Medtronic Global Form	[redacted] Clinical Investigation Plan

Clinical Investigation Plan

Clinical Investigation Plan/Study Title	Ambispective Clinical Evaluation of Sophono™ (ACES)
Clinical Investigation Plan Identifier	[redacted]
Study Product Name	Sophono Alpha 2 and Alpha 2 MPO Systems
Sponsor/Local Sponsor	Medtronic Xomed, Inc. 6743 Southpoint Dr North Jacksonville, FL 32216 Telephone: (904) 296-9600
Document Version	[redacted]

Confidentiality Statement

[redacted]

Version	Summary of Changes	Author(s)/Title
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

2. Investigator Statement

Study product Name	Ambispecitve Clinical Evaluation of Sophono™ (ACES)
Sponsor	Medtronic Xomed, Inc. 6743 Southpoint Dr North Jacksonville, FL 32216 Telephone: (904) 296-9600
Clinical Investigation Plan Identifier	[redacted]
Version Number/Date	[redacted]17Jul2017

I have read the protocol, including all appendices, and I agree that it contains all necessary details for me and my staff to conduct this study as described. I will conduct this study as outlined herein and will make a reasonable effort to complete the study within the time designated.

I agree to comply with International Conference on Harmonization Guidelines on Good Clinical Practice. I agree to ensure that the confidential information contained in this document will not be used for any purpose other than the evaluation and conduct of the clinical investigation without the prior written consent of Medtronic.

I will provide all study personnel under my supervision copies of the protocol and access to all information provided by Medtronic. I will discuss this material with them to ensure that they are fully informed about the products and the study.

Investigator's Signature:	
Investigator's Name:	
Institution:	
Date:	

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3. Glossary

Term	***Definition***
AE	Adverse Event
AC	Air Conduction
ACES	Ambispective Clinical Evaluation of Sophono
ADE	Adverse Device Effect
Ambispective	Inclusion of both retrospective and prospective components
ANSI	American National Standards Institute
APHAB	Abbreviated Profile of Hearing Aid Benefit
BAHA	Bone Anchored Hearing Aid
BC	Bone Conduction
BKB-SIN	Bamford-Kowal-Bench Speech-In-Noise
CFR	Code of Federal Regulations
CHL	Conductive Hearing Loss
CRF	Case Report Form
CROS	Contralateral Routing Of Signal
CSF	Cerebrospinal Fluid

Term	***Definition***
dB	Decibel
DSP	Digital Signal Processing
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
ENT	Ear, Nose and Throat
GCP	Good Clinical Practice
HL	Hearing Loss
Hz	Hertz
IC	Informed Consent
IRB/IEC	Institutional Review Board/Institutional Ethics Committee
MDR	Medical Device Reporting System
MPO	Maximum Power Output
MRI	Magnetic Resonance Imaging
PTA	Pure Tone Average
SNR	Signal-to-Noise Ratio
SRT	Speech Recognition Threshold
SSD	Single-Sided Deafness
QOL	Quality of Life

Term	***Definition***
USADE	Unanticipated Serious Adverse Device Effect

4. Synopsis

Clinical Study Type	Post-market (Ambispective)
Sponsor	Medtronic Xomed, Inc. 6743 Southpoint Dr North Jacksonville, FL 32216 Telephone: (904) 296-9600
Indication under investigation	There is no indication under investigation; this is a post-market study. Below is the currently cleared indication for use: The Otomag™ Alpha 2 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Magnetic Implant (patients 5 years of age and up) for the following patients and indications: • Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB hearing loss (HL) (measured at 500, 1000, 2000, and 3000 Hz). • Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed HL. The difference between the left and right sides' BC thresholds should be less than 10 dB on average measured at 500, 1000, 2000, and 4000 Hz, or less than 15 dB at individual frequencies. • Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use air conduction (AC) Contralateral Routing of Signal (CROS). The PTA AC threshold of the hearing ear should be better than 20 dB HL (measured at 500, 1000, 2000 and 3000 Hz).
Investigation Purpose	Accumulate post-market clinical evidence for the safety and effectiveness of the Sophono Alpha 2 Maximum Power Output (MPO) systems.

Product Status	Cleared for use in the geography where study is being conducted (USA).
Primary Objective(s)	The primary objectives of this study are to • Assess the safety of the Sophono implant • Assess the effectiveness of the Sophono Alpha 2 MPO processor
Secondary Objective(s)	The secondary objectives of this study are to • Compare the effectiveness of the Sophono Alpha 2 processor to the Alpha 2 MPO processor • Assess the effectiveness of the Sophono Alpha 2 and the Sophono Alpha 2 MPO over time • Assess subject satisfaction after system use • Assess Quality of Life (QOL) after system use
Study Design	Ambispective, multi-center, single-blind, intra-subject controlled study to assess safety of the Sophono implant and effectiveness of the Sophono processors in subjects with single-sided deafness (SSD), conductive hearing loss (CHL), and mixed HL. Subject population: Any subject who currently has or who has had the Sophono implant (including those who have been explanted) Follow-up schedule: A clinic visit to evaluate the subject and collect self-assessments.
Study Population	Males and females who meet study criteria will be included in the study. Subjects are expected to represent those diagnosed with CHL, SSD and mixed HL. Subjects will be recruited by Investigators who have implanted the Sophono system.
Sample Size	~100 subjects at up to 15 investigational sites in the US
Inclusion/Exclusion Criteria	**Inclusion Criteria** • Any subject who currently has or who has had the Sophono implant (including those who have been explanted) • Has or has had Sophono implant for 3 months or greater

	Exclusion Criteria • Subject has implant but is unable or unwilling to perform audiologic testing • Subject is currently participating in another clinical study and has not been approved for concurrent enrollment by the Study Sponsor

Study Procedures and Assessments	After proper administration and signing of the Informed Consent (IC) and Research Authorization Forms, all potential subjects will be assessed for study eligibility based on the Inclusion and Exclusion Criteria.
	Retrospective data collection from medical charts for safety and baseline data will be collected by the site.
	<u>Prospective Data Collection (visit)</u>:
	• ENT visit
	  • Examination of implanted ear
	  • Satisfaction Questions
	  • QOL questions: Abbreviated Profile of Hearing Aid Benefit (APHAB)™ Version A
	• Audiologist Visit: Optimization of device programming for all aided tests should be completed.
	  • Hearing in Noise Test: BKB-SIN
	  • Speech and Language Tests: Word Recognition Score, Speech Reception Threshold
	  • Audiograms:
	  • Baseline AC Thresholds at octave intervals at 250, 500, 1000, 2000, 3000, 4000 and 8000 Hz
	  • Test Baseline BC and Aided Thresholds at 500, 1000, 2000, 3000 and 4000 Hz
	• Subjects are blinded to processor types for all tests

