-fitting workflow and user preferences. The user can monitor and control the Earbuds, amplify environmental sounds through the Earbuds, and wirelessly stream audio to the Earbuds. The Earbuds are used with mobile devices through the dedicated smartphone application and a standardized Bluetooth Low Energy (BLE) connection.

The Earbuds are designed to be discrete, but stylish, and are made from premium materials for high wearing comfort for longer periods of time. They are dust and liquid resistant. The Earbuds can be personalized with respect to sound settings and have a push button for control. Sound setting changes can be made directly from the smartphone application. Connectivity-wise, the Earbuds allow for:

- Communication to and from the smartphone application, for:
    - The self-fitting process.
    - Limited fine-tuning adjustments in the form of spectral tilt options.
    - Controls (including volume control and microphone directionality control).
    - Battery / charging state, which is sent to the smartphone application.
    - Firmware updates, which are downloaded from the Internet Cloud to the smartphone and applied to the Earbuds.
- Ear-to-ear communication between the Earbuds for sending relevant control data.
- Streaming of audio (e.g., phone calls) from mobile devices.
- Own voice pickup for phone calls, i.e., traditional hands-free headset functionality.
- Push to talk.
- Connection to the Charger for transmission of charging and battery status to the smartphone application.

The App allows for several different functions:

- Self-fitting of the Earbuds.
- Control of the Earbuds, including volume and spectral tilt options.
- Status monitoring, such as status of the battery and connection to the Earbuds.

The Charger has a stylish appearance, and functions as a carrying case. The Charger itself is rechargeable, such that it can be used without having it plugged into a power source, which can be beneficial for instances when an outlet is not available, e.g., during travel.

2.1.1 Device Instructions

The Jabra Enhance Plus is intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. It is adjusted by the user to meet the

user's hearing needs. No pre-programming or hearing test is necessary. The device is intended for direct-to-consumer sale and use without the assistance of a hearing care professional.

2.1.1.1 Pair Devices

The flow for pairing of Earbuds for the first time is shown in Figure 2. These instructions will be available to the user in written form with illustrative pictures.

Figure 2. Pairing flow for the Earbuds.

Steps for device pairing are as follows:

- The user is instructed to activate the Earbuds and Charger by powering up the charger (with the Earbuds inserted) using the USB cable. This will wake the Charger and the Earbuds from shipping mode.
- The user is instructed to take both Earbuds out of the Charger, keeping them next to each other, and then the LEDs will flash blue.
- The left and the right Earbuds will now enter pairing mode, and they will pair to each other, i.e., ear-to-ear pairing. The ear-to-ear pairing can only take place in the first two minutes after the Earbuds are taken out of the Charger. For the field trial, the ear-to-ear pairing is already set up.
- After the ear-to-ear pairing is established, both Earbuds will now be visible for the smartphone, i.e., smartphone discovery mode. The smartphone discovery window is open for three minutes after the Earbuds are ear-to-ear paired.
- The user is instructed to leave the App and go to the smartphone (iPhone) settings to establish the pairing of the Earbuds to the smartphone.
- If the pairing to the smartphone is established, the LEDs on both Earbuds will light up solid blue for a few seconds to indicate that pairing is done.
- A pairing melody will be played in both devices to indicate that pairing is established. This is the traditional pairing melody already used in GN legacy hearing instruments.

2.1.1.2 Self-fit devices

The Earbuds can be fitted by the user directly, using the dedicated fitting feature on the smartphone App. Before the self-fitting can be started on the smartphone, several things need to be in place:

- The smartphone App must be installed, a trusted bond must be established, and terms, conditions and consent must be acknowledged in the smartphone App. The user will then be directed to the self-fitting feature.
- Earbuds need to be powered on, ear-to-ear paired, and paired with the smartphone (per instructions above).
- During the self-fitting, the broadband level of background environmental noise is monitored by the Earbuds. If the noise level is too loud, the user is instructed to repeat the self-fitting in a quieter environment.

The user initiates the self-fitting flow via the App. The Earbud presents the user with a series of tones and the user marks the App on the smartphone screen to indicate when/if a tone is heard. Based on the user's responses to these tones, initial gain settings are applied according to the NAL-NL2 fitting algorithm. This self-assessment of hearing loss does *not* provide the user with feedback about accuracy of their responses, nor does it provide the user with a diagnosis or information about their hearing loss. The information obtained during this process is used only internally to fit the device to the NAL-NL2 prescribed gain by frequency in each ear. Based on the initial prescribed gain, the user will subsequently be given the option to choose between two alternative gain settings, i.e., limited adjustments of the spectral tilt based on their preference while listening to a streamed sound file. The spectral tilt option that is selected can also be changed at any time during device use, from the settings menu.

If the Earbuds are powered on for the first time, i.e., no fitting has been done, the Earbuds will start up with basic settings, and with a small amount of linear gain. User controls and streaming are prohibited until after the self-fitting process has been done.

2.1.1.3 Fine-tune devices

An important element with the GN Earbuds is the possibility, after the initial fitting is complete, to fine-tune the devices from the smartphone application. Although there are some differences with respect to the fine-tuning features, the vehicle which is used (standard features, volume control, etc.), will be similar to GN legacy hearing instruments currently in commercial distribution in the U.S.

Features that can be set from the home screen of the smartphone application include overall volume and three frequency responses.

2.1.1.4 Remote firmware update

The firmware in the Earbuds can be updated, e.g., to strengthen cybersecurity. A message can be pushed from the Cloud to the smartphone App that an update is available. The update can then be applied.

2.1.1.5 Charge devices

The Earbuds are charged with a dedicated Charger. Charging will not take place wirelessly but will take place via a physical connection over Pogo contact pins in the Charger.

2.1.2 Device Treatment Description

Millions of Americans experience communication and listening difficulties resulting from mild-to-moderate hearing loss. Hearing aids represent the primary treatment for these individuals. The conventional best-practices approach to treatment for such individuals has been to consult with one or more healthcare professionals for assistance in determining candidacy and acquiring hearing aids. It has been estimated that only 20-30% of adults with such difficulties seek and obtain hearing aids within the existing treatment model. The Jabra Enhance Plus (also called simply the “Earbuds” here) is designed to compensate users perceived mild-to-moderate hearing loss without the aid of a hearing care professional in fitting of the device.

2.1.2.1 Device Treatment Examples

This product is designed to help individuals 18 years of age or older with perceived mild to moderate hearing impairment and who may:

- Strain to follow conversations in noisier environments
- Miss important information during conversations
- Have trouble hearing at a distance
- Have trouble understanding the TV or telephone calls

2.1.2.2 Additional features

- Enhanced hearing for clearer conversations and music
- Optimized sound for different environments
- Water and dust resistant, 1-year warranty
- Miniaturized design for a comfortable fit
- Up to 10 hours use with a fully charged battery
- Simple setup through the Jabra Enhance App

2.1.2.3 Troubleshooting

The following troubleshooting instructions are listed in the device labeling:

Issue	Potential Cause	Potential Solution
Feedback or “whistling”	Are the earbuds inserted correctly in your ears?	Reinsert the earbuds in your ears.
	Is the volume very loud?	Reduce the volume.
	Are the EarGels broken or clogged?	Replace the EarGels.
	Are you holding an object (e.g., a hat or a telephone mouthpiece) close to the earbuds?	Move your hand away to create more space between the earbuds and the object.
	Is your ear full of wax?	Visit your physician
No sound	Are the earbuds turned on?	Turn the earbuds on.
	Are the earbuds charged?	Charge the earbuds.
	Is the charging case charged?	Charge the charging case.
	Is your ear full of wax?	Visit your physician.
Earbuds are not charging	Are the earbuds sitting correctly in the charging case?	Reinsert the earbuds in the charging case.
	Is the charging case charged or plugged into a power source?	Charge the charging case.

2.1.3 Device Manufacturing

Jabra Enhance Plus was developed in accordance with 21 CFR 820.30 FDA’s Design Control requirements. The device is currently manufactured/developed at the address below:

GN Hearing A/S
Lautrupbjerg 7
DK-2750 Ballerup
Denmark

2.2 Additional Device(s) and Comparator(s)

In this clinical study, the investigational device is not compared to another device. Instead, this investigation compares outcome between the device fitted by a hearing care professional versus the same device self-fitted by the subject.

If the subject does not have a compatible iPhone running iOS 14, an iPhone 11 (iOS 14) will be supplied for use in this study.

2.3 Regulatory Status

Jabra Enhance Plus is not currently marketed as a medical device in the US or any other global regions and is considered a non-significant risk investigational device for purposes of this study.

2.3.1 Intended Use/Indications for Use

The Jabra Enhance Plus self-fitting hearing aid is intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. It is adjusted by the user to meet the user's hearing needs. No pre-programming or hearing test is necessary. The device is intended for direct-to-consumer sale and use without the assistance of a hearing care professional.

2.4 Risk Category/Rationale

GN Hearing A/S does not consider the Jabra Enhance Plus device or the result of its use in this pivotal study to pose a significant risk to study subjects. Per 21 CFR 812.3, the Jabra Enhance Plus device and its use in this pivotal study are considered non-significant risk (NSR) because:

- It is **not** intended as an implant and thus does not present a potential for serious risk to the health, safety, or welfare of a subject;
- It is **not** purported or represented to be for use in supporting or sustaining human life and thus does not present a potential for serious risk to the health, safety, or welfare of a subject;
- It is **not** for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and thus does not present a potential for serious risk to the health, safety, or welfare of a subject; and
- It does **not** otherwise present a potential for serious risk to the health, safety, or welfare of a subject.

