CONFIDENTIAL

Clinical Investigation Title	Investigating hearing with Ponto 3 SuperPower, a bone anchored hearing aid - Investigating hearing with Ponto 3 SuperPower, a bone anchored hearing solution**.**
Investigation code	BC107 NCT04803279
Investigational Device	Ponto 3 SuperPower
Coordinating investigator/Principal Investigator(s)	John FitzGerald Head of audiology Norfolk and Norwich University Hospital (NNUH) Colney Lane Norwich NR4 7UY, UK
Sponsor	Oticon Medical AB Datavägen 37 B 436 32 Askim Sweden
Date	15-12-2020

Revision history:

Revision no	Date	Description
00		First version (1.0)
1	17-12-2020	New revision for EC application.
2	02-02-2021	New revision including minor updates to the document according to the REC answer
3	30-03-2021	Modify objective C and endpoint H1 as it was discovered that the procedures unaided speech test in noise and quiet for CHL/MHL patients were not part of the clinic's normal procedure, and therefore data will be missing for these. Remove exploratory objective K, as it is not part of the clinic's normal procedure to document usage hours read from Genie Medical for all patients, so data will be missing for this objective as well.

STATEMENT OF COMPLIANCE

This clinical investigation will be performed in consistency with the current version of the Declaration of Helsinki, ISO 14155, the Medical Device Directive (MDD) 93/42/EEC, Regulation (EU) 2017/745 (MDR) and applicable regional or national regulatory requirements as well as any additional requirements imposed by the Ethical Committee's.

2. Synopsis

Clinical Investigation Title	Investigating hearing with Ponto 3 SuperPower, a bone anchored hearing solution
Investigation Code	BC107
Investigational Device	Ponto 3 SuperPower
Coodinating Investigator/ Principal Investigator	John FitzGerald Head of audiology Norfolk and Norwich University Hospital (NNUH) Colney Ln, Norwich NR4 7UY, UK
Sponsor:	Oticon Medical AB Datavägen 37 B 436 32 Askim Sweden
Objective(s):	To investigate the improvement in hearing with the Ponto 3 SuperPower(s) on the implanted ear(s) for patients within intended use.
Methodology:	Retrospective study
Inclusion/exclusion criteria:	**Inclusion criteria** 1. Subjects who have consented to Section 3 of the document: "GDPR – what this means to you" (Appendix A) as part of a clinical routine visit. 2. Fitted unilaterally or bilaterally with the Ponto 3 SuperPower(s) on abutment(s) 3. Adult subjects (18 years or older) 4. Patient has attended a clinical routine visit where fitting of Ponto 3 SuperPower has been performed and at least one following clinical routine visit where audiological measurements has been performed **Exclusion criteria** There are no exclusion criteria in this retrospective study
Primary endpoints	Functional gain with Ponto 3 SuperPower, i.e. the difference between average unaided AC thresholds and aided sound field thresholds as the average (PTA4) of frequencies 500, 1000, 2000 and 4000 Hz.
Duration of study period:	Data will be collected during Q1-Q2 2021
Statistical methods:	Primary analysis: Descriptive statistics; mean and standard deviation; min and max (if the data is normally distributed) or median, 1st and 4th quartile; min and max (if the data is not normally distributed).
Investigation plan prepared by:	Jessica Ågren, Oticon Medical AB Liselotte Borup, Oticon Medical AB

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3. List of Abbreviations

AC	Air Conducted
BAHS	Bone Anchored Hearing System
BC	Bone Conducted
GBI	Glasgow Benefit Inventory
IFU	Instructions for Use
ITT	Intention To Treat
NAL	National Acoustic Laboratory
SI	Speech Intelligibility
SQ	Sound Quality
SSD	Single Sided Deafness
SSQ	Speech Spatial and Qualities of Hearing Scale
PTA4	Pure Tone Average (calculated on 500, 1000, 2000 and 4000 Hz)
PRO	Patient Related Outcome

4. Background

4.1 Background

Bone conduction hearing systems use the body's natural ability to transfer sound through bone conduction. The bone anchored hearing solution picks up sound and converts it into vibrations that are transferred via the skull bone to the inner ear (cochlea). Indication for use for a bone anchored hearing solution is patients with conductive, mixed or single sided deafness. Thus, for subjects with conductive or mixed hearing losses, subjects with lasting hearing loss following a middle ear disease (such as for instance chronic otitis media, cholesteatoma, otosclerosis, or other ossicular diseases) or malformations (such as aural atresia and/or microtia), one utilizes that the vibrations are bypassing the conductive problem in the ear canal or middle ear, stimulating the cochlea directly. For single-sided deaf (SSD) subjects, one utilizes that the vibrations are transmitted to the cochlea on the contralateral side [1].

BAHS have been used since the late 1970s and are divided into three types: transcutaneous direct drive, percutaneous direct drive and transcutaneous skin drive bone conduction [1]. Direct drive denotes systems where the vibrations are transmitted directly to the bone, either by direct bone-transducer contact or by a stiff-metal, in contact with the transducer. In a skin drive system, there is a layer of soft tissue between the transducer and the bone. Percutaneous direct drive, also referred to as bone anchored hearing systems (BAHS) is the most common type with more than 150,000 users world-wide [1].

Oticon Medical first developed a percutaneous system in 2009. Ponto 3 SuperPower was placed on the market in December 2016 and is the most powerful device in the Ponto family with a fitting range up to 65 dB HL The Ponto 3 SuperPower is manufactured by Oticon Medical AB, Askim, Sweden. Oticon Medical AB is ISO 13485 certified and has CE-marked and FDA-cleared products for hearing healthcare on the market.

5. IDENTIFICATION AND DESCRIPTION OF THE INVESTIGATIONAL DEVICE

The investigational device Ponto 3 SuperPower used in the study is CE marked and FDA cleared and has been commercially available since December 2016. Ponto 3 SuperPower sound processors comes in 6 different colors, the article numbers are listed in Table 1. Overview of devices and fitting software and corresponding article numbers. The study intends to follow-up and collect data retrospectively on exciting Ponto 3 SuperPower user's outcomes. The Ponto 3 SuperPower sound processors are fitted with Genie Medical 2016.1.

Sound processor	**Denomination**	**Article number**	**Initial CE**	**FDA clearance**
Ponto 3 SuperPower	Ponto 3 SuperPower, Pure White	52658 (left) 52659 (right)	2016	2016
	Ponto 3 SuperPower, White Silver	52654 (left) 52655 (right)	2016	2016
	Ponto 3 SuperPower, Chroma Beige	52652 (left) 52653 (right)	2016	2016
	Ponto 3 SuperPower, Mocca Brown	52650 (left) 52651 (right)	2016	2016
	Ponto 3 SuperPower, Steel Grey	52656 (left) 52657 (right)	2016	2016
	Ponto 3 SuperPower, Dimond Black	52648 (left) 52649 (right)	2016	2016
	Genie Medical 2016.1 fitting software	50504	2016	2016

Table 1. Overview of devices and fitting software and corresponding article numbers.

The investigational device is intended to improve hearing for subjects with conductive or mixed hearing losses by unilateral or bilateral fitting, as well as for subjects suffering from single-sided deafness. The Ponto 3 SuperPower is intended to be used either with the Ponto implant system or with specific compatible abutments and implants. The investigational device can also be used on a softband, headband or a testband.