<table>
<tr><td></td><td>Audiogram Test Design
<table><tr><th>Tests</th><th>Subject has Alpha 1, Alpha 2, or Alpha 2 MPO Processor*</th></tr><tr><td>Test 1</td><td>No processor</td></tr><tr><td>Test 2</td><td>Alpha 2</td></tr><tr><td>Test 3</td><td>Alpha 2 MPO</td></tr></table>
*Alpha 2 and Alpha 2 MPO processors will be provided to each site for use in the study. Thus, regardless of the processor the subject wears daily, both Alpha2 and Alpha 2 MPO can be tested on each subject.</td></tr>
<tr><td>Safety Assessments</td><td>A review and assessment of all device-related Adverse Events (AE) collected retrospectively via chart review, and any prospective device-related AE that occur from the time of subject consent until the time of study exit.</td></tr>
<tr><td>Statistics</td><td>The primary effectiveness endpoints are the improvement in aided hearing from unaided hearing by the Sophono Alpha 2 MPO processor. This endpoint will be summarized by means of paired (samples) t-test or Wilcoxon signed rank sum test according to the normal or non-normal distribution as appropriate.

The primary safety endpoint is an assessment of all AEs (prospective or retrospective) that are directly attributable to the Sophono device (implant or processor). This endpoint will be the proportion of events reported with confidence interval (95%).</td></tr>
</table>

5. Introduction

5.1. Background

Over the past three decades, bone-anchored hearing devices have become increasingly popular for the restoration of various types of hearing loss (HL) in the adult and pediatric populations. Though the idea of bone-conduction for sound amplification has been known and studied since the Renaissance, the concept of a device fully implanted within bone was not developed until the 1970s.(1)

Percutaneous devices have been successfully used to treat conductive hearing loss (CHL) both in adult and in pediatric patients.(2–4) Percutaneous devices have the advantage of direct transmission of vibrations through the bone, thus providing optimal hearing gain; however, their drawbacks include the need for osseointegration, risk of local infection, soft tissue overgrowth and poor aesthetic outcome.

It has been demonstrated that children with these percutaneous implants are more prone to adverse events (AEs) (e.g. skin reactions and [traumatic] implant loss) compared with adults.(5–7) Recent data show that children experience adverse skin reactions in 7.8% of the implant cases, and 15.2% of these percutaneous implants are lost in children.(8)

Therefore, a device system that provides bone conduction (BC) hearing while the skin remains intact is ideal and such transcutaneous devices (e.g. Sophono Alpha 2 and Alpha 2 Maximum Power Output (MPO)) are currently the subject of new research and optimization.

In 1986, Hough et al. (9) introduced the first transcutaneous concept, the Temporal Bone Stimulator, also termed the Xomed-Audiant device (Audiant). This device system contained a permanent magnet that was implanted in the temporal bone and covered by a thin layer of skin. Sound vibrations were transferred transcutaneously by an external coil that was positioned on the skin to the implanted magnet. Consequently, the implanted magnet was part of the actuator of the Audiant device. The external coil was powered by an amplifier in a behind-the-ear housing or in a larger, bodyworn housing. The major disadvantage of this configuration was the relatively wide distance between the implanted magnet and the external driving coil (10); resultantly, gain and maximum output were low (11) and significantly worse compared with that of the percutaneous alternative.(10) Additionally, the clinical outcomes of the Audiant were less favorable (12), and the device was withdrawn from the market.

In 2005, Siegert developed the Otomag BC hearing device, a transcutaneous BC implant that uses dual magnets implanted snugly onto the temporal bone with five screws. The sound processor attaches to the skin with a magnetic base plate that is available in a variety of strengths to provide options for

attachment strength. Siegert reported no major complications in over 100 patients related to implantation and only minor skin reactions which resolved after adjusting the forces of the magnets.(13,14)

The Otomag device was purchased by Sophono in 2010 and became commercially known as the Sophono Alpha 1 System; the system has gone through a series of upgrades to the sound processor (Alpha 2 and Alpha 2 MPO) while the implant with dual magnets remains relatively unchanged since the inception (note: Otomag will hereafter be referred to as "Sophono™"). Bench audiogram research and ancillary data presented at society meetings indicate an improved feedback free gain from the Alpha 2 MPO device; however, to date no studies have been published. The Sophono Company was acquired by Medtronic in 2015.

The aim of this study is to examine the long-term (implant duration three months or longer) audiologic, safety, and quality of life (QOL) outcomes of subjects implanted with the Sophono bone conduction hearing implant and to compare the Alpha 2 to the Alpha 2 MPO.

5.2. Purpose

Accumulate post-market clinical evidence for the safety and effectiveness of the Sophono Alpha 2 and Alpha 2 MPO systems.

6. Objectives and Endpoints

6.1. Objectives

6.1.1. Primary Objectives

The primary objectives of this study are to

- Assess the safety of the Sophono implant
- Assess the effectiveness of the Sophono Alpha 2 MPO processor

in subjects diagnosed with CHL, SSD and mixed HL who currently has or has had the Sophono implant.

6.1.2. Secondary Objectives

The secondary objectives of this study are to

- Compare the effectiveness of the Sophono Alpha 2 processor to the Alpha 2 MPO processor

- Assess the effectiveness of the Sophono Alpha 2 and the Sophono Alpha 2 MPO over time
- Assess subject satisfaction after system use
- Assess QOL after system use

in subjects diagnosed with CHL, SSD and mixed HL who currently has or has had the Sophono implant.

6.2. Endpoints

6.2.1. Primary Endpoint

6.2.1.1. Primary Safety Endpoint

The primary safety endpoint is the proportion of AEs related to the Sophono implant, which will be assessed through retrospective surgical chart review and prospective ENT exam.

6.2.1.2. Primary Efficacy Endpoint

The primary efficacy endpoint is the difference (gain) in the free-field pure tone audiometry assessed by pure tone average (PTA) unaided (AC) and aided (BC) by the Alpha 2 MPO processor.

6.2.2. Secondary Endpoints

The secondary endpoints include:

- The difference in the free-field pure tone audiometry assessed by PTA aided by Alpha 2 processor compared to the PTA aided by Alpha 2 MPO processor
- Change over time of PTA in the Sophono Alpha 2 and Alpha 2 MPO
- Subject satisfaction, via non-validated satisfaction questions and QOL assessment through validated Abbreviated Profile of Hearing Aid Benefit (APHAB)™ assessment

6.2.3. Other Endpoints

Other endpoints include:

- Change over time in speech reception threshold scores in the Sophono Alpha 2 and Alpha 2 MPO
- Change over time in word recognition scores in the Sophono Alpha 2 and Alpha 2 MPO

7. Study Design

This study is an ambispective, multi-center, single-blind, intra-subject controlled study to assess safety of the Sophono implant and effectiveness of the Sophono Alpha 2 MPO processor in subjects with single-sided deafness (SSD), CHL, and mixed HL. This study will enroll approximately 100 subjects (with unilateral or bilateral implants) at up to 15 investigational sites in the US. (Investigational sites may include separate Audiology Centers, if applicable).