Because the device and its use in this pivotal study is considered NSR, the abbreviated IDE requirements of 21 CFR Part 812 will apply. Submission of an IDE to FDA is not considered necessary.

2.5 Device Classification and Rationale

The Jabra Enhance Plus device is expected to be classified as a Class II medical device. The results of this pivotal study are intended to support a Traditional 510(k) Premarket Notification for submission to the FDA.

2.6 Device Insurance and Replacement

All investigational devices will be issued to the investigational sites by GN Hearing A/S. Any special procedures, such as calibration and maintenance of the devices, will be conducted per the device labeling provided to study subjects. If a device breaks, malfunctions, or is lost,

replacement devices will be issued to the site by GN Hearing A/S for the patient to continue participation in the study.

2.7 Disposition of the Device

Subjects will be required to utilize their Jabra Enhance Plus device to access the Jabra Enhance app. To access the Jabra Enhance Plus device, enrolled subjects will receive a link from the Sponsor prompting them to download the Jabra Enhance Application (app). Once downloaded, the enrolled subjects will be prompted to create their own secure login credentials to utilize during the study. When subject involvement in the investigational study is completed, the Jabra Enhance Plus app will automatically log the subject out, and their account will no longer be usable. The data for the subject's account will be saved.

3.0 OBJECTIVES OF RESEARCH STUDY

3.1 Hypotheses

3.1.1 In-lab validation component-Primary

- Null hypothesis: Mean $|REAG_{PRO\text{-}FIT} - REAG_{SELF\text{-}FIT}| \geq 2.5$ dB
- Alternative hypothesis: Mean $|REAG_{PRO\text{-}FIT} - REAG_{SELF\text{-}FIT}| < 2.5$ dB

3.1.2 In-lab validation component-Secondary

- Null hypothesis: Mean $|QuickSIN_{PRO\text{-}FIT} - QuickSIN_{SELF\text{-}FIT}| \geq 1.5$ dB
- Alternative hypothesis: Mean $|QuickSIN_{PRO\text{-}FIT} - QuickSIN_{SELF\text{-}FIT}| < 1.5$ dB

3.1.3 Wear-Time Field Trial-Primary

- Null hypothesis: Mean difference $(APHAB_{PRO\text{-}FIT} - APHAB_{SELF\text{-}FIT}) \geq .084$
- Alternative hypothesis: Mean difference $(APHAB_{PRO\text{-}FIT} - APHAB_{SELF\text{-}FIT}) < .084$

3.1.4 Wear-Time Field Trial-Secondary

- Null hypothesis: Mean difference $(QuickSIN_{PRO\text{-}FIT} - QuickSIN_{SELF\text{-}FIT}) \geq 1.5$ dB
- Alternative hypothesis: Mean difference $(QuickSIN_{PRO\text{-}FIT} - QuickSIN_{SELF\text{-}FIT}) < 1.5$ dB

3.1.5 In-Lab Session-Reliability Component-Primary

- Null hypothesis: Mean $|REAG_{SELF\text{-}FIT\ A} - REAG_{SELF\text{-}FIT\ B}| \geq 2.5$ dB
- Alternative hypothesis: Mean $|REAG_{SELF\text{-}FIT\ A} - REAG_{SELF\text{-}FIT\ B}| < 2.5$ dB

3.1.6 In-Lab Session-Reliability Component-Secondary

- Null hypothesis: Mean difference $|QuickSIN_{SELF\text{-}FIT\ A} - QuickSIN_{SELF\text{-}FIT\ B}| \geq 1.5$ dB
- Alternative hypothesis: Mean difference $|QuickSIN_{SELF\text{-}FIT\ A} - QuickSIN_{SELF\text{-}FIT\ B}| < 1.5$ dB

3.2 Study Endpoints

3.2.1 Primary Effectiveness Endpoint(s)

For the validation component of the immediate in-lab session comparisons, Real-Ear Aided Gain (REAG) will be measured using both an audiology-best-practices (professional) hearing aid fitting (PRO-FIT) and a self-fitting method (SELF-FIT).

- Success criterion is defined as SELF-FIT REAG is equivalent to PRO-FIT NAL-NL2 prescription REAG targets based on the average real-ear aided gain at 500, 1000, 2000 and 4000 Hz.

For the reliability component of the immediate in-lab session comparisons, Real-Ear Aided Gain (REAG) will be measured twice (A, B) using the SELF-FIT method.

- Success criterion is four-frequency average REAG for SELF-FIT B is equivalent to the REAG for SELF-FIT A based on the average real-ear aided gain at 500, 1000, 2000 and 4000 Hz.

For the wear-time crossover field trial, the APHAB will be measured following both an audiology best-practices hearing aid fitting (PRO-FIT) and a self-fitting method (SELF-FIT).

- Success criterion is defined as SELF-FIT APHAB global score is non-inferior to PRO-FIT APHAB global scores following completion of the wear-time field trial.

3.2.2 Primary Safety Endpoint

Tabulations of Adverse Events (AEs) and Serious Adverse Events (SAEs).

- Success criterion is no recorded device-related AEs or SAEs.

3.2.3 Secondary Effectiveness Endpoints

For the validation component of the immediate in-lab session comparison, aided QuickSIN performance will be compared between SELF-FIT and PRO-FIT.

- Success criterion is the SELF-FIT QuickSIN speech-recognition threshold in noise (signal-to-noise ratio, SNR) is equivalent to that of PRO-FIT.

For the reliability component of the immediate in-lab session comparison, QuickSIN performance will be measured twice (A, B) using the SELF-FIT method to assess test-retest reliability.

- Success criterion is QuickSIN thresholds are equivalent for SELF-FIT A and B.

For the wear-time crossover field trial, QuickSIN performance will be compared between SELF-FIT and PRO-FIT.

- Success criterion is defined as SELF-FIT QuickSIN SNR is equivalent to PRO-FIT QuickSIN SNR following completion of the wear-time field trial.

4.0 DESIGN OF RESEARCH STUDY

4.1 Type of Research Study

This study has two components to assess the safety and effectiveness of the Jabra Enhance Plus device in adults with mild to moderate sensorineural hearing loss. The reliability and validity of the self-fitting method are examined in an in-lab session with counter-balanced conditions. A second component, a single-blind counter-balanced cross-over wear-time field trial, further evaluates the validity of the self-fitting method. Three sites are involved in data collection.

4.2 Controls and Minimization of Bias

The Sponsor, GN Hearing A/S, should avoid improper influence on any parties participating in, or contributing to, the clinical study or the induction thereof. The selection and treatment of subjects and evaluation of study data are potential sources of bias. Methods that are incorporated within the study design to minimize potential bias include, but are not limited to, screening subjects to confirm study eligibility with defined inclusion/exclusion criteria prior to enrollment; maintaining a log of all subjects screened and enrolled for the study, collecting demographics and medical history at baseline to later assess possible characteristics that may influence endpoints; standardizing data collection requirements and study procedures; requiring all study investigators to meet the requirements of 21CFR Part 54 and a Financial Disclosure by Clinical Investigators; using standardized training materials for all study personnel; and conducting regular electronic monitoring to verify adherence to the protocol and source data.

5.0 STUDY SUBJECTS

5.1 Sample Size Determination

The sample size was powered by the primary outcome measure of the wear-time field trial, the APHAB, as it is the most variable of the outcome measures across all components of this study. When the sample size in each sequence group in the crossover trial is 16 (giving a total sample size of 32), a crossover design will have 80% power to reject the null hypothesis that the SELF-FIT APHAB mean is inferior to the PRO-FIT APHAB mean based on the mean difference, in favor of the alternative hypothesis that the SELF-FIT mean is non-inferior to the PRO-FIT mean, assuming that the expected difference in means is 0, the non-inferiority difference margin is .084 (or 8.4%), the Crossover ANOVA $\sqrt{MSE}$ is 0.115 (or 11.5%) (giving a standard deviation of differences, σ, of 0.163 or 16.3%) and that the test is made at the 2.5% significance level.

The overall design for the in-lab session is a repeated-measures design comparing outcomes for three procedures: SELF-FIT A, SELF-FIT B, PRO-FIT. Given that SELF-FIT A and B are the same procedure repeated two times, this results in three possible procedure sequences: (1) SELF-FIT A, SELF-FIT B, PRO-FIT; (2) SELF-FIT A, PRO-FIT, SELF-FIT B; and (3) PRO-FIT, SELF-FIT A, SELF-FIT B. An equal number of subjects will receive each sequence at each site to ensure full counterbalancing of order. A total of 36 subjects, 18 per site, will be included which meets the minimum of 32 required for sufficient statistical power, achieves the desired counterbalancing, and allows for some subject attrition or missing data.

5.2 Subject Population

Adults, 18-75 years of age, with mild to moderate sensorineural hearing loss.

5.3 Protection of Vulnerable Subjects

No vulnerable patients are planned to be enrolled in this study.

5.4 Inclusion Criteria

An initial telephone or internet screening of interested persons will take place.

- During this remote screening, prospective subjects will provide their age (subject to verification at Visit 1) and answer a Yes/No question as to whether they have trouble hearing in noise. Those answering "No" will not be considered further for enrollment.
- Those answering "Yes" will then be asked to describe their perceived hearing loss on a 4-point scale (no trouble, a little trouble, a lot of trouble, and cannot hear). Prospects answering at the two extremes will not be considered further for this study.
- Those answering "a little trouble" or "a lot of trouble" will be invited to the in-person Screen that immediately precedes hearing aid fittings in Visit 1. To be eligible to participate in this study, an individual must meet all of the following criteria:
  (1) Mild-to-moderate bilateral sensorineural hearing loss (thresholds from 250 – 8000 Hz with at least one threshold greater than 20 dB HL and thresholds at 500, 1000, 2000 and 4000 Hz less than or equal to 55, 65, 70, and 80 dB HL, respectively);
  (2) Mix of male and female subjects (aiming for a representative balance);
  (3) Mix of prior hearing-aid use (aiming for 70-80% persons with no prior hearing aid use);
  (4) 18-75 years old (aiming for primarily 50-70 years old, with avg. age ~65 years);
  (5) Able to read and comprehend English; and
  (6) Patient willing to provide informed consent.