The Ponto 3 SuperPower is non-sterile and consists of a coupling, which enables the Ponto 3 SuperPower to be placed on the abutment (or softband, headband, testband), microphones, battery drawer, push button for changing programs and mute function, volume control, safety line attachment, transducer and sound processing electronics. The Ponto 3 SuperPower picks up sound, processes it according to the users individual hearing loss and transmits the signal through the abutment. The investigational device has been fitted and adapted to the subject's needs using the fitting software Genie Medical 2016.1 (CE-marked). Optional connectivity accessories can be used with the Ponto 3 SuperPower, such as Oticon Medical Streamer which can be used as remote control and for streaming phone calls. The Oticon Medical Streamer can be paired with a ConnectLine microphone, ConnectLine TV adapter and ConnectLine phone adapter in order to stream speech from a conversation or a lecture, TV or from a landline phone, see Table 2. All devices in Table 1 are CE-marked and FDA cleared.

Figure 1. Ponto 3 SuperPower

The audiological features that are included in the investigational device can be found in the Product Information sheet [B]. The site always fit adult users with National Acoustic Laboratory prescription method NAL-NL1.

Denomination	Legal manufacturer
Oticon Medical Streamer	Oticon A/S
ConnectLine TV adapter	Oticon A/S
ConnectLine microphone	Oticon A/S
ConnectLine phone adapter	Oticon A/S

Table 2. Overview of optional connectivity devices.

The CE-marked Ponto 3 SuperPower and eventually accessories are the investigational devices in this study. Candidates for this study are existing Ponto 3 SuperPower users. This study only obtain data from subjects who have been fitted with CE-marked Ponto 3 SuperPower(s) (available on the market since December 2016).

Note: Additional information on the investigational device and accessories are available in the Audiological manual [A], product information sheet [B]and IFU [D, F, G, H].

6. JUSTIFICATION OF THE STUDY DESIGN AND OUTCOME MEASURES

6.1. Justification of the study design and outcome measures

This is a post market clinical follow up study (PMCF) with the purpose to gather knowledge on the Ponto 3 SuperPower device on existing Ponto 3 SuperPower users. The study does not include any study visits, treatment or fitting of new devices. Instead the available data reflecting the use of Ponto 3 SuperPower will be collected from clinical routine visits.

The Ponto 3 SuperPower has been commercially available since December 2016 [redacted] A retrospective study design where all data will be retrospectively collected, from previous clinical routine visits and procedures performed according to the clinic's normal procedures, is suitable to evaluate the hearing outcomes on the population using Ponto 3 SuperPower.

The data that will support the primary and secondary endpoint are available from the clinical routine visit where Ponto 3 SuperPower has been fitted and the first clinical routine visit following the fitting. This is typically the procedure for hearing aid rehabilitation and therefore a three-months' time window for data collection from described clinical routine visits, or from the clinical routine visit just prior to the fitting visit where audiometry threshold might have been performed, see section 9.3.3.1).

6.2 Summary of data on comparable devices

A literature review has been undertaken with the purpose of summarizing state-of-the-art treatment options for subjects with a hearing loss within Oticon Medical BAHS indication of use. In this literature review, two percutaneous bone conduction systems were identified; Ponto (Oticon Medical AB) and Baha® Connect (Cochlear BAS, Mölnlycke, Sweden) [E].

Twenty-three publications with clinical data on the performance of the percutaneous systems (452 subjects) were included. The most commonly used performance measures include but are not limited to functional gain (unaided sound field thresholds or AC hearing thresholds relative to aided sound field thresholds), speech reception threshold or speech scores at given speech levels; speech-in-noise performance and self-reported outcome questionnaires.

Data from bone anchored devices consistently showed performance improvement in aided sound field threshold measurement, over the unaided condition. However, there is a strong heterogeneity in the

reported results. All reviewed data report improvements in speech recognition. The reviewed data also report significant improved self-reported performance when comparing aided to unaided condition.

6.3 Justification of outcome measures

The study is a retrospective study where the objectives is determined based on the State of the Art report (E) and what data the clinic has collected. The site collects functional gain only for patients with CHL/MHL, and speech recognition measurements are conducted differently for CHL/MHL and SSD. Therefore, not all objectives cover all patient groups. The primary endpoint is investigating the improvement in hearing with the Ponto 3 SuperPower(s) for patients with CHL/MHL. Secondary objectives includes speech recognition aided with Ponto 3 SuperPower, Patient Reported Outcome (GBI) evaluating the subject's quality of life before intervention and at the clinical routine visit, following the fitting and skin reaction (Holger score) at the clinical routine fitting visit and the clinical routine follow-up visit, which all are collected on all hearing categories (CHL, MHL and SSD).
The outcomes in the study are related to the data the clinic has collected and reflect the benefit of Ponto 3 SuperPower that is that it compensates for hearing loss, i.e. improve the hearing for subjects within the indicated use manifested by:

- Improved ability to hear sounds
- Improved speech intelligibility
- Improved quality of life

For a subject with a unilateral hearing loss, the benefit will primarily be manifested for sounds directed to the fitted side. In general, with BAHS, if the subject has symmetrical BC hearing loss and is bilaterally fitted, binaural benefits, manifested by for example improved ability to localize sounds, can be achieved.
In addition, the Ponto 3 SuperPower is also expected to provide improved quality of life and reduce the disability caused by a hearing loss for subjects already using Ponto 3 SuperPower.

This study will focus on collecting data on the ability to hear sound and speech intelligibility as well as evaluate subjective self-reported outcome on subjects using Ponto 3 SuperPower.

The study is part of the post-market clinical follow-up of Ponto 3 SuperPower with the purpose of refining the knowledge on performance outcomes with Ponto 3 SuperPower from subjects who have been fitted with the Ponto 3 SuperPower after it was CE market and available on the market since December 2016. The primary objective of the study is to evaluate the performance of the Ponto 3 SuperPower for the indicated subjects. The primary endpoint was therefore chosen as the functional gain. Functional gain is the difference between unaided AC thresholds obtained with headphones TDH39, and aided sound field threshold and reflects the hearing benefit with the treatment and is the most common way to report bone anchored hearing aid benefit in the literature [E]. Secondary objectives include speech intelligibility and self-reported outcome.

Not many studies on percutaneous bone conduction systems report longitudinal data on aided sound field thresholds. However, studies that report longitudinal performance on bone conduction hearing systems (with follow-up times between one and 37 months) show no significant change of aided threshold over time [2][3][4][5]. This allows for a primary endpoint analysis on test subjects who have had minimum 1.5 months experience with Ponto 3 SuperPower(s) (chapter 9.3.3.3).

In summary, the primary endpoint of the study addresses the expected benefit of the Ponto 3 SuperPower and is one of the most commonly used performance measures in the research literature. Timing of the measurement is not critical as performance is similar over time, which allows for difference in time of the measurement performed since fitting of Ponto 3 SuperPower. Secondary endpoints address the expected benefit of the Ponto 3 SuperPower terms of speech intelligibility and reported quality of life.