The subject population includes any patient who currently has or has had the Sophono implant, including those patients who have been explanted.

The study will consist of a retrospective medical chart review to collect data on AEs for all subjects upon receiving informed consent. A prospective clinic visit for subjects still implanted with the Sophono implant will be conducted to evaluate the subject's implant site and conduct hearing tests, along with a QOL and satisfaction self-assessment.

7.1. Duration

It is anticipated this study will conclude within 15 months of enrollment of the first subject. This estimation is based on the following assumptions: 12 months for subject enrollment/participation, 3 months for data cleaning, analysis, and final report.

7.2. Rationale

This study is being conducted to provide an expanded data portfolio of the post-market safety and performance of the Sophono Alpha 2 MPO system. [redacted]

8. Product Description

8.1. General

The Sophono Bone Conduction Hearing Systems are a family of sound processors and accessories that operate on the principle of BC of sound vibrations. The Sophono Bone Conduction Hearing Systems

transmits audio vibrations through the skin into the bone where sound is sensed by the inner ear/cochlea.

The Sophono Sound Processor is magnetically attracted to the Magnetic Implant and Magnetic Spacer. The Magnetic Implant, which is secured to the skull bone, affixes the Magnetic Spacer to the head transcutaneously through magnetic attraction forces, and the Sound Processor is magnetically affixed to the Magnetic Spacer. Vibration from the Sound Processor is transduced through the Magnetic Spacer to the Magnetic Implant and through the bone to the inner ear.

Figure 1 Sophono Bone Conduction Hearing System

The Magnetic Implant is the same size and configuration for all subjects, regardless of the processor. The Attract® Magnetic Spacer comes in various strengths. The appropriate strength for daily wear is recommended by the Audiologist at the time of processor optimization. The results of the hearing tests with these magnets are out of scope of this study.

8.1.1. Magnetic Implant

The Sophono Magnetic Implant is comprised of [redacted] The implant casing is designed to use 5 craniomaxillofacial screws to secure

it to the bone. The implant provides magnetic retention through the skin to a magnetic spacer, which in turn holds the audio processor.

8.1.2. Magnetic Spacer

The Sophono Magnetic Spacer is an externally worn component that magnetically couples the Sophono Sound processor to the Sophono magnetic implant. The Magnetic Spacers also contain [redacted] Spacers are available in a range of magnetic strengths. They are labeled with "dots" to note the magnetic strength (1-dot represents a lower magnetic strength; 5-dots represent a higher magnetic strength). The strength is also indicated by the first digit in the engraved numbers (as shown in Figure 1). Typically a processor is shipped with five spacers (dots 1 through 5). Other spacers (both weaker and stronger) are also available.

8.1.3. Sound Processors

The Sophono Processor is an audio processor that converts sound into mechanical vibrations. Sound enters the audio processor through the microphones, which then goes through [redacted] he vibrations are carried through the patient's skin and skull to the cochlea where they are perceived as sound. The Sophono Sound Processors have a simple user interface with a combined on/off and volume switch wheel, and a push button switch that allows the user to swap between four programmable settings configured by the clinician during the fitting session.

Table 1. Sophono Sound Processors

Sophono Sound Processor	*Product Number*
Alpha 1	S0001-XX
Alpha 2	S0415-XX
Alpha 2 MPO	S0415-XX
Alpha 2 MPO Low Profile	S0415-XX

8.2. Manufacturer

Sophono, Inc.
5744 Central Ave. #100
Boulder, CO 80301

8.3. Intended Population

The Sophono Systems are designed for use for those patients with CHL, those patients who have sensorineural hearing loss up to 45 dB in combination with their CHL, and SSD as defined in the indications for use. The prescriptive formula and adjustments available to the audiologist in the software allow for programming the Sophono Systems for individual patient HL.

8.4. Equipment

The following auditory measurement equipment is required for the subject follow-up visit:

- Audiometer
- BKB-SIN Hearing in Noise Test Software (provided by Sponsor)
- Speech Recognition Test digital recording (provided by Sponsor)
- Word Recognition NU-6 digital recording (provided by Sponsor)
- Sophono Alpha 2 and Alpha 2 MPO processors (provided by Sponsor)

8.5. Product Use

The Sophono Alpha 2 and Alpha 2 MPO Processors will be used in accordance with the study design in Section 10. All testing is performed according to standard audiology protocol.

8.6. Product Training Requirements

Study Investigators and Audiologists will be qualified for this study based on their experience with the product as currently on the market. No additional product training is expected but will be provided upon request.

8.7. Product Receipt and Tracking

Alpha 2 and Alpha 2 MPO processors provided to each site will be tracked by identification number in the Device Accountability Log. As soon as possible after receipt, and prior to first use, the site will connect

the processor to the software to confirm processor response and ensure no damage was sustained during shipping. Any damage to the processors will be documented. The product will be compared to the Log by a site representative and signed. The signed Log will be copied and faxed or scanned back to the Sponsor. The original will be retained at the site in the Study Binder.

8.8. Product Storage

Each participating site will receive one Alpha 2 and one Alpha 2 MPO sound processor to use as a comparator in the study. These processors will be stored in a secure location at the clinical site with access restricted to designated study personnel only. Storage requirements should be in accordance with the Instructions for Use provided with the processors, sites' operating policies, and applicable federal and geographic regulations.

8.9. Product Return

The Alpha 2 and Alpha 2 MPO processors provided to the sites for the study should be returned as part of site closure activities to **Medtronic, Inc.** at the following address:

[redacted]

8.10. Product Accountability

A Device Accountability Log will be maintained for the receipt of the Alpha 2 and Alpha 2 MPO processors provided to each site. Devices will only be used on subjects who have qualified for the study and have signed an Informed Consent (IC) and Research Authorization as part of the enrollment process. Device accountability is required by the site to ensure accurate and secure inventory stores. Device reconciliation must include receipt and final disposition and method of final allocation per device.

9. Selection of Subjects

9.1. Study Population

The subject population for this study includes male and female patients who have received the Sophono implant. Subjects will be recruited from Investigators who have implanted Sophono systems or from other non-investigator physician referrals. Subjects are expected to represent a population diagnosed with CHL, SSD, and mixed HL.

9.2. Subject Enrollment

All subjects will be screened for study eligibility. A qualified member of the investigational site's research team will review the inclusion and exclusion criteria to screen each subject. Subjects will be considered enrolled into the study when they have both:

- Been informed of the study design, objectives, risks and benefits
- Confirmed interest in participation by signing an IC and Research Authorization Forms

A Log of subjects treated with Sophono at each site will be reviewed for eligibility criteria. Any subject who currently has or who has had the Sophono implant (including those who have been explanted) may be enrolled. This means subjects implanted outside of the intended indications may have data collected as part of this study.