5.5 Exclusion Criteria

An individual who meets any of the following criteria will be excluded from participation in this study:

(1) Hearing outside of limits noted above; or
(2) Self-reported ear-related pathology (including chronic severe dizziness or chronic severe tinnitus).

5.6 Concomitant Treatments

No known concomitant treatments exist for this device.

5.7 Enrollment Screening

Screening for eligibility of this study will be made within 28 days prior to the treatment. If a patient who meets the study criteria joins the study, preliminary effectiveness and safety using the Jabra Enhance Plus in the study will be measured.

6.0 RESEARCH STUDY PROCEDURES

6.1 Study Assessments

A description of all assessments being performed are provided within Section 3.0.

6.2 Study Procedures

6.2.1 Pre-Fitting Procedures: After consent, otoscopy, and audiological measurements verifying candidacy for the study, the subject completes Pre-Fitting of the devices. If the subject does not have a compatible iPhone running iOS 14, one will be supplied for use in this study. The investigator will install the app on the subject's smartphone, pair the devices to the smartphone, and select the appropriate earbud size for each ear prior to the PRO-FIT and SELF-FIT procedures. (These aspects of the fitting process for the Jabra Enhance Plus will be evaluated separately in a usability study.)

i. Fitting begins by placing probe-tube microphones in the subject's ear canals and measuring the Real-Ear Unaided Response (REUR) for each ear.

ii. The Jabra Enhance Plus, powered off, will be placed in the subject's ear with medium-sized earbuds and the Real-Ear Occluded Response (REOR) measured.

- If measurable passive attenuation at frequencies above 500 Hz is not seen, a smaller or larger earbud will be selected by the audiologist and REOR will be remeasured.
- This process will be repeated as needed until a good seal is obtained as verified by the REOR.
- The selected earbud size for each ear will be used by the subject during the remainder of the study.

6.2.2 PRO-FIT: The audiologist will use the air-conduction thresholds measured during the initial screening to generate REAR targets for the NAL-NL2 prescriptive procedure.

i. Targets will be generated for a speech input level of 65 dB SPL.

ii. Fine-tuning of REAR by the audiologist to match NAL-NL2 targets will be accomplished using custom device-programming software (AlgoLabTest) to program the gain and compression parameters for NAL-NL2.

iii. The Audioscan Verifit 1 or 2 real-ear measurement system will be used to verify and fine-tune the fit to match targets for this initial fit for speech input level of 65-dB SPL.

iv. If the subject has immediate sound-quality complaints, the audiologist will fine-tune the fitting to accommodate those complaints (as was done for the predicate device study; Sabin *et al*., 2020). The range of adjustments to the frequency response will be constrained to the two alternative responses available on the device via the app. This will be the final fit for PRO-FIT to be worn during the wear-time trial.

v. No additional fine-tuning will be made by the audiologist to the PRO-FIT fitting for the duration of this study, including the field trial. Although such adjustments *may* be common practice, there is little evidence available about the benefits of such adjustments and they are *not* included in national best-practice guidelines for hearing-aid fitting. The validation study of the Bose Hearing Aid (Sabin *et al*., 2020) allowed additional adjustments by the audiologist to the PRO-FIT condition in that study after a brief wear-time period (M=5.3 days). However, the gain from 500-4000 Hz was not adjusted in 77% of those subjects and another 14% of their subjects required adjustments of only 5 dB at one or more of those frequencies in either ear after this brief wear-time period. In other words, 91% of the time, no or very minor adjustments, within the range of adjustments that will be available to the user during the wear-time trial in this study, occurred. Further, the user will have access to self-adjustment of volume and choice of frequency response tilt as desired during the wearing period.

6.2.3 SELF-FIT A: Once the earbuds have been selected by the audiologist for the subject and are placed in the ear, subjects will complete the first self-fitting process (Section 16.0, Attachment A).

i. Subjects will open the mobile device screen, launch the app, and select from drop-down menus to indicate age and gender. (These data facilitate the starting point for the fitting process, but the process can still be completed if left blank.)

ii. Subjects will be presented with step-by-step fitting instructions on their smartphone describing their task during the self-fitting flow (See Section 16.0, Attachment A.).

iii. Subjects will be presented with the “Heard It” design of the self-fitting procedure, meaning that they will tap the smartphone screen to indicate when a tone is detected.

iv. The self-fitting flow requires 5 practice tones and 25 test tones per self-fit. This procedure results in settings as determined by the Jabra Enhance Plus software and is referred to as the "initial fit" and is designed to match NAL-NL2 targets. REAG targets and measures will be calculated by subtracting the input signal level in the sound field from the REAR targets and measures. Comparison of REAG and QuickSIN measures among PRO-FIT, SELF-FIT A, and SELF-FIT B in Visit 1 (in-lab) will be made using these saved *initial-fit* settings for SELF-FIT.

v. The SELF-FIT process continues uninterrupted with user-preferred adjustments of "filters" or frequency-gain responses. These user-driven fine-tuning adjustments are made while streaming a sound file to the devices and comparing filter settings. (See Attachment 4A for details.) When the subject selects the final settings, these

device settings are saved and become the new default settings for when the device is powered on. These settings are referred to as the "final fit" for the SELF-FIT procedure. Measurements made for SELF-FIT A and PRO-FIT at the end of each wear-time crossover field trial will make use of these *final-fit* settings.

vi. Once the subject has completed the test, the app will indicate that the subject is finished with personalization of the devices and will return to the home screen of the app.

6.2.4 SELF-FIT B: To assess test-retest reliability, subjects will complete the self-fitting procedure a second time (repeat steps for SELF-FIT A above).

6.2.5 Overview of Procedures at Visits 1, 2, and 3

Successive subjects will be assigned to one of these six condition sequences illustrated in Figure 1 with a total of two cycles through the full set of six sequences at each of the three sites. In the end, two subjects will have been tested in each of the six sequences at each site, six per sequence for the entire study, and any effects of order will be equalized across conditions following the counterbalancing illustrated in Figure 1.

The table below summarizes the primary and secondary outcome assessments to be completed during each study visit. For Visits 2 and 3, REAG will also be established but only for potential explanatory purposes and not as an outcome measure.

Visit	Primary Outcome	Secondary Outcome
1	REAG from REAR; initial fit	QuickSIN; initial fit
2	APHAB; final fit	QuickSIN; final fit
3	APHAB; final fit	QuickSIN; final fit

After the final in-lab measures have been completed during Visit 1, 9 subjects at each site will wear the devices with the final-fit SELF-FIT A settings and the other 9 at each site will begin the crossover trial with the final-fit PRO-FIT settings. After the initial 10-to-14-day wear-time trial, the subjects will return to the lab for the measurement of REAG, aided APHAB, and aided QuickSIN during Visit 2. Each subject will then embark on a second 10-to-14-day wear-time period using the devices with the other fitting settings (SELF-FIT A settings if PRO-FIT settings were worn first, and vice versa). Subjects will return after the second 10-to-14-day wear-time period for completion of REAG, aided APHAB and aided QuickSIN measures with this second fitting, during Visit 3.

Subjects will follow the instructions for the “Self-fitting flow” (Section 16.0, Attachment A) to complete SELF-FIT A and SELF-FIT B procedures. After the installation of software on the smartphone, the pairing of the devices to the smartphone, and the physical fit of the devices, no further assistance will be provided to the subject by the professional or research staff until the completion of Visit 1. When Visit 1 has been completed, the subject will be provided with the devices, the charger, the USB-C cable, and a copy of the User's Manual (Attachment A). The research audiologist will answer questions raised by the subject as he or she pages through the manual. Prior to leaving for the first phase of the field trial, the subject will demonstrate to the audiologist that he or she can insert and remove the devices, adjust the

volume with the app, and place the devices in the charger. The audiologist will log any errors made in this verification of basic use and will correct the subject on those errors once, if needed, prior to the subject leaving with the devices.

For the wear-time field trial, subjects will be asked to wear the devices in a variety of listening situations during the trial including while listening to music and while using the telephone. Subjects will be asked to wear their devices a minimum of two hours per day.

6.2.6 REAR Measurement and REAG Calculation

SELF-FIT A & B: Personalization begins with an estimate of hearing acuity obtained through the Jabra Enhance Plus. The hearing acuity measurements are used internally by the device and are not shared with the wearer. Once this step has been completed, devices will apply NAL-NL2 gain prescriptions directly using the estimated hearing acuity to generate the initial fit. Probe-tube microphone measures of the REAR (REAG=REAR-input) will be obtained for a 65-dB speech input using the Audioscan Verifit real-ear measurement system. All probe-tube microphone measures will make use of the custom dome/probe-tube assembly supplied by GN Hearing. (Attachment B for details.)

PRO-FIT: Audiometric thresholds will be imported and the devices programmed using custom device programming software (AlgoLabTest) for NAL-NL2 target gains. Probe-tube microphone measures of the REUR and REAR (REAG=REAR-input) will be obtained for a 65-dB speech input using the Audioscan Verifit real-ear measurement system. All probe-tube microphone measures will make use of the custom dome/probe-tube assembly supplied by GN Hearing. (See Attachment B for details.)