7. RISKS AND BENEFITS OF THE INVESTIGATIONAL DEVICE AND CLINICAL INVESTIGATION

The study is part of the Post Market Clinical Follow (PMCF) activity. The investigational device is the CE-marked Ponto 3 SuperPower (available on the market since December 2016) already fitted to the subjects, and data is collected retrospectively from clinical routine visits.

No study visits for treatment or follow-up are provided in the study therefore there are no risk for the subjects in regards to collecting their already provided data for the study.

8. OBJECTIVES AND ENDPOINTS OF THE CLINICAL INVESTIGATION

The objectives is determined based on the State of the Art report (E) and what data the clinic has collected.

8.1 Primary Objectives and Corresponding endpoint/outcome variable(s)

The primary objective and corresponding endpoint/outcome variables for the study are listed in Table 3 below.

Primary objectives	Corresponding endpoint/outcome variable(s)	Sec.
A. To investigate the improvement in hearing with the Ponto 3 SuperPower for patients with CHL/MHL.	1. Functional gain with Ponto 3 SuperPower, i.e. the difference between average unaided AC thresholds and aided sound field thresholds as the average (PTA4) of frequencies 500, 1000, 2000 and 4000 Hz	9.3.3.3-9.3.3.4

Table 3. Primary objective and corresponding endpoint/outcome variables.

8.2 Secondary Objectives and Corresponding endpoint/outcome variable(s)

The secondary objectives and corresponding endpoints/outcome variables for the study are listed in table 4 below.

Secondary objectives	Corresponding endpoint/outcome variable(s)	Sec.
B. To investigate the improvement in hearing with the Ponto 3 SuperPower for patients with CHL/MHL.	1 Functional gain with Ponto 3 SuperPower, i.e. the difference between average unaided AC thresholds and aided sound field thresholds for frequencies 500, 1000, 2000, 3000 and 4000 Hz	9.3.3.4
C. To assess speech recognition in quiet and in noise with Ponto 3 SuperPower on the implanted ear(s) for patients with CHL/MHL.[1]	1. Aided speech recognition (%) in quiet. 2. Aided speech recognition (%) in noise.	

[1] The AB Isophonemic Monosyllabic Word test -short has been used for most of the patients. The BKB sentence test has been conducted when needed as per the audiologist discretion.

D.	To assess the speech recognition in noise with Ponto 3 SuperPower on for patients with SSD	1. Difference in speech recognition score (%) for speech recognition in noise between unaided and aided when speech is directed to the aided ear, and noise is directed to the non-implanted ear 2. Difference in speech recognition score (%) for speech recognition in noise between unaided and aided when speech is directed to the non-implanted ear, and noise is directed to the aided ear.	9.3.3.6
E.	To assess the degree to which the Ponto 3 SuperPower compensates for the BC hearing loss on the implanted ear(s) for patients with CHL/MHL.	1. Effective gain with Ponto 3 SuperPower, i.e. the difference between aided sound field thresholds and the BC In-situ thresholds on the aided ear(s) measured when the Ponto 3 SuperPower(s) was fitted. The effective gain is calculated as the average (PTA4) of frequencies 500, 1000, 2000 and 4000 Hz.	9.3.3.5
F.	To assess the degree to which the Ponto 3 SuperPower compensates for the BC hearing loss on the implanted ear(s) for patients with CHL/MHL	2. Effective gain with Ponto 3 SuperPower, i.e. the difference between aided sound field thresholds and the BC In-situ thresholds on the aided ear(s) measured when the Ponto 3 SuperPower(s) was fitted. The effective gain is calculated for frequencies 500, 1000, 2000, 3000 & 4000 Hz.	9.3.3.5
G.	To assess the quality of life of the Ponto 3 SuperPower	1. Glasgow Benefit Inventory (GBI) scores.	9.3.3.8
H.	To evaluate the above objectives on individual levels	1. Endpoints A, B, D, analyzed as the proportion of subjects whose performance is better or equal in the unaided to aided comparisons, i.e. have a difference ≥0	9.3.3.4-9.3.3.6
I.	To assess the air to bone gap (PTA4) on the implanted ear(s) for patients with CHL/MHL	1. The difference between masked (if not available unmasked) BC and AC thresholds, denoted 'air to bone gap', calculated for frequencies 500, 1000 and 2000 Hz from audiogram measured in connection with the fitting of Ponto 3 SuperPower	9.3.3.10
J.	To assess the skin condition around the abutment	1. Holgers score (scale 0–4) assigned by investigator at fitting and post-fitting follow up.	9.3.3.7

Table 4 Secondary objectives and corresponding endpoint/outcome variables

9 DESIGN OF THE CLINICAL INVESTIGATION

9.1 General

The study is a retrospective study. Subject inclusion for this clinical investigation (see inclusion and exclusion criteria below) will be performed among subjects who has been fitted with the Ponto 3 SuperPower [redacted]

The endpoints in the study will investigate the improvement of hearing with the Ponto 3 SuperPower. An overview of the data collections performed in the study can be found in table 5 below.

All study data collected will be recorded in electronic Case Report Forms (eCRF) via an electronic Data Capture System (described in more details in chapter 12).

Data collection Schedule	Retrospectively collected from clinical routine visits:	
	Ponto 3 SuperPower fitting	Follow-up visit(s) [2]
1: Inclusion/exclusion criteria	X*	
2: Eligibility	X	
3: Subject characteristics	X	
4: BC In-situ thresholds	X	
5: Audiometry thresholds (AC and BC thresholds)[3]	X	
6: Speech recognition test (AB Isophonemic Monosyllabic Word test -short, and/or BKB sentence test)[4] 1. Speech recognition in noise 2. Speech recognition in quiet		X
7: Aided sound field audiometry		X[5]
8: Patient Reported Outcomes (GBI)		X
9: Skin reaction (Holger score)	X	X

Table 5 overview of the data collections performed in the study. * as described in section 17.

9.1.1 Subject enrolment

The investigational device Ponto 3 SuperPower used in the study is CE marked and FDA cleared and has been commercially available since December 2016, which is approximately 4 years. To have a wide representative selection of subjects, enrollment will be spread over the 4 years, ensuring capture of the population fitted with Ponto 3 SuperPower at the clinic over the time when the device has been available. [redacted] In this retrospective study 55 [redacted] patients will be included in the study. The total number of test subjects will include the aim of having around 15 with hearing loss <45 dB HL, around 15 with mixed hearing loss 45>≤55 dB HL and around 15 with a mixed hearing loss >55 dB HL, this to represent all indications for Ponto 3 SuperPower and a wide spread in hearing loss degree.
The data will be collected from the subjects in the time period from the clinical routine visit where the Ponto 3 SuperPower where fitted or just prior, and from the clinical routine visit following the fitting, where audiologic fitting follow-up procedures are performed (approximately 3 months).

[2] The data from this column can be spread across the first 2 follow-up clinical routine visits following the fitting visit
[3] Masked and unmasked, might have been performed prior to the clinical routine visit where Ponto 3 SuperPower was fitted
[4] Aided for CHL/MHL patients, and unaided and aided in the implanted or non-implanted side for SSD patients.
[5] Might have been performed at the clinical routine visit where Ponto 3 SuperPower was fitted or at the clinical routine visit following the fitting.