A Screening and Enrollment Log will be maintained for all subjects and will include information regarding subjects who have met the screening criteria and subjects who have not met the screening criteria (screen-fail). For screen-fail subjects, a reason for failure will be noted (e.g., patient declined participation, eligibility criterion not met, etc.).

To be enrolled in this study, subjects must meet **ALL** of the inclusion criteria and **NONE** of the exclusion criteria:

9.3. Inclusion Criteria

- Any subject who currently has or who has had the Sophono implant (including those who have been explanted)
- Has or has had Sophono implant for 3 months or longer

9.4. Exclusion Criteria

- Subject has implant but is unable or unwilling to perform audiologic testing
- Subject is currently participating in another clinical study and has not been approved for concurrent enrollment by the Study Sponsor

10. Study Procedures

Prior to enrolling subjects, the Study Investigator and associated study personnel will undergo study-related training. All training will be documented and maintained in the study files.

After signing the IC and Research Authorization Forms, subjects will be screened for eligibility of the Inclusion/Exclusion criteria, which will be documented on the Inclusion/Exclusion Criteria Case Report Form (CRF).

10.1. Schedule of Events

After proper administration and signing of the IC and Research Authorization Forms, all potential subjects will be assessed for study eligibility based on the Inclusion and Exclusion Criteria. Inclusion and Exclusions data as well as limited demographic information will be captured in the subject CRFs.

A ***retrospective review*** of the subject's medical chart will be performed to gather and report data on subject surgical history, reportable AEs from the time of implantation to time of chart review, previous QOL scores, and previous audiometric testing results for Alpha 2 and/or Alpha 2 MPO processors.

An ***in-office visit*** will be conducted with an ENT physician and Audiologist, ideally on the same day, where the following assessments will take place:

ENT Visit:

The ENT visit will consist of an examination of the ear and implant site for skin complications (according to the *Holger Skin Evaluation Index* in Table 2) or other potential AEs (see Section 12 for reportable AEs). The ENT Visit CRF will detail findings (such as erythema, scar, etc.) as well as complications (skin loss, infection, etc.). Any such complications will be recorded on an AE form.

Sophono system satisfaction and QOL questions shall also be administered to allow the subjects' perceived benefits to be assessed. The QOL assessment will be done using the APHAB Version A.

Table 2. Holger Skin Evaluation Index

The skin directly over the implant site will be evaluated on the Holger Skin Evaluation Index.

Holger Skin Evaluation Index
0 = No irritation. Epithelium debris removed if present.
1 = Slight redness, local treatment.
2 = Red and slightly moist tissue. No granuloma formation noted. Local treatment. Extra controls.
3 = Status as in 1 and 2 but local revision became necessary.
4 = Removal of skin-penetrating implant necessary due to infection.
R = Removed implant for reasons not related to skin problems.

Audiology Visit:

All audiometric testing equipment should be calibrated and tested to American National Standards Institute (ANSI) standards, in good repair and functioning well.

All tests should be performed in the order presented in Table 3. Subject will be blinded to processor order.

In sound field testing the good ear should be plugged using an ear plug. The speech presented should be a recording. When results indicate the need for masking, effective masking should be presented in the non-test ear through the use of inserts or headphones using speech weighted noise. Testing should be performed on the affected ear unless otherwise noted.

All audiometric testing shall include aided and unaided testing since completing basic pure tone and speech audiometry in the unaided and aided condition allows functional gain measurements to be made.

Unaided

1. Audiometry thresholds should be obtained for **both** ears at the following frequencies:
    - Basic Audiometry (inserts or headphones) AC: 250, 500, 1000, 2000, 3000, 4000 & 8000 Hz
    - BC: 500, 1000, 2000, 3000 & 4000 Hz

2. Speech Reception Threshold should be conducted using spondee words. The speech presented should be a recording.

3. Word Recognition should be conducted using *one* NU-6 list for each test. The speech presented should be a recording. The standardized monosyllabic word list should be presented at **65 dBHL** (Hearing Level).

4. Hearing in Noise Testing (HINT) should be conducted using the BKB-SIN. Recording is presented via a single loudspeaker **in the sound field**.

   Recorded testing should have babble and speech presented from the same speaker **at 70 dBHL** with the subject 1 meter from speaker at 0° azimuth.

Aided

1. Audiometry thresholds should be obtained at the following frequencies:
    - Aided (sound field): 500, 1000, 2000, 3000 & 4000 Hz

   Processors should start at 100% optimization and only be lowered if feedback is intolerable for subject.

2. Speech Reception Threshold should be conducted using spondee words in the sound field. The speech presented should be a recording.

3. Word Recognition should be conducted using *one* NU-6 list for each test in the sound field. The speech presented should be a recording. The standardized monosyllabic word list should be presented at **65 dBHL**.

4. HINT should be conducted using the BKB-SIN. Recording is presented via a single loudspeaker in the sound field.

   Recorded testing should have babble and speech presented from the same speaker at **70 dBHL** with the subject 1 meter from speaker at 0° azimuth.