6.2.7 QuickSIN

The subject will be seated in a sound-attenuated booth facing a single loudspeaker. All QuickSIN measures, unaided and aided, will be binaural. The QuickSIN test consists of lists of six sentences that will be played from that loudspeaker at a constant level of 65 dB SPL (at location of subject's head using the method of substitution). This speech level was chosen as one approximating a typical conversational level (60-65 dB SPL) and matching the speech input level used for the REAR measures (65 dB SPL). The level of the co-located background four-talker babble increases across the six sentences for signal-to-noise ratios (SNRs) ranging from +25 to 0 dB SNR (in steps of 5 dB). The subject is asked to repeat each sentence. The audiologist scores whether the subject correctly repeated the predetermined key words in each sentence. The resulting score is interpreted as an SNR loss where a value near 0 indicates better hearing and larger values indicate more difficulty listening in noise.

There are 18 lists of the QuickSIN, but McArdle and Wilson (2006) found four of these to be non-equivalent to the others. The remaining 14 lists will be used as follows. Before the first QuickSIN measure at the end of the initial screening (Visit 1), two lists will be presented as practice lists (Lists 4 and 5). For the remaining 12 lists (Lists 1-3, 6, 8-12, 15, 17, 18), two will be assigned to each of the following conditions: unaided (during initial screen; to permit measures of relative benefit), in-lab initial SELF-FIT A, in-lab initial SELF-FIT B, in-lab initial PRO-FIT (the condition order and list pair assigned for each condition will be randomized for each participant), at end of first 10-to-14-day wear period (Visit 2; either final SELF-FIT A or final PRO-FIT), and at end of

final 10-to-14-day wear period (Visit 3; either final PRO-FIT or final SELF-FIT A). Each QuickSIN score will be based on two lists, 60 keywords, and no lists will be repeated for a given subject.

6.2.7.1 QuickSIN Test Procedure

Four conditions: **Unaided, Self-Fit A, Self-Fit B, Pro-Fit**

i. Listener will sit in a chair in the center of a sound-treated booth facing the speaker from which the test materials will be elicited (0 degrees azimuth, 1 meter distance).

ii. Training: To familiarize subjects with the speech task, listeners will be presented with two practice lists (Lists 4 and 5) before commencing with the experimental protocol (Visit 1, Unaided only).

iii. The test will be presented in a sound field at 65 dB SPL.

iv. There are six sentences in each list of the QuickSIN and 5 keywords that are scored per sentence, resulting in a total of 30 keywords scored per list. Speech levels are automatically presented at SNRs of +25, +20, +15, +10, +5 and 0 dB, one SNR per sentence. The signal-to-noise ratio (SNR) for which 50% of the presented words are intelligible is calculated by subtracting the number of words correct (out of 30) for a given list from 25.5 (Killion *et al.*, 2004).

v. The microphone setting will be set to "Wide" (omni-directional) during these measurements.

6.2.8 APHAB

The APHAB is a 24-item self-assessment inventory in which the subject reports the amount of trouble they are having with communication or noises in various everyday situations. Benefit from a hearing aid is calculated by comparing the subject's unaided score to their aided score. Although it is possible to collect unaided and aided scores at the same time by asking the subject to reflect back on unaided listening, we will obtain unaided APHAB scores during Visit 1 prior to initiation of the cross-over wear-time trial.

A sample question is as follows: "When I'm at the dinner table with several people, and I am trying to have a conversation with one person, understanding speech is difficult." For each of the 24 items the subject is asked to select one of the following percentages to indicate how frequently this occurs: Always (99%); Almost Always (87%); Generally (75%); Half-the-time (50%); Occasionally (25%); Seldom (12%); or Never (1%). The APHAB will be administered and scored via a tablet PC or iPad.

The APHAB produces scores for 4 subscales: Ease of Communication (EC), Reverberation (RV), Background Noise (BN), and Aversiveness (AV). To increase reliability, only an APHAB-global score based on all 24 items will be used here.

Three conditions: Unaided (Visit 1), Aided (Visit 2), Aided (Visit 3). These three conditions are: 1) prior to the onset of the wear-time field trial, 2) after the first 10-14-day wear period with the first fitting settings (final-fit SELF-FIT A or final-fit PRO-FIT), and 3) after the second 10-14-day wear period with the other fitting settings (final-fit PRO-FIT or final-fit SELF-FIT A).

6.2.9 Telephone Communication and Music Listening

A custom 2-item survey will be completed during Visits 2 and 3 following the APHAB. This survey assesses the enhancement of telephone communication and music listening by the GN prototype devices and makes use of a 7-point response scale ("Strongly Agree" to "Strongly Disagree") for each item. Prior to the beginning of each phase of the cross-over trial, subjects will be encouraged to use their devices in a wide range of listening conditions during the wear-time period, including using the telephone and listening to music.

6.3 Study Duration and Sites

Given the number of study subjects required within this population and the recruitment capabilities of the sites and sponsor, this investigation is expected to last approximately 90-120 days from enrollment of the first subject to completion of the final study subject. This study includes 3 sites: (1) Northwestern University, Evanston, IL; (2) Sertoma Speech and Hearing Center, Palos Hills, IL; and (3) Vanderbilt University, Nashville, TN.

6.4 Monitoring and Treatment of Subjects with Worsening Clinical Condition

Subjects will be monitored for worsening clinical status, including complaints of decreased hearing or increased tinnitus, via self-report at Visits 2 and 3.

6.5 Withdrawal and Discontinuation Criteria

Study subjects may withdraw voluntarily from the research investigation for any reason and at any time during the investigation.

A study subject may also be removed from the investigation for the following medical or administrative reasons:

- Withdrawal of informed consent
- Request to withdraw from the investigation
- Non-compliance (less than 85%) with, or inability to complete, CIP procedures
- Lost to follow-up
- Adverse event (if the subject experiences an AE that, in the judgment of the Site Investigator, presents an unacceptable consequence or risk to the participant).

If a subject is withdrawn from treatment, the Sponsor will be notified and the date and reason(s) for the withdrawal will be documented. If a subject is withdrawn, efforts will be made to perform all follow-up assessments, if possible. Other procedures may be performed at the Investigator's (or designee's) and/or Sponsor's discretion. The Investigator (or designee) may also request that the subject return for an additional Follow-up visit. All withdrawn subjects will be followed until

resolution of all their AEs or until the unresolved AEs are judged by the Investigator (or designee) to have stabilized.

Subjects who are withdrawn for reasons not related to the investigational treatment may be replaced following discussion between the Investigator and the Sponsor. Subjects withdrawn as a result of AEs thought to be related to the investigational treatment will generally not be replaced.

The following actions must be taken if a subject fails to return to the laboratory for a required study visit:

- The site will attempt to contact the subject and reschedule the missed visit within 3 working days and counsel the subject on the importance of maintaining the assigned visit schedule and ascertain if the subject wishes to and/or should continue in the study.
- Before a subject is deemed lost to follow-up, the investigator or designee will make every effort to regain contact with the subject (where possible, 3 telephone calls and, if necessary, a certified letter to the participant's last known mailing address or local equivalent methods). These contact attempts should be documented in the participant's medical record or study file.
- Should the subject continue to be unreachable, he or she will be considered to have withdrawn from the study with a primary reason of lost to follow-up.

A subject will be considered lost to follow-up if he or she fails to return for scheduled visits and is unable to be contacted by the study site staff.

6.6 Prohibited Medications

No medications are prohibited during this brief trial. For those wearing hearing aids at the time of the trial, they are asked to refrain from use of their personal hearing aids during the course of this study and while using the Jabra Enhance Plus devices.

7.0 TRAINING PLAN

7.1 Training Plan for Research Device

All relevant study site personnel and participating subjects will be trained on the investigational device using standardized training materials. All study site personnel will be trained before research begins.

7.2 Training Plan for Protocol

All study site personnel will be trained on the study protocol using standardized training materials. All study site personnel will be trained before research begins.

8.0 DATA ANALYSIS AND STATISTICS

8.1 Statistical Analysis Methods

8.1.1 In-Lab – *Test-Retest Reliability* (initial Self-Fit A vs. initial Self-Fit B)

i. Paired-sample t-tests of equivalence of the four-frequency (500, 1000, 2000 and 4000 Hz) average REAG and the QuickSIN comparing initial-fit settings from the SELF-FIT A procedure and the initial-fit settings from the SELF-FIT B procedure.

ii. Supplementary analyses will include examination of the distribution of differences in dB between the four-frequency average REAGs and the QuickSIN threshold SNRs for initial-fit settings from the SELF-FIT A and B procedures, as well as computation of test-retest correlation coefficients for each measure.

8.1.2 In-Lab *REAG – Validity* (initial Pro-Fit vs initial Self-Fit A)

i. Paired-sample t-test for equivalence of the means of the initial-fit settings of the SELF-FIT A procedure to the means of the initial-fit settings of the PRO-FIT procedure

ii. Supplementary analyses will include examination of the distribution of differences in dB between the four-frequency average REAGs for initial-fit settings of the SELF-FIT A procedure and initial-fit settings of the PRO-FIT procedure, as well as computation of correlation coefficients between the two measures.

8.1.3 In-Lab *QuickSIN Test - Validity* (initial Pro-Fit vs. initial Self-Fit A)

i. Paired-sample t-test for equivalence of the means of the initial-fit settings of the SELF-FIT A procedure to initial-fit settings of the PRO-FIT procedure

ii. Supplementary analyses will include examination of the distribution of differences in dB between the QuickSIN threshold SNRs for initial-fit settings of the SELF-FIT A procedure and the initial-fit settings of the PRO-FIT procedure, as well as computation of correlation coefficients between the threshold SNRs for each method.

