

**Comparison of Hearing Aid Fitting Outcomes Between Self-fit and Professional Fit for MDHearing Smart Hearing Aids**

**NCT05165121**

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## Exhibit B

### MDHearing App Clinical Research Protocol

- Part One: Human Factors Testing – To be completed prior to the clinical trials.
  - Subjects
    - 20 subjects with mild to moderate sensorineural hearing loss.
    - Subjects must have and be able to use a smartphone that is compatible with the MDHearing app.
    - Subjects will not be allowed to participate if they have any signs of middle or outer ear infection or abnormality.
    - All subjects will undergo a hearing evaluation to ensure they do not have any of the following conditions:
      - Visible congenital or traumatic deformity of the ear.
      - History of active drainage from the ear in the previous 90 days.
      - History of sudden or rapidly progressive hearing loss within the previous 90 days.
      - Acute or chronic dizziness.
      - Unilateral hearing loss of sudden or recent onset within the previous 90 days.
      - Audiometric air-bone gap equal to or greater than 15 decibels at 500 Hz, 1,000 Hz, and 2,000 Hz.
      - Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
      - Pain or discomfort in the ear.
    - Subjects will be at least 18 years old. There are no other limits on subject age.
  - Protocol
    - Subjects will unbox the CORE hearing aid and perform usability tasks in simulated use environments.
    - Subjects will have access to the manuals and quick start guide for the CORE hearing aid and for the MDHearing app.
    - Tasks for usability will include the following:
      - Downloading the MDHearing app.
      - Registering for the MDHearing app.
      - Placing a battery in the CORE hearing aid.
      - Pairing the MDHearing app to the CORE hearing aid.
      - Using the app to take the personalization profile.
      - Using the app to adjust the volume, program, noise reduction, microphone direction, bass, treble, and mid pitched settings.
      - Turning off the CORE hearing aid.
    - Tasks for safety will include the following:
      - Identify how a user knows they are a candidate for a hearing aid. See Identification Information.

- Sound awareness safety. Identification of sounds that should require wearing hearing protection ie mowing the lawn, attending a loud concert, shooting a gun, etc. Recognition that hearing aids do not provide hearing protection.
- Program safety. Recognition that certain programs are not appropriate for certain situations. E.g. Program 4 is a directional microphone program and thus is not appropriate for driving a car due to compromised awareness of sound behind you such as sirens.

## Part Two: Clinical Testing Protocol: Laboratory Evaluation of Validity of MDHearing Self-Fitting Method

- Subjects:
  - 75 subjects with mild to moderate sensorineural hearing loss.
  - Subjects will not be allowed to participate if they have any signs of middle or outer ear infection or abnormality.
  - All subjects will undergo a hearing evaluation to ensure they do not have any of the following conditions:
    - Visible congenital or traumatic deformity of the ear.
    - History of active drainage from the ear in the previous 90 days.
    - History of sudden or rapidly progressive hearing loss within the previous 90 days.
    - Acute or chronic dizziness.
    - Unilateral hearing loss of sudden or recent onset within the previous 90 days.
    - Audiometric air-bone gap equal to or greater than 15 decibels at 500 Hz, 1,000 Hz, and 2,000 Hz.
    - Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
    - Pain or discomfort in the ear.
  - At least one air conduction threshold must be above 25dB. All air conduction thresholds must be below 60db.
  - Subjects will be at least 18 years old. There are no other limits on subject age.
- Protocol and ANSI specs
  - Subjects take the personalization profile on an iPad tablet.
  - Subjects then listen to the same recorded speech passage at their Most Comfortable Listening level 3 times and adjust the aids for comfort (volume, bass, treble, and mid) while the passage is playing. Subjects do not have to make changes if they are content with the sound quality.
  - After each passage, Real Ear measurements will be taken. Gain results at 500, 1000, 2000, and 4000Hz for a 60dB input will be recorded.