The collection of the patient's data will be performed like this: The subjects are included over the last 4 years where the Ponto 3 SuperPower has been on the market, the aim is to distribute the subjects as equal as possible over the years 2017 to 2020. As the COVID-19 pandemic had an impact on the hospitals ability to see patients for clinical routine rehabilitation visit, fewer patients have been fitted with Ponto 3 SuperPower during 2020. Thus, a lower number of subjects will be included from 2020 is expected. Dependent on the enrollment of subject from 2020, approximately 20 subjects are collected from each year from 2017-2019.

9.1.2 Screening according to in- exclusion criteria

The investigator will ensure that the patient complies with the inclusion criteria, based on a review of the already available information in the patients' medical file.

9.2 Subject population

A total number of 55 test subjects will be included in this study. Subject inclusion for this clinical investigation will be performed among subjects who has been fitted with the Ponto 3 SuperPower after it was CE market and available on the market since December 2016.
The subjects will not participate in any study related visits, instead investigator will collect relevant data retrospectively from already performed clinical routine visits.

9.2.1 Inclusion criteria

1. Subjects who have consented to Section 3 of the document: "GDPR – what this means to you" (Appendix A) as part of a clinical routine visit.
2. Fitted unilaterally or bilaterally with the Ponto 3 SuperPower(s) on abutment(s)
3. Adult subjects (18 years or older)
4. Patient has attended a clinical routine visit where fitting of Ponto 3 SuperPower has been performed and at least one following clinical routine visit where audiological measurements has been performed

9.2.2 Exclusion criteria

There are no exclusion criteria in this study due to the retrospective nature of the study.

9.2.3 Procedure for identifying potential candidates

Potential candidates will be identified via the Investigators knowledge of the clinic's pool of patients with Ponto 3 SuperPower.
The medical records, Genie Medical and Auditbase at Norfolk and Norwich university hospital will be basis for identifying relevant data during the period of data collection in order to collect described data, by investigator, starting from the date 01-01-2017.

9.2.4 Subject withdrawal

Not applicable as the study is retrospective study.

9.3 Clinical Investigation Procedures

9.3.1 Subject characteristics

The following subject characteristics will be collected:

- Gender
- Age at fitting visit
- Type of hearing/hearing loss on right and left ear (MHL/CHL; SSD and SNHL, normal hearing)
- Type of hearing solution on right and/or left ear
- BAHS surgery, side(s) and year
- Date of Ponto 3 SuperPower fitting on abutment (mm.year)
- Connectivity devices (device: Oticon Medical streamer, ConnectLine Tv adapter, ConnectLine microphone, Connectline phone adapter, usage:)

9.3.2 Safety assessments

This study is a retrospective study, only focusing on the performance of the Ponto 3 Superpower, and only collecting data during the short interval between the clinical routine visit where the Ponto 3 SuperPower has been fitted or just prior to that visit (where audiometry thresholds might have been performed, see 9.3.3.1) and the subsequent clinical routine visit(s) following the fitting, therefore there are no safety risk involved. Safety events, see section 18, will be collected to the following extent; if the investigator finds documentation in the audiological file regarding mentioning of a safety event, these will be recorded in the e-CRF. Only the audiology file will be reviewed and only for the time of the data collection time window. Any adverse event (AE) that is judged as related to the device by the investigator will be reconciled against the Sponsor's complaint system, and if not previously reported added as a new complaint. Any device-related AE will be investigated according to the Sponsor's procedure for complaint handling.

9.3.3 Data Collection

Any information on how the data obtained in this retrospective study have been described to reflect the Norwich and Norfolk university hospital´s routine.

9.3.3.1 Collection of Pure tone thresholds from audiogram measured prior to fitting of Ponto 3 SuperPower

Unmasked and if available masked BC thresholds for frequencies 500 Hz, 1kHz and 2 kHz and AC thresholds for frequencies 250 Hz, 500Hz, 1kHz, 2 kHz, 3kHz, 4kHz, 6kHz and 8kHz will be collected from audiogram obtained prior to Ponto 3 SuperPower were fitted.

9.3.3.2 Collection of BC In-situ thresholds from BC In-situ audiogram measured during fitting of Ponto 3 SuperPower

BC In-situ thresholds for frequencies 250 Hz, 500 Hz, 1 kHz, 2 kHz, 3 kHz,4 kHz, 6 kHz and 8 kHz will be collected from the BC In-situ audiogram obtained when Ponto 3 SuperPower were fitted.

9.3.3.3 Collection of Aided sound field thresholds measured with the Ponto 3 SuperPower

Sound field thresholds for frequencies 500Hz, 1kHz, 2 kHz, 3kHz and 4kHz will be collected from sound field audiogram obtained as follow-up after Ponto 3 SuperPower fitting, typically this is collected 3 months post fitting, alternatively from the fitting visit. Thresholds will be obtained aided for the CHL/MHL patients. Sound field thresholds are obtained 1-2 m azimuth. The measurement has been conducted with the contralateral ear left open, hence no masking has been applied. The measurement has been conducted in the patients user settings, with no disabling of DFC or NR. The directionality has been in user settings, which for most patients is an [automatic TriMode] which during this measurement was equivalent to have the device in an omni mode, because the measurement is conducted in a quiet room with warble tones

from the front.

9.3.3.4 Functional gain

The functional gain is a calculation and uses the masked, if not available unmasked, AC thresholds obtained with headphone TDH39 and aided sound field thresholds as described above (9.3.3.1-9.3.3.3). Functional gain is defined as the difference between the unaided AC and aided sound field thresholds. Functional gain can be calculated for frequencies 500Hz, 1kHz, 2 kHz, 3kHz and 4kHz. The average functional gain will be also be calculated for PTA4.

No blocking or masking of the non-implanted ear has been performed during the sound field measurement.

Unaided AC for the implanted ear will be used for the calculation of functional gain. In case of a bilateral Ponto fitting it is the best ear AC that will be used.
The aided soundfield has only been conducted on patients with CHL/MHL, and not for SSD.

9.3.3.5 Effective gain

Effective gain is a calculation and is defined as the difference between aided sound field thresholds measurement with Ponto 3 SuperPower(s) and BC In-situ thresholds at the time when the Ponto 3 SuperPower was fitted as described above (9.3.3.3-9.3.3.2). Effective gain can be calculated for frequencies 250 Hz, 500Hz, 1 kHz, 2 kHz, 3 kHz and 4 kHz. The average effective gain will be calculated for PTA4.

9.3.3.6 Collection of speech intelligibility scores

Speech intelligibility is measured in a sound treated room using sentence tests. The sentence tests used at Norwich and Norfolk hospital is the The AB[s] Isophonemic Monosyllabic Word test (7) and/or the BKB (Bamford-Kowal-Bench). BKB is never measured with SSD patients.
The sentence tests are measured in quiet and/or with background speech-weighted noise.
For patients with CHL/MHL speech intelligibility (percent (%)) was collected in quiet at the level of 60-65 dB HL for aided condition. For speech in noise the speech intelligibility percent (%) will be collected at the speech level of 60-65 dB HL when speech is presented from the front (0°) and 50-55 dB HL noise is presented from behind (180°) for aided condition.
For patients with SSD speech intelligibility in noise (percent (%)) was collected for unaided and aided conditions for two test setups with +10 dB fixed signal to noise ratio (SNR) : 1. Speech signal at 60-65 dB HL directed to the implanted ear and noise at 50-55 dB HL directed to the non-implanted ear, and 2. Speech signal at 60-65 dB HL directed to the non-implanted ear and noise at 50 -55 dB HL directed to the implanted ear.