8.1.4 Wear-Time Field Trial - *Validity*: APHAB (final PRO-FIT vs. final SELF-FIT A)

i. Non-Inferiority t-Test for 2 (wear-time sequences) X 2 (fit conditions)

ii. Supplementary analyses will include examination of the distribution of differences between the APHAB-global scores for final-fit settings of the SELF-FIT A procedure and final-fit settings of the PRO-FIT procedure, as well as computation of correlation coefficients between the two measures. Datalogging will also provide details of the subject's adjustment of the devices during each segment of the cross-over wear-time trial.

8.1.5 Wear-Time Field Trial - *Validity*: QuickSIN (final PRO-FIT vs final SELF-FIT A)

i. Non-Inferiority t-Test for 2 (wear-time sequences) X 2 (fit conditions)

ii. Supplementary analyses will include examination of the distribution of differences in dB between the QuickSIN threshold SNRs for final-fit settings of the SELF-FIT A procedure and the final-fit settings of the PRO-FIT procedure, as well as computation of correlation coefficients between the threshold SNRs for each method.

8.2 Interim Analysis

No interim analysis will be performed for this investigation.

8.3 Missing Data Management

All planned data will be collected as complete and as timely as possible. No imputation of missing data is anticipated.

8.4 Pass/Fail Criteria of the Study

For the in-lab session, the primary effectiveness endpoint will be assessed by the differences in acoustical real-ear aided gain (REAG), a gold-standard measure for the acoustical function of hearing devices for the study population. This endpoint will be used to assess mean absolute-value differences between two replications of the self-fit method (reliability) and between the self-fit and professional-fit methods (validity or effectiveness).

For the wear-time trial, the primary outcome measure is a widely used clinical self-report measure of benefit (Abbreviated Profile of Hearing Aid Benefit, APHAB). The APHAB is also a gold-standard, validated assessment of hearing-aid benefit relevant for the study population.

Secondary effectiveness endpoints for both the laboratory and field-trial components will be assessed by a standardized measure of speech communication in noise, the QuickSIN. This is a widely used clinical measure of an adult's ability to understand speech in noise and is closely tied to the wearer's primary complaint, difficulty communicating in noise.

Overall study success will be defined by meeting all primary endpoints for the reliability, effectiveness, and safety of the devices and the self-fitting process in the laboratory and field-trial components of this study. Effectiveness outcomes from the SELF-FIT process should be equivalent to those of the PRO-FIT method in the in-lab session and non-inferior to PRO-FIT in the wear-time trial for the study to be considered successful.

9.0 DEVIATIONS

9.1 Management of Protocol Deviations

A CIP deviation is any noncompliance with the CIP, ISO 14155 Good Clinical Practice (ISO GCP), or Manual of Procedures requirements. The noncompliance may be either on the part of the subject, the site investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly. These practices are consistent with ISO 14155 GCP 9.6 Compliance with the CIP and 8.1 Clinical quality Assurance and Quality Control.

There are two types of CIP deviations, critical deviations and non-critical deviations. All deviations must be documented and reported, the criticality of the deviation will determine the reporting path.

Critical Deviations: Deviations that significantly affect the safety, effectiveness, integrity or conduct of the study. These deviations must be reported to the Sponsor no later than 5 working days from awareness of occurrence and reported to the IRB per the deviation reporting policy.

Note: If an Investigator uses a device without obtaining informed consent, the Investigator shall consider this a critical deviation and report the event to the Sponsor and the IRB within 5 working days of the occurrence.

Non-Critical Deviations: CIP deviations that do not significantly affect the safety, effectiveness, integrity or conduct of the study are considered non-critical deviations. These deviations must be documented and will be reviewed by the study monitor.

It is the responsibility of the site investigator to use continuous vigilance in order to identify deviations. All deviations must be addressed in study source documents with explanations as well as reported to GN Hearing A/S as soon as possible. CIP deviations must be sent to the reviewing IRB per their policies. The site investigator is responsible for knowing and adhering to the reviewing IRB requirements.

The site investigator is not allowed to deviate from the CIP without prior authorization received from the Sponsor, except under emergency situations when necessary to preserve the rights, safety, or well-being of investigation subjects. In the event the deviation involves a failure to obtain a subject's consent or is made to protect the life or physical well-being of a subject in an emergency, the deviation must be reported to the IRB as well as GN Hearing A/S as soon as possible but no later than five (5) working days from the date of the deviation occurrence.

Larry E. Humes is responsible for analyzing deviations, assessing their significance, and identifying any additional corrective and/or preventive actions which may include amending the CIP, conducting additional training, terminating the investigation, etc. Repetitive or serious investigator compliance issues may represent a need to initiate a corrective action plan with the investigator and site, and in some cases, necessitate suspending enrollment at that site until the problem is resolved or ultimately terminating the site investigator's participation in the study.

10.0 COMPLAINT HANDLING AND ADVERSE EVENT REPORTING

10.1 Foreseeable Adverse Events and Device Effects

Adverse events (AEs) are expected to be extremely rare based on the low risk profile of the device. In rare cases, it is foreseeable that study subjects may experience moderate to mild and typically spontaneously resolving:

- Psychological distress or exacerbation of existing psychological or anxiety conditions, related to the requirements of various features of the device
- Effects related to mechanical interaction with the device, such as eye strain leading to headaches or in rare cases blurred vision, strain of the digits, or transient discomfort

For the purposes of this study, the following will not be considered or reported as AEs:

- Unchanged, chronic, non-worsening of a pre-existing conditions
- A planned hospitalization for pre-existing condition, any outpatient medical or surgical procedures, or hospitalization due to an elective surgery planned prior to screening/baseline visit
- Stable, intermittent chronic conditions present prior to screening/baseline visit that do not worsen during the study
- Outpatient medical or surgical procedures planned prior to screening/baseline visit

As with any medical device that involves electronic transfer of subject data, use of the device may pose risk to study subject privacy. These risks have been mitigated by design to levels considered As Low as Possible in compliance with ISO 14971:2019 Medical Devices – Application of risk management to medical devices.

These foreseeable risks are not elevated beyond levels that would have occurred within the study subject's standard care. The site investigator or designee will be responsible for determining whether an adverse event is foreseeable or not foreseeable. An AE will be considered not foreseeable if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study.

As in any medical device study, defects may be discovered during testing of the medical device. All defects will be documented during the course of the study as per ISO 14155 and applicable CFR requirements.

10.2 Adverse Event Definitions

An **Adverse Event (AE)** is any untoward medical occurrence in a clinical investigation subject receiving investigational treatment, which does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and/or unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of an investigational medical device, whether or not related to the investigational medical device. Section 1.5, Device Risk Analysis contains a list of foreseeable AEs and adverse device effects. Specific adverse event protocols are defined the by IRBs at Vanderbilt UniversityNorthwestern University, and Sertoma Speech and Hearing Center; however, these protocols are consistent with the following. In addition, Device Risk Assessments and determinations will be performed by the appropriate committees at Vanderbilt and Northwestern Universities as well as Sertoma Speech and Hearing Center.

Treatment-Emergent AEs are AEs that are new-onset, or worsen in severity, and are not anticipated due to the nature of this study and device.

A **Serious Adverse Event (SAE)** is defined as any untoward medical occurrence that either:

- results in death
- is life threatening
- requires inpatient hospitalization or prolongation of existing hospitalization
- results in persistent or significant disability/incapacity (disability is defined as a substantial disruption of a person's ability to conduct normal life functions)
- results in a congenital anomaly/birth defect
- requires intervention to prevent permanent impairment or damage
- results in an important medical event

Device issue or deficiency is an inadequacy of a medical device related to its identity, quality, durability, reliability, safety, or performance, such as malfunction, misuse, or use error and inadequate labeling.

An **Adverse Device Effect (ADE)** is an AE related to the use of an investigational medical device. This definition includes AEs resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation, or any malfunction of the investigational medical device. The definition also includes any event resulting from use error or from intentional misuse of the investigational medical device.

Unanticipated Adverse Device Effect (UADE) means any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects, according to 21 CFR 812.3.

10.3 Monitoring

The condition of each subject will be monitored from the time of signing the ICF to final discharge from the investigation. Subjects will be observed for any signs or symptoms and asked about their condition by open questioning, such as "How have you been feeling since you were last asked?" at least once each day at each investigation visit. Subjects will also be encouraged to spontaneously report AEs occurring at any other time during the investigation.

All nonserious AEs, whether reported by the subject voluntarily or upon questioning, or noted on physical examination, will be recorded from initiation of investigation treatment until investigation completion. Serious AEs will be recorded from the time the subject signs the ICF until investigation completion. The nature, time of onset, duration, and severity will be documented, together with an Investigator's, or designee's, opinion of the relationship to investigation treatment.

If an AE occurs, appropriate diagnostic and therapeutic measures are to be taken and the investigational treatment must be discontinued if appropriate. Follow-up evaluations of the subject

are to be performed until the subject recovers or until the clinical Investigator considers the situation to be no longer clinically significant.

If clinically significant laboratory abnormalities appear at the final treatment, appropriate additional tests may be performed to clarify the nature of any clinically significant laboratory abnormalities that occur.