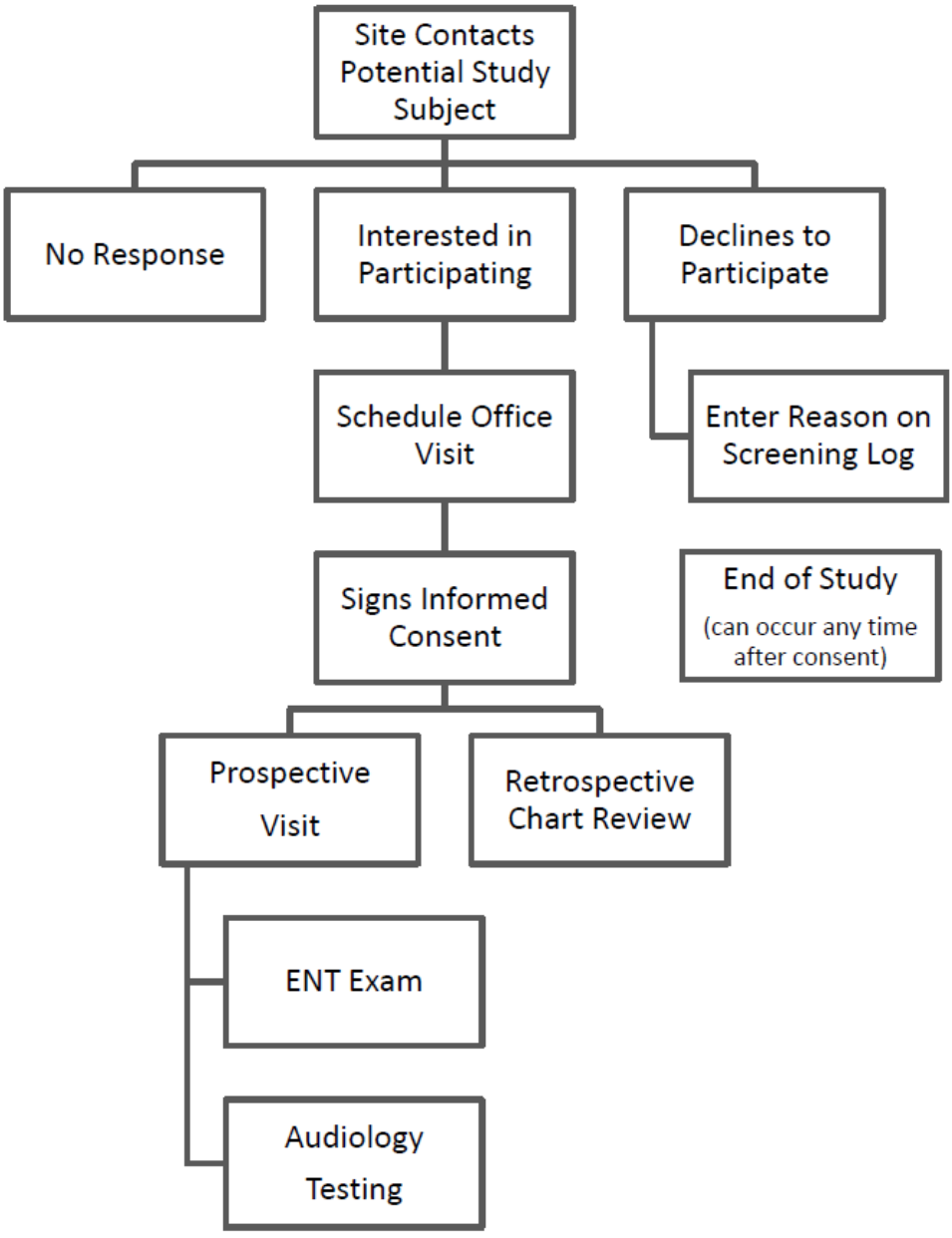

Figure 2. Study Flow Chart

10.2. Subject Screening

Sites will have a log of all patients at their Institution who have been implanted with the Sophono implant, including those who have been explanted. All subjects will be contacted for interest in study participation and asked to sign the IC and Research Authorization Form for retrospective medical chart review as well as a prospective data collection visit. Any subject's unwillingness to participate will be documented in the Subject Screening/Enrollment Log.

10.3. Prior and Concomitant Medications

No change in medication is required for this study, nor will any additional medications be required. Medications will not be collected unless relevant to an AE.

10.4. Subject Consent

Prior to study enrollment and before any study visits are initiated, all subjects must document their consent by signing an IC and Research Authorization Form. The Study Investigator or his/her authorized designee will conduct the informed consent process during which the subject will have the opportunity to ask questions and receive answers about the study. Subjects will be made aware that the study includes a medical chart review, as well as an in-office follow-up visit, and they should be willing to comply with the study requirements to be available for study visits. If they decide not to come in for the in-office follow-up visit the data from the medical chart review will still be used in data analysis.

A copy of the signed IC and Research Authorization will be provided to the subject, and the original signed version will be retained in the site's study files. The site will record the date of consent in the CRFs.

Obtaining data from a subject's medical chart or a follow-up visit without obtaining informed consent is a protocol violation and is to be recorded in the Protocol Deviation CRF and reported to the Sponsor, as well as the respective IRB/IEC as soon as possible, **but no later than five (5) working days after the event occurred, or sooner if required by the IRB/IEC**.

10.5. Randomization and Treatment Assignment

There is no randomization in this study as bias is expected to be negligible. All subjects will undergo testing with two (2) processors and a blank in the order given below (Table 3).

Table 3. Audiogram Test Design

Tests	Subject has Alpha 1, Alpha 2, or Alpha 2 MPO Processor
Test 1	No processor
Test 2	Alpha 2
Test 3	Alpha 2 MPO

10.6. Assessment of Safety

Retrospective data collection will include the collection and recording of device and procedure-related AEs which occurred from the time of implant until present day. No safety reporting to IRBs will be executed for retrospective events. AEs found via the retrospective chart review will be reported to Medtronic Product Quality Experience Group as required by regulations.

Prospective data collection will be from the date of signed IC, and will be reported to Medtronic's Product Quality Experience Group and the IRBs per Institutional reporting requirements.

10.7. Recording Data

Data will be recorded on electronic Case Report Forms (eCRFs) in the Electronic Data Capture (EDC) system, Oracle Clinical. For the retrospective portion of the study medical charts, operative notes, and other medical records will be considered as the source documents. For the prospective portion of the study, CRFs can be used as source for this study as well as medical charts. Source document worksheets will be provided to the sites if requested.

10.8. Deviation Handling

It is expected that the Investigator will adhere to the protocol and not deviate unless medically necessary in response to an emergency situation to protect the rights, safety and well-being of the subject. Planned deviations may be submitted to the Sponsor in advance for review and approval, as necessary. Protocol deviations that occur will be documented on the Protocol Deviation CRF and reported to the IRB based on the IRB schedule.

10.9. Subject Withdrawal or Discontinuation

If a subject is consented but subsequently decides to withdraw from the study before coming in for the prospective data collection visit, the subject will be considered to be withdrawn from the study, and the reason will be captured on the Study Exit CRF.

Subjects who are unresponsive after a minimum of 3 attempts to contact them by phone or other means for their prospective data collection visit will be considered lost to follow-up. The types of attempts (phone, email, text, mail) will also be captured on the Study Exit CRF. Note: retrospective safety data collected may still be used in the study.

11. Risks and Benefits

11.1. Potential Risks

The risks for this study are minimal. Risks inherent to use of the Sophono system or surgical procedure are outlined in the potential AEs found in Section 12.

11.2. Potential Benefits

There may not be any direct medical benefits to the study subjects. This study will help the Sponsor evaluate the safety and effectiveness of the hearing system to develop future products to assist others with similar hearing impairment. Subjects will be reimbursed for their participation.

11.3. Risk-Benefit Rationale

As the risks to this study are minimal (limited to subject inconvenience), the benefits of the increased data portfolio on the safety and processor effectiveness outweigh the associated risks.

12. Adverse Event Assessments

12.1. Definitions/Classifications

The below definitions are standard ISO regulation definitions required for all Medtronic studies. These definitions are given with the understanding that the Sophono device is an approved device and not considered investigational.