All measurements have been conducted in user settings, and with no masking or plugging of the contralateral ear in case of unilateral patient.

Population	Speech test in quiet (%) – BKB[1]	Speech test in quiet (%) – AB[s]	Speech test in noise (%) at fixed SNR (+10 dB) – BKB[1]	Speech test in noise (%) at fixed SNR (+10 dB)– AB[s]	Loudspeakers
CHL/MHL	60-65 dB HL	60-65 dB HL	Speech 60-65 dB HL Noise 50-55 dB HL	Speech 60-65 dB HL Noise 50-55 dB HL	Speech (0°) Noise (180°)
SSD				Speech 60-65 dB HL Noise 50-55 dB HL	SimplatedNnon-implanted

Population	Speech test in quiet (%) – BKB[1]	Speech test in quiet (%) – AB[s]	Speech test in noise (%) at fixed SNR (+10 dB) – BKB[1]	Speech test in noise (%) at fixed SNR (+10 dB)– AB[s]	Loudspeakers
SSD				Speech 60-65 dB HL Noise 50-55 dB HL	Snon-implatedNimplanted

[1] Only conducted as per the audiologist discretion.

9.3.3.6.1 BKB sentence test

BKB sentence test is an open-set speech perception test developed for use with hearing-impaired children (usually >8 years of age). It can also be used with adults. The test can be administered in quiet conditions or in the presence of background noise. Each BKB list consists of 16 short sentences and is scored on the number of words correctly repeated out of 50 key words.
BKB sentence test might be measured for CHL/MHL, but never for the SSD patients.

9.3.3.6.2 AB[s] word list

The AB[s] Isophonemic Monosyllabic Word test (7) is an open-set speech perception test comprising fifteen lists with each having 10-word lists. The lists are composed of CVC (consonant, vowel, consonant) words in isolation, constructed from the same 10 vowels and 20 consonants. They are used to test adults with mild to profound hearing impairment using residual hearing alone or when aided with a hearing aid. The lists are phonemically balanced and are usually scored phonemically, which increases the test reliability. The AB[s] word lists are spoken by English male speaker.
AB[s] word list is most often measured for all patient groups.

9.3.3.7 Skin reaction

Classification of skin reactions around skin penetrating implants will be made using the Holgers score [8]. The Holgers classification is a scale from 0 to 4 that is used to grade skin reactions. Grade 0 indicates a reaction-free area whereas 4 indicates a severe infection often requiring removal of the implant, see table Table 6. Overview of grades of reaction on the Holger score. The Holger score is collected at the fitting and post-fitting follow up.

Holgers score	
0	No reaction
1	Erythema with slight swelling around abutment
2	Erythema, moistness and moderate swelling
3	Erythema, moistness and moderate swelling with granulation around abutment
4	Overt signs of infection resulting in removal of implant

Table 6. Overview of grades of reaction on the Holger score.

9.3.3.8 Collection of Glasgow Benefit Inventory

The Glasgow Benefit Inventory (GBI) contains 18 health status questions, which ask specific questions about how the health problem, in this study hearing loss, has affected their quality of life at the time the GBI is

completed. In this study GBI has been collected on patients before intervention and 3 months after fitting of Ponto 3 SuperPower on abutment.

9.3.3.9 Calculation of air-to-bone gap

Air-to-bone gap is a calculation of the difference between unaided masked (unmasked is masked is not available) AC thresholds and BC thresholds, measured with TDH-39 and BC-71 respectively, for the implanted ear. The air-to-bone gap will be calculated for frequencies 500 Hz, 1 kHz & 2 kHz.

10. MONITORING

During the investigation, authorized representatives from Oticon Medical will have regular contact with the investigational sites with the purpose to oversee the investigation. Monitoring activities will be performed by appointed monitors according to applicable standards (i.e. ISO14155) and internal guidance documents. The overall purposes of the monitoring are to make sure that the rights, safety and wellbeing of the subjects are protected, that the reported data are accurate, complete, and verifiable from source documents, and the conduct of the clinical investigation complies with the approved CIP, subsequent amendments (if any), applicable standards (i.e. ISO14155), and applicable regulatory and Ethics Committee requirements.

10.1 Monitoring plan

As this is a retrospective study, there are no direct risks to the patients, and this will be reflected in the study specific Monitoring Plan.

A Site Initiation Visit will be held online.

Interim monitoring will be performed via online meetings, and this is also due to the ongoing COVID 19 pandemic and new challenges when it comes to on-site monitoring. Centralized and/or remote monitoring will be performed on an interim basis by e.g. reviewing the data entered in the e-CRFs. Should the need for an increase of monitoring besides the planned monitoring occur, e.g. for quality concerns, this will be decided on a case by case basis.

The Investigator Site File (ISF) will be reviewed, also remote, for accuracy and completeness throughout the investigation.

Further details on the extent and the nature of monitoring activities as well as access to source data and the strategy of source data verification, will be outlined in a study specific, risk-based Monitoring Plan.

10.2 Inspections and audits

Audits of the clinical investigation may be conducted by authorized sponsor representatives, third parties designated by the sponsor or by competent authorities and notified bodies to evaluate compliance with the CIP, agreements, ISO 14155, and the applicable regulatory requirements. These audits may cover all involved parties, systems and facilities and are independent of, and separate from, routine monitoring or quality control functions. The institution's quality assurance department (or equivalent) may also visit the investigation site to perform an audit.

11 STATISTICAL DESIGN AND ANALYSIS

11.1 Study design, analysis populations, groups and methods

This is a retrospective post market clinical follow up (PMCF) study with the purpose to gather knowledge on Ponto 3 SuperPower by investigating 55 subjects fitted with this sound processor between December 2016 (market release) and December 2020.
Due to the retrospective design, no safety population will be defined for the study. The intention-to-treat (ITT) population will include all subjects included in the study. No per-protocol (PP) population will be defined as this study collects data retrospectively and thus the expectation is that not all data for the described procedures (see section 9.3.3) will be available for all patients. Instead, the ITT population will be divided into two separate target groups depending on the type of hearing loss in the subjects.

The Target populations (TPs) are defined as:

- TP1: Subjects with conductive or mixed hearing losses (within intended use for Ponto 3 SuperPower): pure tone average (PTA) bone conduction (BC) threshold on the BAHS(s) ear(s) better than or equal to 65 dB HL, based on BC threshold when Ponto 3 SuperPower were fitted.
- TP2: Subjects with single sided deafness (SSD) (within intended use for Ponto 3 SuperPower): pure tone average air conduction (AC) threshold of the hearing ear being better than or equal to 20 dB HL AC (measured at 0.5, 1, 2 and 3 kHz). In case AC is larger than 20 dB HL then the patients must not use a hearing aid on the other side.