10.4 Assessment of Severity

The site Investigator will be asked to provide an assessment of the severity of the AE using the following categories:

Event Severity	Severity Definition
Mild	Usually transient and may require only minimal treatment or therapeutic intervention. The event does not generally interfere with usual activities of daily living. The AE does not influence performance or functioning. Prescription drugs are not ordinarily needed for relief of symptom(s).
Moderate	Usually alleviated with additional specific therapeutic intervention. The event interferes with usual activities of daily living, causing discomfort but poses no significant or permanent risk of harm to the participant. Performance of daily activities is influenced. Treatment of symptom(s) may be needed.
Severe	Interrupts usual activities of daily living, or significantly affects clinical status, or may require intensive therapeutic intervention. Treatment for symptom(s) may be given.

10.5 Relationship to Investigation Treatment

The site Investigator will determine the relationship of the AE to the investigational device according to the following guidelines:

Event Relationship	Relationship Definition
Unrelated	The adverse event is reasonably expected to be related to (or caused by) a concurrent illness, effect of another device/drug or other cause, and is unlikely related to the investigational product.
Possibly Related	The adverse event is reasonably expected to be related to the investigational product, and an alternative etiology is equally or less likely compared to the potential relationship to investigational product.
Probably Related	There is a strong relationship to investigational product, or recurs on re-challenge, and another etiology is unlikely, or there is no other reasonable medical explanation for the event.

10.6 Action Taken for Adverse Events

The site investigator or designee will record the action taken for the AE in the Case Report Form. Actions taken will include:

Action	Action Definition
Treatment Interrupted	The treatment was modified by temporarily terminating the treatment.
Treatment Withdrawn	The treatment was modified through termination of the treatment.
Not Applicable	No action is needed.
Unknown	The action is unknown or to be determined.

10.7 Follow-up of Adverse Events

Every reasonable effort will be made to follow up with subjects who have AEs. Any subject who has an ongoing AE that is related to the investigational medical device during visits will be followed up with, where possible, until resolution. This will be completed at the site investigator's (or designee's) discretion. Any subject who has an ongoing AE that is not related to the investigational medical device at follow-up visits can be closed out as ongoing at the Investigator's discretion.

10.8 Reporting

10.8.1 Device Issue or Deficiency

Any issues regarding the operation of the device or any malfunctions are to be reported to the sponsor. All reported issues will be processed per the Manufacturer's standard operating procedures outside of the study. Information about device issues to be provided to manufacturers will include a description of the event, dates of onset and resolution, action taken, and the outcome.

Copies of all issues documentation submitted to manufacture(s) will be stored as part of the study record. If additional information is needed from sites or investigators, the Sponsor or its delegate may contact the investigator for follow-up information necessary to investigate reported device issue.

It is the responsibility of the site investigator to report any issues associated with a medical device distributed by the Sponsor, regardless of whether they are related to intended use, misuse, or abuse of the product. Reporting must be done as soon as possible (within 48 hours).

10.8.2 Adverse Events

Adverse events are monitored and registered at each visit. In absence of a specific diagnosis, an individual AE form must be filled in for each sign or symptom. Adverse events will be reported to the local IRB as required by their policy and monitored by the Sponsor's delegated monitor.

Persistent AEs will be recorded once until they are resolved or if a new event must be documented due to deterioration. These AEs will be carefully monitored; further details of monitoring of persistent AEs will be provided in the monitoring plan. If an AE is still not resolved at the end of the investigation, this will be documented as ongoing.

For recurrent AEs (i.e., AEs of the same nature, but with a different date of onset), an individual AE form must be completed for each of them.

Adverse events occurring after the termination of the investigation individually and/or of the investigation in total are to be reported to the Sponsor even after the clinical investigation has been finished if, in the judgment of the Investigator, there is an association between the event and the previous use of the Device under investigation.

10.8.3 Anticipated/Unanticipated Adverse Device Effect

All relevant observations, including records concerning adverse device effects (whether anticipated or unanticipated) will be recorded of each subject's study record, per 21 CFR 812.140 or relevant national regulation.

The site investigator will notify the Sponsor or designee and reviewing IRB in writing (e.g., facsimile) immediately, but no later than 72 hours of when an UADE, that is potentially FDA reportable, is first recognized or reported.

The sponsor will immediately conduct an evaluation of any UADE reported. The sponsor will report the results of the evaluation to FDA and to all reviewing IRB and participating investigators within 10 working days after the sponsor first receives notice of the effect. Thereafter the sponsor will continue to submit additional reports to the FDA when requested.

If the sponsor determines that an UADE presents an unreasonable risk to subjects, the sponsor shall terminate all investigations or parts of investigations presenting that risk as soon as possible. Termination shall occur not later than 5 working days after the sponsor makes this determination and not later than 15 working days after the sponsor first received notice of the effect.

11.0 EARLY TERMINATION OR SUSPENSION

11.1 Study Closure, Early Termination or Suspension Criteria

Study closure is defined as closure of a clinical study that occurs when GN Hearing A/S and/or regulatory requirements have been satisfied per the protocol and/or by a decision by GN Hearing A/S or regulatory authority, whichever occurs first. Study Closure is a process initiated by distribution of an initial study closure letter. The study closure process is complete upon distribution of the Final Report or after final payments, whichever occurs last.

The study may be terminated early if the Sponsor determines that unanticipated adverse event(s) presents an unreasonable risk to subjects or for any other reason as Sponsor determines to be appropriate. Termination shall occur no later than five (5) working days after the sponsor makes the determination and no later than fifteen (15) working days after Sponsor first received notice of the effect.

The Sponsor will promptly notify the Investigators of any determination to terminate the study outside of the protocol timeframe. The Sponsor will provide each Investigator with written guidelines/instructions on termination processes and timelines. The Investigator is responsible for reporting the early termination to their local IRB.

Possible reasons for considering study suspension or termination of the study for all centers include but are not limited to AEs and device deficiencies associated with the system or product under investigation which might endanger the safety or welfare of subjects; observed/suspected

performance different from the product's design intent; cancelation of device development; and/or a decision by GN Hearing A/S or regulatory body.

Possible reasons for clinical investigator or center termination or suspension include but are not limited to a failure to obtain initial IRB approval or annual renewal of the study; consistent non-compliance to the protocol; lack of enrollment; noncompliance to regulations and the terms of the Clinical Study Agreement, such as failure to submit data in a timely manner, failure to follow-up on data queries and monitoring findings in a timely manner, etc.; IRB suspension of the center; fraud or fraudulent misconduct, as defined by local law and regulations; and/or Investigator request.

11.2 Withdrawal of IRB Approval

The site investigator is to notify the Sponsor of any withdrawal of IRB approval within 5 working days of such occurrence. If the IRB terminates or suspends its approval of the Study, the site investigator will promptly notify Sponsor and provide a detailed written explanation of the termination or suspension. Upon receipt, the sponsor will provide written guidelines/instructions on subject withdrawal/termination processes and timelines.

12.0 INSTITUTIONAL REVIEW BOARD (IRB) AND REGULATORY REQUIREMENTS

12.1 Regulatory Requirements

To ensure the quality and integrity of research, this study will be conducted according to 21 CFR Part 812 and related regulations, principles of ISO 14155 Good Clinical Practice (GCP), and the Declaration of Helsinki and its amendments.

12.2 IRB Approval Requirements

To approve the research described in the Clinical Investigation Plan (CIP), the IRB shall determine that all the following are satisfied in accordance with 21 CFR 56.111.

- Risks to subjects are reasonable in relation to anticipated benefits
- Selection of subjects is equitable
- Informed consent will be sought and appropriately documented
- Data will be monitored and collected, where appropriate, to ensure the safety of subjects
- Safeguards have been included to protect the rights and welfare of subjects that are likely to be vulnerable to coercion or undue influence

This investigation will be conducted in accordance with the CIP and with the following:

- Consensus ethical principles derived from international guidelines including the Declaration of Helsinki and Council for International Organizations of Medical Sciences International Ethical Guidelines
- Applicable International Organization for Standardization (ISO) Good Clinical Practice (GCP) Guidelines
- Applicable regulations:
    - 21 CFR 50, *Protection of Human Subjects*, provides the requirements and general elements of informed consent;
    - 21 CFR 56, *Institutional Review Boards*, covers the procedures and responsibilities for institutional review boards (IRBs) that approve clinical investigations protocols;
    - 21 CFR 54, *Financial Disclosure by Clinical Investigators*, covers the disclosure of financial compensation to clinical investigators which is part of FDA's assessment of the reliability of the clinical data.
    - 21 CFR 820 Subpart C, *Design Controls of the Quality System Regulation*, provides the requirement for procedures to control the design of the device in order to ensure that the specified design requirements are met.

Where applicable and consistent with local regulations and prior to enrolment of subjects, the CIP, CIP amendments, Informed Consent Form (ICF), Investigator Brochure, and other relevant documents must be submitted to an IRB by the Investigator and reviewed and approved by the IRB before the investigation is initiated. Any additional requirements imposed by the IRB or regulatory authority shall be followed, if appropriate. Enrollment will not start before written confirmation of approval from the relevant central or local IRB.

The site investigator will be responsible for the following:

- Providing written summaries of the status of the investigation to the IRB annually or more frequently in accordance with the requirements, policies, and procedures established by the IRB.
- Notifying the IRB of serious adverse events or other significant safety findings as required by IRB procedures.
- Providing oversight of the conduct of the investigation at the site and adherence to requirements of 21 Code of Federal Regulations (CFR), ISO 14155 guidelines, the IRB, and all other applicable local regulations.

12.3 Subject Compensation

Participants who fail the inclusion criteria will be compensated $60. All others will be compensated at a rate of $60 for each of the three lab sessions plus $70 for the wear trial (a total of $250). Payment will be given at one time at the end of the study.