Adverse Event (ISO 14155:2011, 3.2)	Any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device. Note: This definition includes events related to the investigational medical device or the comparator. Note: This definition includes events related to the procedures involved. Note: for users or other persons, this definition is restricted to events related to investigational medical devices.
Adverse Device Effect (ADE) (ISO 14155:2011, 3.1)	Adverse event related to the use of an investigational medical device. Note: This definition includes adverse events resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation or any malfunction of the investigational medical device. Note: This definition includes any event resulting from use error or from intentional misuse of the investigational medical device.
Serious Adverse Event (SAE) (ISO 14155:2011, 3.37)	Adverse event that: a) Led to a death, b) Led to a serious deterioration in the health of the subject, that either resulted in: 1) Resulted in a life threatening illness or injury, or

	2) Resulted in a permanent impairment of a body structure or a body function, or 3) In-patient or prolonged hospitalization, or 4) Medical or surgical intervention to prevent life threatening illness or injury or permanent impairment to a body structure or a body function, or Led to fetal distress, fetal death or a congenital abnormality or birth defect. Note: Planned hospitalization for a pre-existing condition, or a procedure required by the CIP, without serious deterioration in health, is not considered a serious adverse event.
Serious Adverse Device Effect (SADE) (ISO 14155:2011, 3.36)	Adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event.

Information regarding any reportable AEs and outlined in Tables 4 & 5 below, in relation to the device or the procedure (as determined by the Investigator) that occur during the study will be recorded. This information will include, at a minimum, the date of the event, the seriousness of the event (prospective), the severity, actions taken, the outcome, and the relationship (if any) of the event to the device. Subject continuation in the study as prescribed in this protocol following an AE is anticipated, unless determined otherwise by the Investigator.

12.1.1. Classification of adverse events

SEVERITY OF EVENT

All AEs will be assessed by the clinician using the following guidelines to describe severity.

- **Mild** – Events require minimal or no treatment and do not interfere with the participant's daily activities.
- **Moderate** – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- **Severe** – Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating.

RELATIONSHIP OF DEVICE

The clinician's assessment of an AE's relationship to study device is part of the documentation process, but it is not a factor in determining what is or is not reported in the study. If there is any doubt as to whether a clinical observation is an AE, the event should be reported. All AEs must have their relationship to study device assessed. In a clinical trial, the study product must always be suspect. To help assess, the following guidelines are used.

Not related: relationship to the device or procedures can be excluded when:

- the event is not a known side effect of the product category the device belongs to or of similar devices and procedures;
- the event has no temporal relationship with the use of the investigational device or the procedures;
- the serious event does not follow a known response pattern to the medical device (if the response pattern is previously known) and is biologically implausible;
- the discontinuation of medical device application or the reduction of the level of activation/exposure - when clinically feasible – and reintroduction of its use (or increase of the level of activation/exposure), do not impact on the serious event;
- the event involves a body-site or an organ not expected to be affected by the device or procedure;
- the serious event can be attributed to another cause (e.g. an underlying or concurrent illness/ clinical condition, an effect of another device, drug, treatment or other risk factors);
- the event does not depend on a false result given by the investigational device used for diagnosis, when applicable;
- harms to the subject are not clearly due to use error;
- In order to establish the non-relatedness, not all the criteria listed above might be met at the same time, depending on the type of device/procedures and the serious event.

Unlikely: the relationship with the use of the device seems not relevant and/or the event can be reasonably explained by another cause, but additional information may be obtained.

Possible: the relationship with the use of the investigational device is weak but cannot be ruled out completely. Alternative causes are also possible (e.g. an underlying or concurrent illness/ clinical condition or/and an effect of another device, drug or treatment). Cases were relatedness cannot be assessed or no information has been obtained should also be classified as possible.

Probable: the relationship with the use of the investigational device seems relevant and/or the event cannot reasonably explained by another cause, but additional information may be obtained.

Causal relationship: the serious event is associated with the investigational device or with procedures beyond reasonable doubt when:

- the event is a known side effect of the product category the device belongs to or of similar devices and procedures;
- the event has a temporal relationship with investigational device use/application or procedures;
- the event involves a body-site or organ that
    - the investigational device or procedures are applied to;
    - the investigational device or procedures have an effect on;
- the serious event follows a known response pattern to the medical device (if the response pattern is previously known);
- the discontinuation of medical device application (or reduction of the level of activation/exposure) and reintroduction of its use (or increase of the level of activation/exposure), impact on the serious event (when clinically feasible);
- other possible causes (e.g. an underlying or concurrent illness/ clinical condition or/and an effect of another device, drug or treatment) have been adequately ruled out;
- harm to the subject is due to error in use;
- the event depends on a false result given by the investigational device used for diagnosis, when applicable;
- In order to establish the relatedness, not all the criteria listed above might be met at the same time, depending on the type of device/procedures and the serious event.

Where the relationship remains uncertain, it should not exclude the relatedness and the event should be classified as "possible".

EXPECTEDNESS

An anticipated adverse event is defined as an AE, the nature, severity, or degree of incidence of which is known and identified in applicable product labeling, published literature or the Investigational Plan or Informed Consent.

Based on event reports through literature review (15-19) anticipated Surgical Related AE's possibly noted in the Operative Report during the retrospective medical chart review should be reported on the appropriate CRF. These events may include:

Table 4. Surgical Related Adverse Events

Event
Excessive Bleeding
Rupture of Dura
Cerebrospinal Fluid (CSF) Leak
Anesthesia Related Complications

Anticipated Post-operative Related AE's possibly seen in the retrospective medical chart review or at the office visit and their reportability within the study may include:

Table 5. Post-Operative Related Adverse Events

Event	***Reportable Criteria***
Abscess	Requiring medical intervention
Bleeding	Requiring medical intervention
Dehiscence (at Incision Site)	Requiring medical intervention
Depilation (Loss of Hair at Implant Site)	Excessive or cosmetically bothersome
Hematoma	Requiring medical intervention
Hyperemia	Excessive or requiring medical intervention
Infection (i.e. Cellulitis, Bacterial, etc.)	Requiring medical intervention
Inflammation/Skin Irritation (Redness)	Holger 2, 3, 4
Numbness (Hypoesthesia)	Notable or bothersome to subject

Pain (Local)	Prolonged surgical procedure pain or pain lasting more than 10 days
Pressure (at the Implant Site)	Feeling of pressure continuing after subject begins using the processor
Scarring	Abnormal or Hypertrophic
Skin Necrosis (Pressure)	Requiring medical intervention
Swelling	Continuing after subject begins using the processor

12.2. Reporting of Adverse Events

Clinical information on AEs (as defined above), their presentation, date of event, management, relationship and outcome must be reported on a CRF and sent to Medtronic. Subjects with ongoing AEs at the time of the prospective visit may not exit the study until the AE has been resolved or is determined not able to be resolved. As this is a post-market study of a marketed device the sponsor and investigator will comply with regulations on event reporting according to the Medical Device Reporting System (MDR). The designated study personnel will have two opportunities to collect AE's for each subject:

At the retrospective data collection of Sophono implantation and post-implantation, any surgical procedure or device related AE will be recorded on the applicable CRF. This data collection may occur at any time after the subject consents to the study. No safety reporting to IRBs will be required for retrospective events.