The primary objective of the study is to investigate the improvement in hearing with the Ponto 3 SuperPower sound processor for patients with CHL/MHL.The related endpoint is defined as:

- Functional gain with Ponto 3 SuperPower, i.e. the difference between average unaided AC thresholds and aided sound field thresholds as the average (PTA4) of frequencies 500, 1000, 2000 and 4000 Hz

Unaided AC for the implanted ear will be used for the calculation of functional gain. In case of a bilateral Ponto fitting it is the best ear AC that will be used. The aided sound field measurement has only been conducted on patients with CHL/MHL, and not for SSD.

In this study, all analyses will be performed on the ITT population and the Target populations (

Objectives	ITT	Target	Effect of Ponto 3 SuperPower (bilaterally fitted CHL/MHL subjects)
A	X	X (TP1)	X
B	X	X (TP1)	X
C	X	X (TP1)	X
D	X	X (TP2)	
E	X	X (TP1)	X
F	X	X (TP1)	X
G	X	X (TP1 + TP2)	
H	X	X (TP1 + TP2)	X
I	X	X (TP1)	

J	X	X (TP1 + TP2)	

Table 7. Overview of analyses for objectives A-J.). Additional analyses will be perfomed to assess the hering benefit of the Ponto 3 SuperPower alone (i.e. without "interference" from a normal-hearing ear). The hearing benefit of Ponto 3 SuperPower will be calculated on a subset of the Target population 1 (TP1), including only bilaterally fitted Ponto 3 SuperPower users with conductive or mixed hearing losses. This is to avoid any contribution from the non-Ponto 3 SuperPower fitted ear in unilaterally fitted users or bimodially users (BAHS on one ear, hearing aid on the other), since all measurements have been performed without masking or blocking of the contralateral ear.

Objectives	ITT	Target	Effect of Ponto 3 SuperPower (bilaterally fitted CHL/MHL subjects)
A	X	X (TP1)	X
B	X	X (TP1)	X
C	X	X (TP1)	X
D	X	X (TP2)	
E	X	X (TP1)	X
F	X	X (TP1)	X
G	X	X (TP1 + TP2)	
H	X	X (TP1 + TP2)	X
I	X	X (TP1)	
J	X	X (TP1 + TP2)	

Table 7. Overview of analyses for objectives A-J.

11.2 Sample size

The sample size in the investigation is based on the typical size of retrospective studies on sound processor outcomes within the bone-anchored hearing system field.
For the primary endpoint there is no hypothesis to test, but a sample size at least as large as similar studies within state-of-the-art is considered appropriate. A total of 3 retrospective studies on sound processors from recent years that included functional gain as outcome, were identified [E]. The number of included subjects with functional gain reported on in the identified studies ranged from 6 to 53. The study with 6 subjects actually included 46 in total whereof 40 were fitted on softband (9). One study included 20 subjects for which functional gain where reported whereas the total number of subjects in the study was 49 (29 subjects only had surgical outcomes reported) (10). The third study included 53 subjects, all of which had functional gain reported (11), table 8.

Year	Title	Author	Number of subjects	Number of subjects in groups
2018	Hearing improvement with softband and implanted bone-anchored devices and modified implantation surgery in patients with bilateral microtia-atresia.	Wang et al.	46	6 (percutaneus) 40 (softband)

2016	Bone anchored hearing implants without skin thinning: the Gruppo Otologico surgical and audiological experience	Caruso et al.	49	20 (audiological outcome) 29 (surgical outcome)
2016	Bone Anchored Hearin Aid (BAHA) in children: Experience of tertiary referral centre in Portugal	Rosa et al.	53	

Table 8. Overview of retrospective studies including functional gain as outcome measure.

Due to the retrospective design, no drop-outs are considered. Based on the typical sample size in similar studies within state-of-the-art and achieving a sufficient number of patient represented in the hearing loss categories for CHL/MHL population (see section 9.1.1), 55 subjects was concluded as an appropriate number to include in the study.

11.3 Statistical methods and analytical procedures

The general methodology for the analysis of primary and secondary endpoints are described below. The descriptive statistics of continuous variables will be given as Mean, standard deviation (SD), Minimum and Maximum (Mean (SD) (Min; Max)). The distribution of categorical and dichotomous variables will be given as number and percentage (n = (%)).
In case of one factor involved in the design, data will be tested for normality using the Shapiro-Wilk test. Paired t-test will be performed if the data is normally distributed. Wilcoxon signed-rank test will be performed if the data is not normally distributed. In case of more than one factor involved in the design, mixed-model ANOVAs will be performed with subject as a random factor. The decision of the hypothesis test is done at the 5% significance level. Pearson's correlations (or Spearman's if the data is not normally distributed) will be used to test correlations.
The analysis of the primary endpoint will be performed with descriptive statistics (mean and standard deviation; min and max(if the data is normally distributed) or a median, 1st and 4th quartile; min and max (if the data is not normally distributed). The analysis of secondary and exploratory endpoints will follow the general methodology described above.

All statistical analyses are to be explained in detail in a statistical analysis plan (SAP). Any deviations from the original analysis plan will be described in a CIP amendment, as deemed appropriate.
No pass/fail criteria will be applied to the results of the investigation.

11.4 Missing Data

Missing data (e.g., single questions, experimental repetitions) will not be imputed and will be disregarded from the analysis. In case of a full variable missing for a subject, case-wise deletion will be performed for this variable.

11.5 Timing of analysis

Results will be compiled and reported when all data for all subjects has been collected. No interim analysis is planned for.

12 DATA-MANAGEMENT

All data collected and processed concerning the subjects participating in the investigation is protected under the Data Protection Act 2018 (the UK's implementation of the (EU) Regulation 2016/679 (GDPR) and the Health Act and will be handled accordingly. Further, professional secrecy regarding subject information and data applies to all involved personnel, including sponsor representatives.

All subjects included in the clinical investigation will be assigned a Subject Identification Number linked to their personal identification. Subject will only be identifiable in a Subject Identification Log, where the personal identification information matches the Subject Identification Number. The subject Identification Number will be used for all data collected and recorded from the subject. Names and/or personal identification information will not be collected or recorded for investigational purposes. It is the responsibility of the investigator to make sure that the Subject Identification Log is always kept up to date. The Subject Identification Log will only be available as part of the Investigator Site File (ISF) in a secure location with restricted access, and not, at any time during the investigation, be available to any unauthorized party, nor available in sponsor files.

All subjects included in the investigation will be provided with a Subject Identification Number (i.e. pseudonymization), consisting of a three digit code, where the leading digit represents the investigation site number, (1 for site no. 1, 2 for site no. 2 etc.) and the two following numbers represents the consecutive subject number (e.g. 101 for the first included subject at site no. 1, 202 for the second included subject at site no. 2 etc.).

12.1 Case Report Form recording and processing

Data captured will be recorded by the investigator and/or delegated site staff in electronic Case Report Forms (eCRF) by means of an Electronic Data Capture (EDC) system (SMART-TRIAL) provided/hosted by an external party (MEDEI ApS, Copenhagen, Denmark). The system has built in features that enables users to be compliant with applicable regulatory standards and regulations. All data in relation to SMART-TRIAL is stored on secured Microsoft Azure hardware located in the EU, i.e. Dublin, Ireland.
All users of the EDC system have personal accounts, accessed by two-factor authentication, allowing tracking of all data entries and changes in the system (i.e. audit trail).