12.4 CIP Revision/Amendment Management

Changes to the CIP will be documented in written CIP amendments. Major, substantial or significant, amendments will usually require submission to the relevant IRB for approval. In such cases, the amendment will be implemented only after approval from the IRB has been obtained, except for changes necessary to eliminate an immediate hazard to investigation subjects. Minor,

non-substantial, CIP amendments, including administrative changes, will be filed by the designee at each participating site and will be submitted to the relevant IRB or regulatory authorities where required by pertinent regulations. Any amendment that could have an impact on the participant's agreement to participate in the study requires the participant's informed consent prior to continued participation in the study.

12.5 Informed Consent and Privacy Requirements

12.5.1 Informed Consent

Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study and continues throughout the individual's study participation. Consent forms will be IRB/IEC-approved, and the subject will be asked to read and review the document. The investigator will explain the research study to the subject and answer any questions that may arise. A verbal explanation will be provided in terms suited to the participant's comprehension of the purposes, procedures, and potential risks of the study and of their rights as research subjects. Subjects will have the opportunity to carefully review the written consent form and ask questions prior to signing. The subjects should have the opportunity to discuss the study with their family or surrogates or think about it prior to agreeing to participate. The subject will sign the informed consent document prior to any procedures being done specifically for the study. Subjects must be informed that participation is voluntary and that they may withdraw from the study at any time, without prejudice. A copy of the informed consent document will be given to the subjects for their records. The informed consent process will be conducted and documented in the source document, including the date, and the form provided, before the subject undergoes any study-specific procedures. The rights and welfare of the subjects will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this study.

The informed consent forms (ICFs) will describe in detail the study intervention, study procedures, and risks are given to the participant, and written documentation of informed consent is required prior to the study start.

The site investigator or authorized designee must administer the approved ICF to each prospective study patient without coercion or undue improper influence on, or inducement of, the patient to participate. During the consent discussion the site investigator (or designee) must fully inform the patient of all pertinent aspects of the study, using native non-technical language that is understandable to the patient. The subject must be informed about their right to withdraw from the study at any time and for any reason without sanction, penalty, or loss of benefits to which the subject is otherwise entitled and also informed that withdrawal from the study will not jeopardize their future medical care. The subject must also be informed that by participating in the study, they are not waiving their legal rights. The patient must have ample time and opportunity to inquire about details of the study, and to decide whether or not to participate in the clinical study. All

questions about the study should be answered to the satisfaction of the participant. All items discussed in the ICF must be explained.

The ICF should be revised whenever there are changes to procedures outlined in the informed consent or when new information becomes available that may affect the willingness of the subject to participate. For any updated or revised ICFs, the medical file for each subject should document the informed consent process and that written informed consent was obtained for the updated/revised ICF for continued participation in the study.

12.5.2 Privacy Requirements

Subject confidentiality and privacy is strictly held in trust by the participating investigators, their staff, and the sponsor(s). All health data collection is conducted in a manner compliant with 21 CFR Part 11 and applicable data privacy law and regulation in the US. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study, or the data will be released to any unauthorized third party without prior written approval of the sponsor. Additionally, all research activities will be conducted in as private a setting as possible.

Data protection and privacy regulations will be strictly observed in capturing, forwarding, processing, and storing subject data. Every effort will be made to protect subject confidentiality. To maintain patient confidentiality, each patient will be assigned a unique subject identifier upon study enrolment. This subject identifier will be used in place of subject name for data analysis and reporting. Medical record number or other local reference identifiers are not collected as part of the database. All parties will ensure protection of subject personal data and will not include subject names on any study forms, reports, publications, or in any other disclosures, except where required by law. In accordance with local regulations in each of the registry countries, subjects will be informed about data handling procedures and asked for their consent. Data protection and privacy regulations will be observed in capturing, forwarding, processing, and storing patient data.

The study monitor, other authorized representatives of the sponsor, representatives of the IRB, regulatory agencies or Sponsor supplying study product may inspect all documents and records required to be maintained by the investigator, including but not limited to, medical records for the subjects in this study. The clinical study site will permit access to such records.

Subjects will be assigned a unique identifier and will not be identified by name in electronic databases, investigation-related forms, investigation reports, or any related publications. Subject and Investigator personal data will be treated in compliance with all applicable laws and regulations. In the event the CIP, investigation report, or investigation data are included in a public registry, all identifiable information from individual subjects or Investigators will be redacted according to applicable laws and regulations.

The subject must be informed that her personal investigation-related data will be used by the Sponsor in accordance with local data protection law. The level of disclosure must also be explained to the participant. The subject must also be informed that her investigation-related data may be examined by Sponsor or Contract Research Organization (CRO) auditors or other

authorized personnel appointed by the Sponsor, by appropriate IRB members, and by inspectors from regulatory authorities.

13.0 DATA AND QUALITY MANAGEMENT

This study will be performed by Northwestern University, Sertoma Speech and Hearing Center, and Vanderbilt University with guidance, input, review, and approval of GN Hearing A/S, including development of materials, recruitment, training and management of the site, electronic data capture and data management.

13.1 Management of Data

High data quality standards will be maintained, and processes and procedures utilized to repeatedly ensure that the data are as clean and accurate as possible when presented for analysis. Data quality will be enhanced through a series of programmed data quality checks that automatically detect out of range or anomalous data.

The following practices are adopted to ensure data integrity and participant safety:

1. Data, including outcomes data, should not be shared with GN Hearing A/S until study completion. There are two components to this study: (1) in-lab session (Visit 1); and wear-time crossover trial (Visits 2 and 3). Outcome data can be shared with GN Hearing A/S at the completion of each component to this study. That is, the results from Visit 1 can be shared with the sponsor as soon as they are available and prior to the completion of the entire study.

2. The site investigators should be blinded from the raw data and the research staff on site should enter the data into an electronic database (REDCap). Weekly reports of completed data for each visit will be generated by research staff at each site and will be sent to Larry Humes. Progress reports, generated by Larry Humes, will tabulate the number of subjects who have complete data for Visit 1, Visit 2, and Visit 3, for each site separately and combined. Such progress reports will be provided via email to GN Hearing A/S (Troels Vingborg and Todd Fortune) and shared with the site investigators (Ricketts, Dhar) on a weekly basis.

3. Larry Humes will monitor the quality of the data exported from REDCap. PRO-FIT REAG values will be checked to determine that they are reasonable, within 5-7 dB of NAL targets, for the measured pure-tone hearing loss for that participant. The pattern across frequency for the REAG differences between test and retest will also be examined to assess data validity. Such differences should generally be less than 5 dB at a given frequency and also should not decrease with increasing frequency. Concerns about the quality of data being gathered will be shared with each site investigator and GN Hearing A/S as soon as possible.

4. Trained research staff at each site should report any concerns about the quality or validity of the raw data being obtained to the local site investigator immediately and this feedback should be shared among the two site investigators and Larry Humes immediately to determine if protocol amendments are warranted to address these concerns.

5. At study completion at each site, Larry Humes will be primarily responsible for data reduction and analyses with drafts shared with GN Hearing A/S and that site's PI. When both sites have completed data collection, Larry Humes will complete the data reduction and analyses, draft a report, and share this report with both site PIs and GN Hearing A/S.

7. Any adverse events experienced by the participants should be reported by the site investigator to Larry Humes and Carol Sammeth with serious adverse events reported immediately to GN Hearing A/S and the FDA as well. See Section 10.0 for additional details.

13.2 Subject De-Identification

At the end of the study, all study databases will be de-identified and archived at the designated data coordinating center.

Data collected for this study will be analyzed and stored at the data coordinating center. After the study is completed, the de-identified, archived data will be transmitted to and stored at the designated data repository, for use by other researchers including those outside of the study. Permission to transmit data to the data repository will be included in the informed consent.

When the study is completed, access to study data and/or samples will be provided through the data repository.

13.3 Site Record Retention

Site Record retention will be defined by the IRB policies at Vanderbilt University, Northwestern University, and Sertoma Speech and Hearing Center.

14.0 MONITORING PLAN

14.1 Brief Description

In collaboration with investigational site(s), the Sponsor will ensure proper monitoring of the study to confirm that all Sponsor obligations are met and that the study is performed in accordance with the CIP. Monitoring calls and emails will ensure adherence to the CIP, completion of informed consents, IRB/IEC review of the study, maintenance of records, primary outcomes review and source documentation for accuracy and completeness. Further information and details regarding monitoring arrangements can be found in the monitoring plan.

14.2 Reference to Approved Monitoring Plan

The approved monitoring plan will be maintained by the Sponsor or its delegate throughout the study.

15.0 PUBLICATION POLICY

Any publication of the results from this study must be consistent with the Sponsor's publication policy. The rights of the investigator and of the Sponsor with regards to publication of the results of this study/registry are described in the investigator contract.

The results of this study are intended for use in submission to the FDA in support of a 510k submission for the Jabra Enhance Plus device. This study will be registered into the clinicaltrials.gov website.