At the follow-up visit, the designated study personnel will examine and query the subject on the experience of any AEs, and designated study personnel will record data on the applicable CRF. This data collection may occur at any time after the subject consents to the study. These prospective observed events will be reported to IRBs or other committees according to the rules and timeframe of the governing site or IRB.

No AEs will be collected after the subject exits the study.

13. Statistical Design and Methods

13.1. Sample size

Since the primary endpoint is composed of a safety and efficacy endpoint, the sample was determined by the primary objective on safety because it requires the larger sample size. An approximate total of 100 subjects will be enrolled.

Sample size on safety

The sample size calculation was estimated using data from previous studies with a precision-based calculation. (20, 21) Recent data have shown that 15.2% of percutaneous implants are lost in children and adverse skin reactions were found in 7.8 % during follow-up visits. (21) Using this information and assuming a lower incidence of implant loss in transcutaneous devices (19, 22, 23) and a lower incidence of skin reaction (18, 24), a minimum incidence of 14% of any adverse events with a sample size of 72 subjects will be able to obtain a 95% confidence level with a precision of +/- 9% (ranging from 5% to 23%). Considering a 25% withdrawal or potential dropout rate, a total of approximately 100 subjects will be enrolled.

Sample size on efficacy

It is expected that at least 6 paired subjects with the pure tone audiometry evaluation will be needed in order to demonstrate a difference in means between unaided and aided measurements in Hearing Improvement measured as PTA. From a literature search we found that studies have shown an average of 50% improvement on hearing measured as PTA.(13, 20, 21, 25-34) In the paper of Siegert (34) the mean and standard deviation of pure tone audiometry in 21 patients was 58.7±8.2 dB HL unaided and 29.7± 8.2 dB HL aided. Based on these values, alpha level 5%, power 95% and two-sided test, a total of 6 paired subjects are needed.

13.2. Data analysis and reporting

A detailed description of the statistical methods will be contained in the Statistical Analysis Plan. Any change to the data analysis methods described in this section and/or the Statistical Analysis Plan will require an amendment only if it changes a principal feature of the study description. Any other changes to the data analysis methods will be described and justified in the Final Report or publication.

It is anticipated that SAS (SAS Institute Inc., Cary, NC, USA) will be used to perform all statistical analyses. Statistical tests will be based on a two-sided significance level of 0.05. No adjustments for

multiple comparisons will be performed. Since the impact of missing data is expected to be small no multiple imputation method for missing data is planned. However, should the issue of missing data arise, the choice of the imputation method for missing data will depend on the pattern of missing data and the type of the imputed variable.

The study is a multicenter trial and a multicenter impact on primary outcome will be investigated. A description on primary outcome by sites will be provided.

Outliers and influential observations will be identified via graphical plots. Once outliers or influential observations are identified, the study team will be informed and according to their decision the analysis for primary endpoint may be repeated excluding the outliers. Additional exploratory analyses will be conducted as deemed appropriate.

Descriptive statistics will be used to summarize patient characteristics. For categorical variables, the minimum description will consist of the sample size, numbers of missing data and valid data, the frequency and the percentage of each category. Denominators for calculation of percentages will be taken as the number of subjects with available (not missing or unknown) observations in the specified patients sets and groups unless otherwise stated. Percentages will be presented with no decimal. For continuous variables, the description will consist at least of the sample size (N), number of subjects with non-missing observation (n), mean, standard deviation, standard error, minimum, median and maximum. For n<3, only mean, minimum and maximum will be displayed. In general, minimums and maximums will be presented to the same level of accuracy as the raw data; means and medians will be presented to 1 further decimal place; if appropriate, standard deviation and standard error will be presented to 2 further decimal places.

The primary analysis is based on safety and effectiveness.

13.3. Safety endpoint

Event rates, weighted for center, will be displayed together with their 95% confidence interval (95%CI); for each possible sub-group, analyses will be compared by means of a mixed Poisson model, with center included as random effect. In the presence of over dispersion, negative binomial regression will be used. Over dispersion will be assessed both with a goodness-of-fit test and a likelihood ratio test for alpha=0. The incidence rate ratio (IRR) and 95%CI will be reported [IRR=rate group1 / rate group2]. The exposure time (days/months) will be computed from implantation to the date of the follow-up visit for each patient [(data end – data in)/30.4].

Specific events will be analyzed using survival analysis. The analysis will be supported by a Kaplan Meier curve indicating the number of patients at risk and comparison of curves will be done using the generalized Log-Rank Test where appropriate. The exposure time (months) will be computed from the date of the implantation to the date of the last available follow-up or date of event: [(data end – data in)/30.4].

13.4. Effectiveness endpoint

The change between unaided and aided measurements will be analyzed by means of paired (samples) t-test or Wilcoxon signed rank sum test according to the normal or non-normal distribution or McNemar test for categorical variables where appropriate. Categorical variable comparisons will be performed using a Chi-square test or a Cochran-Mantel-Haenszel test for trend for ordinal variables with 3 or more categories. The mean change will be displayed together with their 95% confidence interval (95%CI).

Analysis of secondary endpoints based on comparisons between groups on continuous measurements will be performed by Student's t-test or non-parametric test (Mann–Whitney U test) for normal and non-normal distributions, respectively. Normality will be assessed by means of Shapiro-Wilks test and the p-value will be reported. Analysis of secondary endpoints based on the change over time (if more than 3 measurements) will be analyzed by means of GEE models or mixed models for continuous outcomes to account for repeated measures using patient as the subject. The dependent variable will be pre-log transformed depending on normal or non-normal distribution. The model will have the clinical outcomes as dependent variables and baseline values, visits and other covariates as explanatory variables. All assumptions for regression models will be assessed by viewing plots of the residual values. The plot for the mean change over time will be reported.

14. Ethics

14.1. Statement(s) of Compliance

- The study shall be conducted in accordance with the protocol and ethical principles that have their origin in the Declaration of Helsinki.
- The study will be conducted in compliance with this protocol, GCP, and 21 CFR 50, 21 CFR 54, and 21 CFR 56.
- The clinical study will not begin at the site until IRB approval is received.