All data, subject and product related, are to be recorded into the EDC system by the delegated site staff. This also includes the already collected subject reported outcomes (PRO).

12.2 Source documents

Source documents will be the original records, including the existing medical records, Auditbase, NOAH and Genie Medical. Where printouts or copies of the source documentation are used for the study, these shall be signed and dated (i.e. certified) by a member of the investigation site team.

12.3 Data Management Plan

Data management-related activities, e.g. data cleaning and query handling, will be performed on interim basis within the EDC system by the data manager or monitor assigned by the sponsor.
Once all data has been captured, reviewed and declared clean the database will be locked before any data analysis. Further details on the extent and the nature of data management activities will be outlined in a study specific Data Management Plan.

12.4 Storage of data

It is the responsibility of the investigator to make sure that medical files of the clinical investigation subject are stored in accordance with this CIP or according to national regulations whichever is most stringent, after the investigation has been completed. The principal investigator must take measures to prevent accidental or premature destruction of these documents.

Readable copies of the eCRF data, either in printed form or in a digital format, as per the site's preference, will be archived in the ISF at the study site after study closure. Oticon Medical will not at any time point be in control of the eCRF data archived in the ISF, unless only for the purpose of delivering it to the study site.
All study data and study related documents will be securely stored at Oticon Medical and respective sites with restricted access and retained for at least 15 years, or in accordance to national regulations whichever is most stringent, after the study has been completed.
The principal investigator must take measures to prevent accidental or premature destruction of these documents and at the end of the storage period, acquire a confirmation from the sponsor before proceeding with the destruction of the documentation.

13 AMENDMENTS TO THE CLINICAL INVESTIGATION PLAN

Changes to an approved CIP can either be classified as non-substantial (administrative/minor changes with no significant impact on investigation) or as substantial amendments (changes with impact on scientific value, conduct and management, quality and safety of the investigation).

In general, an EC approval is required when implementing a substantial amendment whereas, in case of a non-substantial CIP Amendments, it is generally not required. This needs to be confirmed with the EC and relevant authorizing parties on a case by case basis.

In addition, substantial amendments to the Subject Information and Consent Form and/or other applicable documents previously approved by the EC must be approved by the EC, as applicable, before they will come into effect.

14 DEVIATIONS FROM CLINICAL INVESTIGATION PLAN

A CIP deviation is an intentional or unintentional failure to follow the requirements of the CIP. Every effort should be made to comply with the requirements of the CIP. The Investigator, and other representatives of the investigational site team, is not allowed to deviate from the CIP, unless needed to protect the rights, safety and well-being of the subjects (i.e. emergencies). However, as there will be no study visits, and all

data collected for this study are already existing in the patients' medical files, no major deviations are expected. The sponsor is aware that there might be some datapoints missing in the final datafile, due to the fact that they might not have been collected originally. These will not be regarded as deviations

If other deviations occur, the Investigator should inform the monitor/clinical trial manager and make a record in the CIP Deviation Log provided in the study site file. The implications of the deviation must be reviewed and discussed between the Sponsor and the Investigator. If deviations are found during monitoring visits, they should also be documented in the monitoring report and handled as above. This should be done as soon as possible after detection to avoid repetitive deviations. Continuous review of protocol deviations during monitoring visits aim to detect systematic errors and to identify retraining needs at the site. Frequency of monitoring is described in the monitoring plan and should be increased if systematic deviations are identified. All protocol deviations must be documented stating the reason, date, the action(s) taken, and the impact for the subjects and/or the study. If serious or repeated deviations occur at a site, the Sponsor has the right to initiate early termination of the study.

At the end of the study, or in connection to a predefined interim analysis, protocol deviations, if any, will be categorized as minor or major and their consequence on analysis populations will be determined.

15 Device Accountability

Due to the nature of the study device accountability is not applicable.

16 Statements of compliance

This clinical investigation will be conducted in compliance with this CIP, the current versions of the declaration of Helsinki and the ISO 14155 standard, the Medical Device Directive (MDD) 93/42/EEC, The Medical Device Regulation (EU) 2017/745 (MDR) as well as applicable regional and/or local regulatory requirements.
The CIP and other required documents must be reviewed and approved in writing by an Ethics Committee (EC) before enrollment of subjects into the clinical investigation can be initiated. Since the investigational device holds the CE-mark, approval from a National Competent Authority (NCA) is not required. If applicable, an approval from a local Institutional review board (or equivalent) will be applied for by the sites.
Oticon Medical has a Public and Product Liability Insurance (Policy number: DKLSCA03184), issued by CHUBB, that includes coverage of clinical trials.

Oticon Medical will have a Clinical Agreement with the investigational site, and details regarding costs, payments, publication policy etc. will be specifically outlined in this agreement.

17 Informed consent procedure

No study specific informed consent will be collected from the patients. As this is an observational (non-interventional) retrospective investigation the informed consent usually required for human research subjects may be waived by an ethics committee.

The rational for arguing for a waiver from the investigation-related informed consent requirement is mainly related to the nature and type of investigation, as indicated above. There are also additional arguments which may be considered for this investigation; the additional workload (disproportionate effort) for the investigation site team and the potential bias in subject inclusion (e.g. patients that either doesn't respond

to the invitation or refuse participation) with corresponding scientific shortcomings. To ensure high quality data, partly by including as many applicable subjects into the investigation as possible, there is a need to enhance subject recruitment without the corresponding disproportionate effort and population bias an informed consent procedure would impose. Should an informed consent be required for this retrospective non-interventional investigation there is a potential risk for non-responsiveness and refusals that may result in inconclusive and biased data on e.g. non-users, indications, types of hearing losses etc.

In an effort to comply with applicable subject data protection regulations while developing service improvements all patients treated at the investigation site, as part of the daily clinical routine practice, are asked to provide their consent to the document: "GDPR – what this means to you" (Appendix A). Section 3 of this document reads:

"We may also share information about you which will not identify you as an individual for our Service Improvement such as patient experience, patient survey or improvement regarding your treatment if you have had any. Again, you may decide you do not want us to use your information for research and trials, but it will help the hospital"

Even though the sponsor nor the investigation site does not rely on consent as the basis for lawful processing of personal data when conducting clinical research, it is decided that only subjects who already have consented to the referred document and section will be included in the investigation. The rational for this decision is based on the assumption that the potential 'change of data usage', in relation to the given consent, is justified by the type and purpose of the investigation, i.e. a non-interventional retrospective evaluation of hearing improvement when using the prescribed sound processor within its intended use.

As indicated above, applicable data will only be collected retrospectively and will be pseudonymized when recorded in the eCRF. Data collection will be performed by the appointed investigators, who are also involved in the daily clinical routine at the investigation site. The collection is limited to data from the audiology records, and specifically within the pre-defined time window between the clinical routine visit when fitting of the Ponto 3 SuperPower sound processor was performed, and up and until the first clinical routine visit following this where audiology measurements were made. In addition, audiometric measurements for audiometry thresholds, that might have been performed at a clinical routine visit preceding the fitting, data will be collected from there.