- The differences between gain for each frequency will be evaluated per subject. See table below for example:

Subject 1		500Hz	1000Hz	2000Hz	4000Hz	Total gain deviation
	Passage 1	15dB	18dB	20dB	23dB	
	Passage 2	17dB	19dB	22dB	22dB	
	Passage 3	14dB	18dB	19dB	24dB	
	Average deviations	2.5	1	2.5	1.5	1.9dB

### Part Three: Comparative Clinical Testing Protocol: Clinical Validation of MDHearing Self-Fitting Method

- Subjects
  - 75 subjects with mild to moderate sensorineural hearing loss.
  - Subjects must have and be able to use a smartphone that is compatible with the MDHearing app.
  - Subjects will not be allowed to participate if they have any signs of middle or outer ear infection or abnormality.
  - All subjects will undergo a hearing evaluation to ensure they do not have any of the following conditions:
    - Visible congenital or traumatic deformity of the ear.
    - History of active drainage from the ear in the previous 90 days.
    - History of sudden or rapidly progressive hearing loss within the previous 90 days.
    - Acute or chronic dizziness.
    - Unilateral hearing loss of sudden or recent onset within the previous 90 days.
    - Audiometric air-bone gap equal to or greater than 15 decibels at 500 Hz, 1,000 Hz, and 2,000 Hz.
    - Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
    - Pain or discomfort in the ear.
  - At least one air conduction threshold must be greater than 25dB. All air conduction thresholds must be less than 60db.
  - Subjects will be at least 18 years old. There are no other limits on subject age.
- First visit
  - A hearing test is performed on all subjects.
  - Subjects complete the Abbreviated Profile of Hearing Aid Benefit (APHAB) and Speech, Spatial, and Qualities of Hearing Scale (SSQ-12).
  - Subjects complete the Quick SIN. (Speech in Noise test)

- All subjects use the MDHearing CORE with the tubing and ComfortTIP that is appropriate for their hearing loss. The tubing and ComfortTIP selection is audiologist fit to half the participants. The other half of the participants chose their own tubing and ComfortTIP. The tubing options are thin tubing with open ComfortTIP or thin tubing with closed ComfortTIP.
- The subjects are split into two groups.
  - The groups are controlled for demographic such as age, gender, length of hearing loss, previous hearing aid use, length of hearing aid use, comfort with technology and level of sensorineural hearing loss.
- Half of the subjects take the MDHearing personalization profile and are fit using NAL NL 2 fitting software embedded in the MDHearing app. (Self-fit group)
- Half of the subjects are fit using hearing aid fitting software with the NAL NL 2 fitting method. (Audiologist fit group)
- The subjects that are self-fit have access to changing their volume control, programs, bass, treble, and mid pitched settings, noise reduction, and microphone direction using the MDHearing app.
- The subjects that are audiologist fit have access to changing their volume control and programs on the CORE hearing aid. The audiologists have access to changing the bass, treble, and mid pitched settings, noise reduction, and microphone direction using the fitting software.
- Wearing period
  - Subjects wear the hearing aids for one month to acclimate. Minimum of 8 hours per day usage is required.
  - Subjects in the audiology fit group will have one audiology appointment approximately 2 weeks after being fit. This will give them a chance to have questions answered and for fine tuning adjustments to programming as needed.
  - Both groups have access to online rehabilitation programs such as Angelsound, if they wish to use it.
- Second visit – One month later
  - Subjects in the self-fit group answer the MDHearing questionnaire.
  - Perform Quick SIN on subjects in both groups. Compare results for statistically significant differences.
  - Ask subjects to complete the Abbreviated Profile of Hearing Aid Benefit (APHAB) and Speech, Spatial, and Qualities of Hearing Scale (SSQ-12). Compare results for statistically significant differences.
  - Perform Real Ear on all subjects using their preferred settings.
  - Compare overall gain settings in relation to hearing loss in both groups. Compare gain settings at 500, 1000, 2000, and 4000Hz as a 4 frequency average in both groups.
    - See Figure 7 in the Bose DeNovo for information on this.