16.0 ADDITIONAL STUDY MATERIALS

ATTACHMENT A: See attached clinical study user's manual for Jabra Enhance Plus

ATTACHMENT B: Real-ear measurement details

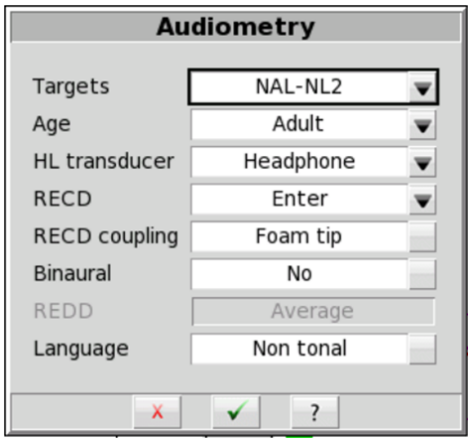
A. **SELF-FIT A & B**: Personalization begins with an estimate of hearing acuity obtained through the Jabra Enhance Plus. The hearing acuity measurements are used internally by the device and are not shared with the hearing aid wearer. Once this step has been completed, devices will apply NAL-NL2 gain prescriptions directly using the estimated hearing acuity to generate the initial fit. For the clinical validation study, probe-tube microphone measures of the REUR and REAR (REAG=REAR in input) will be obtained on the initial fit for a 65-dB speech input using the Audioscan Verifit real-ear measurement system, with instructions as follows:

i. Use the Audioscan Verifit (see procedure below) to measure Real Ear Aided Response (REAR) using the GN-supplied dome/probe tube assembly.
ii. Without adjusting the gain, determine how close the 65 dB-Input referenced Response curve from the output of the device is to the NAL-NL2 65 dB REAR Targets in the Verifit 1 or 2.
iii. Audioscan includes a method for saving measurements to a USB drive. Please use this method for saving the REAR measurements and Targets for analysis of the output.
iv. The file saved to the USB drive should include a .html or .csv file with frequency-specific values that can be used for plotting and analyzing the results.

B. **PRO-FIT**: Audiometric thresholds will be imported, and the devices programmed using custom device programming software (AlgoLabTest) and configured for NAL-NL2 target gains. Probe-tube microphone measures of the REUR and REAR (REAG=REAR-REUR) will be obtained for a 65-dB speech input using the Audioscan Verifit real-ear measurement system, with instructions as follows:

i. Use the Audioscan Verifit (see procedure below) to measure Real Ear Aided Response (REAR) using the GN-supplied dome/probe tube assembly.
ii. Using AlgoLabTest to adjust the gain, attempt to match the 65 dB Gain curve from the output of the device to the NAL-NL2 65 dB Gain Targets in Verifit.
iii. Audioscan includes a method for saving measurements to a USB drive. Please use this method for saving the REAR measurements and targets for analysis of the output.
iv. The file saved to the USB drive should include a .html or .csv file with frequency-specific values that can be used for plotting and analyzing the results.

C. Audioscan Verifit; Speechmap Configuration (https://docs.audioscan.com/userguides/vf2manual.pdf):



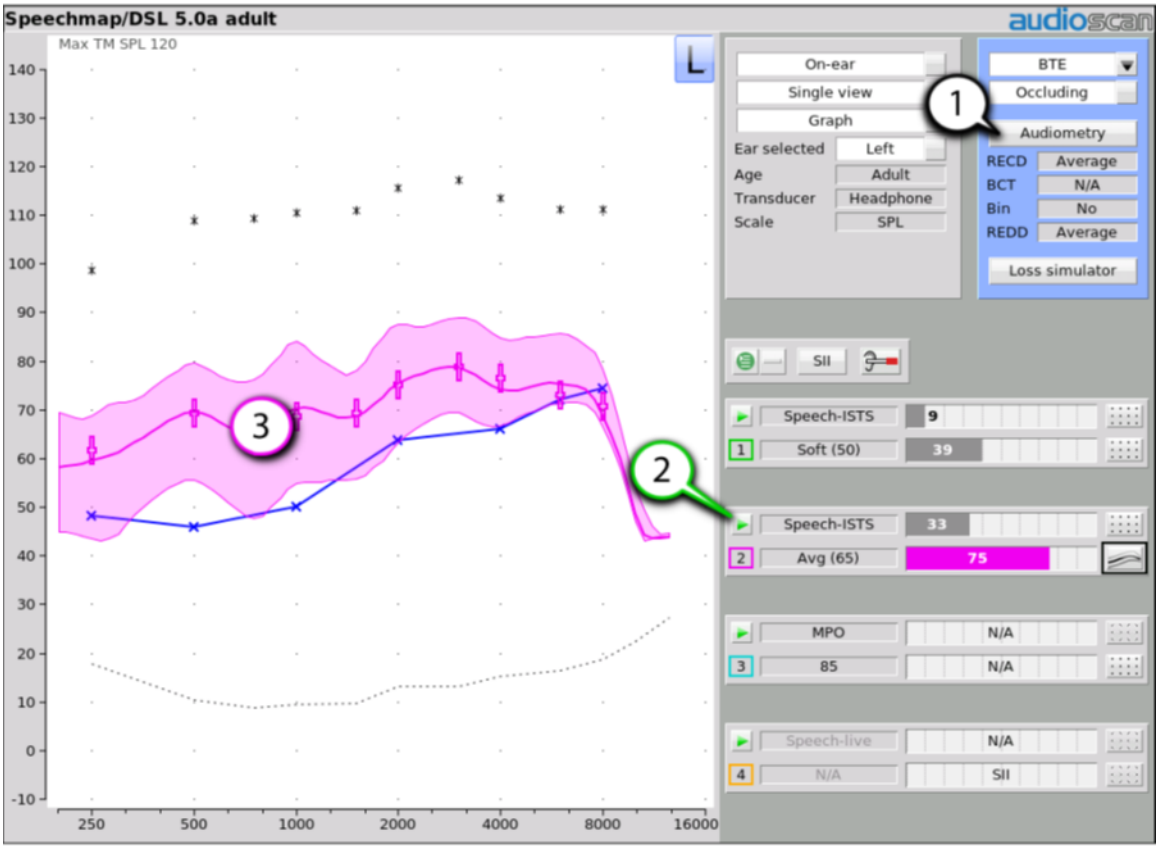
i. Targets: Select [NAL-NL2]
ii. Age: Select [Adult; age ≥ 18 years]
iii. HL Transducer: Select [the Headphone or insert earphone used for testing]
iv. RECD: Select [average]
v. Binaural: Select [Yes]
vi. Language: Select [Non tonal]

D. Audiometric Threshold Entry

i. On the Threshold entry prompt, enter each threshold from the initial screening using a mouse or an external keyboard. Left click the mouse to enter a point. Click again to delete the point. On the keyboard, the arrow keys change frequency and level and the ENTER key on the numeric keypad enters or deletes a point. The keyboard's numeric keypad can also be used to type in data. Switch sides by moving mouse cursor over to other side.
ii. Use the X button to erase the curve next to it.
iii. Use the Copy button at the bottom of the entry screen to copy points on either side to the other side if there are data on one side and no data on the other. The button is disabled and does nothing if both sides contain data or both sides do not contain data.
iv. Click [check] to save the data and exit the entry screen. In case of error: Click [X] to exit the entry screen without saving the data.

E. Fitting to Targets for Average Speech

i.



Follow the instructions in Speechmap screen choices to enter audiometric data and select the fitting rule (NAL-NL2).

ii. Click [play] in the "2" area to start the test. Once the test is started, click the [Stimulus] list button to select the stimulus type. Select “Speech-ISTS” as the stimulus type. Click the [Level] list button and select a stimulus level of 65 dB. The upper bar in this area shows the SII for the unaided stimulus at 65 dB SPL.

iii. PRO-FIT ONLY: While the passage is being presented, adjust the hearing instrument's frequency shaping and gain for average sounds so that the middle curve (the LTASS) falls within the target range, shown by the symbols.

iv. Click [record] to signal average and store a complete passage. Repeat as necessary.

v. In case of error: Click [black square] to stop the test without recording any test data.

vi. Upon completion of a test recording, a colored Aided Audibar shows the SII for the aided average speech signal. The difference between the unaided and aided SII score (and the associated length of their respective 'Audibars') visually quantifies the speech intelligibility improvement for soft speech likely provided by the hearing instrument being fit.

17.0 REFERENCES

1. Cox, R.M. & Alexander, G.C. (1995). The Abbreviated Profile of Hearing Aid Benefit (APHAB). Ear & Hearing, 16, 176-186.

2. Killion, M. C., Niquette, P. A., Gudmundsen, G. I., Revit,L. J., & Banerjee, S. (2004). Development of a quick speech-in-noise test for measuring signal-to-noise ratio loss in normal-hearing and hearing-impaired listeners. Journal of the Acoustical Society of America, 116, 2395–2405.
3. McArdle, R. A., & Wilson, R. H. (2006). Homogeneity of the 18 QuickSIN lists. Journal of the American Academy of Audiology, 17, 157–167.
4. Sabin, A.T., Van Tasell, D.J., Rabinowitz, B. & Dhar, S. (2020). Validation of a self-fitting method for over-the-counter hearing aids. Trends in Hearing, 24, 1-19.

18.0 APPENDICES

Appendix A: List of Abbreviations

ADE	Adverse Device Event
AE	Adverse Event
APHAB	Abbreviated Profile of Hearing Aid Benefit
CFR	Code of Federal Regulations
CIP	Clinical Investigation Plan
FDA	U.S. Food and Drug Administration
GCP	Good Clinical Practices
HIPAA	Health Insurance Portability and Accountability Act of 1996
ICF	Informed Consent Form
IDE	Investigational Device Exemption
IEC	Independent Ethics Committee
NAL-NL2	National Acoustics Laboratories' Nonlinear prescription, Version 2
PRO	Patient-Reported Outcome
QA	Quality Assurance
QC	Quality Control
QuickSIN	Quick Speech-In-Noise test
REAG	Real-Ear Aided Gain
REAR	Real-Ear Aided Response
REOR	Real-Ear Occluded Response

REUR	Real-Ear Unaided Response
SAE	Serious Adverse Event
SNR	Signal-to-Noise Ratio
TAE	Treatment-Emergent AEs
UADE	Unanticipated Adverse Device Effect
WHO	World Health Organization

Appendix B: Investigational Sites

United States, Illinois

Northwestern University
Evanston, Illinois, United States, 60209
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