Safety data will, in the case of identification of any safety events, be followed up using standard post-market surveillance/vigilance reporting, see section 9.3.2.

All data concerning investigation subjects is protected under the Data Protection Act 2018 and General Data Protection Regulation (GDPR) and will be handled accordingly. For the sponsor, the legal basis for collecting and processing personal data in this investigation is 'Legitimate interest' (GDPR, Art. 6.1(f), in combination with Art. 9.2(i)).

In summary, the research interest and the risk for research bias introduced by an additional informed consent procedure for this specific investigation justifies the limited, if any, change in use of data compared to what the subjects have already consented to as part of their regular care.

18 ADVERSE EVENT, ADVERSE DEVICE EFFECTS AND DEVICE DEFICIENCIES ADVERSE EVENT (AE)

An adverse event (AE) is defined as any untoward medical occurrence, unintended disease or injury or any untoward clinical signs (including an abnormal laboratory finding) in subjects, users or other persons, in the context of a clinical investigation, whether or not related to the investigational medical device.

Note 1. This definition includes events related to the investigational medical device or the comparator.
Note 2. This definition includes events related to the procedures involved.
Note 3. For users or other persons, this definition is restricted to events related to the use of investigational medical devices.

18.1 Serious Adverse Events (SAE)

A serious adverse event (SAE) is an adverse event that led to any of the following:

a) death,
b) serious deterioration in the health of the subject, users or other persons as defined by one or more of the following:
    1. a life-threatening illness or injury, or
    2. a permanent impairment of a body structure or a body function including chronic diseases, or
    3. in-subject or prolonged hospitalisation, or
    4. medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,
c) foetal distress, foetal death or a congenital abnormality or birth defect including physical or mental impairment

Note: Planned hospitalisation for a pre-existing condition, or a procedure required by the CIP, without serious deterioration in health, is not considered a serious adverse event.

18.1.1 Adverse Device Effect (ADE)

An adverse device effect is an adverse event related to the use of an investigational medical device.

Note 1: 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 2: This definition includes any event resulting from use error or from intentional misuse of the investigational medical device.

18.1.2 Serious Adverse Device Effect (SADE)

A serious adverse device effect is an adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event (see section 18.1).

18.1.2.1 Unanticipated Serious Adverse Device Effect (USADE)

An unanticipated serious adverse device effect is a serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report.

Note: Anticipated Serious Adverse Device Effect (ASADE) is an effect which by its nature, incidence, severity or outcome has been identified in the risk analysis.

18.2 Device deficiency (DD)

A device deficiency is defined as any inadequacy of an investigational medical device related to its identity, quality, durability, reliability, usability, safety or performance.

Note 1: Device deficiencies include malfunctions, use errors, and inadequacy in the information supplied by the manufacturer including labelling
Note 2: This definition includes device deficiencies related to the investigational medical device or the comparator.

Note: To distinguish between a DD and an ADE it may be useful to consider DDs as not directly affecting or involving the subject.

18.3 Reporting of safety events

18.3.1 Reporting of Adverse Event(s)

All health problems, whether judged as related or not, that are assessed as described in section 9.3.2, must be recorded by the PI, or authorised designee, in the eCRF accordingly. For events judged as related, will be followed up using standard post-market surveillance/vigilance reporting, see section 9.3.2. Due to the retrospective approach no specific time limits are required regarding reporting time, but all reporting must be completed at the time of the closure of the study.

18.4 Device deficiency reporting

The Investigator is responsible for recording the following in the eCRF, for all device deficiencies identified as described in section 9.3.2:

- Device deficiency details (e. g. date and description of occurrence).
- Device deficiencies that might have led to a SADE if:
    - suitable action had not been taken or
    - intervention had not been made or
    - if circumstances had been less fortunate

For device deficiencies that fulfil the SADE definition, the Investigator must provide Oticon Medical with detailed information.

18.5 Safety event follow-up

See section 9.3.2.

18.6 Safety related contacts

Should the need for further guidance on safety-related issues or how to record these be evident, the following contact details applies:

Oticon Medical:
Phone: +46 31 748 61 70 (vigilance)
Mail: QA@oticonmedical.se

Postal address: Oticon Medical
Datavägen 37,
SE-436 32 Askim, Sweden

Clinical Trial Manager: Liselotte Borup
Phone: +45 4124 1964
e-mail: lsbo@oticonmedical.com

19 SUSPENSION OR PREMATURE TERMINATION OF THE CLINICAL INVESTIGATION

If the investigation is terminated early or suspended due to any reason, the Sponsor will promptly inform the Principal Investigators and the investigation sites of the termination or suspension and the reason(s) thereof. The EC will also be informed promptly and provided with the reason(s) for the termination or suspension by the Sponsor or by the PI/investigation sites.

In addition, CIP deviations may result in termination of the Clinical Investigation at a site.

20 PUBLICATION POLICY

This investigation will be registered on ClinicalTrials.gov.

The results obtained in the investigation will be compiled in a final Clinical Investigation Report and submitted for publication by the investigators in cooperation with the Sponsor. The Sponsor reserves the right to postpone publication and/or communication of the results for a short period of time to protect intellectual property as according to the Clinical Investigation Agreement Privacy and confidentiality of information about each subject will be preserved in any publication of the clinical investigation data.

21 SIGNATURE PAGE

21.1 Sponsor

On behalf of Oticon Medical AB I agree to the terms of this investigation plan.

Date and signature:

Tove Rosenbom, Senior Director Clinical Research and Audiology

Name and title

21.2 Principal Investigator

I agree to the terms of this investigation plan. I will conduct the investigation according to the procedures specified herein and in consistency with the current version of the declaration of Helsinki and ISO 14155, Clinical investigation of medical devices for human subjects - Good Clinical Practice (GCP).

Date and signature:

John E FitzGerald ,Consultant Clinical Scientist
Head of Audiological Services

Name and title

22 REFERENCES

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11. Rosa, F., et al. Bone Anchored Heairng Aid (BAHA) in children: Experience of tertiary referral centre in Portugal. Acta Otorrinolaringológica Espanola. (2016)

23 REFERENCE DOCUMENTS

[A] 197424	Audiological Manual Ponto system
[B] M52682	Product information sheet
[D] M52611	UK IFU Ponto 3 SuperPower
[E] EDMS DOC-00067091	State of the Art – BAHS
[F] M153631	UK IFU Oticon Medical Streamer
[I] M164253	UK IFU Connectline microphone
[J] M185563	UK IFU Connectline phone adapter

24 APPENDIX A

GDPR - What this means to you.
Sharing of Information

The hospital keeps your information such as your name address, contact number and information relevant to your visits to the hospital. We may share this information with other hospitals or other organisations if they are involved in your care or to your GP practice.

We may share your information with other agencies that can help you in the community settings such as Health Visitors, Social services, Housing and voluntary organisation who can support you with your condition. You may decide you do not want to share your information.

We may also share information about you which will not identify you as an individual for our Service Improvement such as patient experience, patient survey or improvement regarding your treatment if you have had any. Again, you may decide you do not want us to use your information for research and trials but it will help the hospital