15. Study Administration

15.1. Monitoring

This study will be conducted and monitored according to the highest scientific and ethical standards, based on standard operating procedures of the Sponsor or designee, and ethics guidelines as required by regulation and law, and as appropriate to the prospective research populations. The following guidance's and regulations have been consulted in preparing the study's protocol and procedures:

-Title 21 of the Code of Federal Regulations (21 CFR) Parts:

- 50 Protection of Human Subjects
- 54 Financial Disclosure by Clinical Investigators
- 56 Institutional Review Boards

Employees of the Sponsor, or its designees, who have received appropriate training, will serve as the Study Monitor(s). Study monitoring activities will include review of completed study documents, source document verification and reporting, verification of database accuracy, and assessment of the completeness and accuracy of the data. A final monitoring report will be prepared to document that all protocol requirements were satisfied. The Study Monitor(s) will also assume responsibility for communications between the Study Investigators and the Sponsor.

15.2. Data Management

All data required for this study will be captured via eCRFs using Oracle Clinical's Remote Data Capture (RDC) module. The associated software and database have been designed to meet regulatory compliance requirements for deployment as part of a validated system compliant with laws and regulations applicable to the conduct of clinical studies that use electronic records and signatures. System backups for data stored in the Oracle Clinical system will be consistent with Medtronic standard procedures.

The Investigator will ensure that all eCRFs are completed promptly, completely, and accurately. Only authorized study personnel are permitted to enter data. These tasks may be delegated by the Investigator as desired and noted on a Delegation of Authority Log. The Sponsor will provide training and instructions to assist with eCRF completion. In the event of data discrepancies, the study center staff will be contacted and asked to resolve queries electronically in the RDC system. Any irresolvable data-related

issues will be routed to the Sponsor for review and final disposition. An audit trail is maintained in Oracle Clinical to capture any corrections or changes of the eCRFs.

Medtronic will only consider eCRFs to be complete when all data discrepancies between source data and eCRFs have been resolved and eCRF content has been reviewed by a Sponsor-representative monitor. In addition, all eCRFs must also be reviewed and electronically signed by the Investigator, indicating his/her agreement with the accuracy of all recorded data. The Investigator will provide his/her electronic signature on the eCRFs.

Prior to data extraction, all collected data will undergo a final verification by Data Management. Documentation of this verification will be maintained in the Sponsor study files. Upon the completion of the verification, data will be extracted and transferred to the appropriate personnel for analysis.

15.3. Direct Access to Source Data/Documents

The Sponsor, its affiliates, IRB, or government officials may audit the study site to evaluate the conduct of the study. The sponsor and its representatives expect to have access to the source data for this study including medical records.

15.4. Confidentiality

The Sponsor and its affiliates may access subject confidential information during the course of the study. Confidentiality of the data shall be observed by all parties at all times throughout the clinical study. All data shall be secured against unauthorized access.

15.5. CIP Amendments

If during the course of the study the Sponsor assesses that an amendment is necessary the Sponsor will follow all applicable internal procedures to amend the protocol, and if applicable, the IC. Any amendments to the protocol or IC will be reviewed and approved by the IRB.

15.6. Record Retention

All documentation generated as a result of this clinical study must be properly prepared and maintained. Records must be maintained by the investigational site for a minimum of two years after study completion. No study document shall be destroyed without prior written agreement between the Sponsor

and the investigational site. All documentation generated as a result of this clinical study must be properly prepared and maintained. Table 6, below, describes the records and reports to be maintained during and after the study.

15.6.1. Sponsor Requirements

All original hard copy or certified copies and electronic data will be retained by the Sponsor per standard operating policy on documentation retention.

15.6.2. Investigational Site Requirements

All site generated hard copy and electronic data will be retained by the site per specific institutional standard operating policy. Should the investigator wish to assign the study record to another party or move them to another location, the Sponsor must be notified in writing and agree to the change.

Table 6. Sponsor and Investigator Records and Reports

Records	**Maintained by Sponsor**	**Maintained by Investigator**
Device Accountability (shipment/receipt, assignment, destruction, return)	x	x
Case Histories (CRFs, IC/PIS, AE)	x	x
Protocols/Deviations (obsolete, change history record, rationale)	x	x
Agreements (Confidential, Investigator, Consulting)	x	x
Training Records (Sponsor, institution, topic)	x	x
Report	**Prepared by Sponsor For**	**Prepared by Investigator For**
Lack of IC/Authorization	N/A	Sponsor, IRB
Unanticipated Serious Adverse Device Effects (USADE)	Investigators, IRB	Sponsor, IRB
Protocol Deviations	N/A	Sponsor, IRB*
Withdrawal of IRB Approval	Investigators, IRB	Sponsor, IRB
Final Report	Investigators, IRB (if required)	IRB (if required)

*In accordance with specific Ethics Committee requirements

15.7. Publication and Use of Information

The Sponsor must be notified of any intent to publish data stemming from this clinical study. Conditions of use of the data are governed by the terms of the Investigator Agreement and Publication Plan.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov.

15.8. Suspension or Early Termination

Should the study be terminated for cause, or prior to achieving the protocol objectives, the Sponsor reserves the right to resume or discontinue the study at its discretion. If the study is terminated or suspended, the Sponsor will promptly inform the Investigators/Institutions of the reason(s) for termination or suspension.

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17. Appendices

Appendix A: APHAB Version A

Appendix B: Satisfaction Questionnaire

Appendix A

Appendix B

Satisfaction Questionnaire

Name: _____ Date :_____

Please answer the following questions regarding your current use of the Sophono and quality of life. Please choose only one option for each question:

Overall, how satisfied are you with your Sophono processor?

□ Very Satisfied

□ Satisfied

□ Neutral (Neither Satisfied or Dissatisfied)

□ Dissatisfied

□ Very Dissatisfied

Would you recommend the Sophono system to another patient with a conductive hearing problem?

□ Yes

□ No

□ Not Sure

How satisfied or dissatisfied are you with the appearance of the hearing device?

□ Very Satisfied

□ Satisfied

□ Neutral (Neither Satisfied or Dissatisfied)

□ Dissatisfied

□ Very Dissatisfied

How easy or difficult is it to operate the hearing device as instructed?

□ Very Easy

□ Easy

□ Neutral (Neither Easy or Difficult)

□ Difficult

□ Very Difficult

Listed below are some Sophono features. For each feature, please indicate how satisfied you are with that feature. Please choose only one option for each question.

Overall comfort of device	□ Always □ Sometimes □ Never
Visibility to others	□ Always □ Sometimes □ Never
Clearness of tone and sounds	□ Always □ Sometimes □ Never
Durability	□ Always □ Sometimes □ Never
Reliability	□ Always □ Sometimes □ Never

Magnet-spacer strength in day to day activities	□ Always □ Sometimes □ Never
Magnet-spacer strength in physical activities	□ Always □ Sometimes □ Never
Do you use a different strength for physical activities?	□ Yes □ No
Ability to tell locations of sounds	□ Always □ Sometimes □ Never