CONFIDENTIAL

Title	Cross-sectional evaluation of the subjective performance and satisfaction with Ponto sound processors
Study Code	BC112
Device (s)	Ponto Sound Processors
Sponsor	Oticon Medical AB Datavägen 37 B 436 32 Askim Sweden
Date/Version	15-MAR-2022

Revision history:

Revision no	*Date*	*Description*
0	09MAR2022	First version
1	15MAR2022	Updated with clarification of study flow and minor corrections throughout the document

STATEMENT OF COMPLIANCE

This study will be performed in consistency with applicable parts of the current versions of the Declaration of Helsinki, ISO 14155, Regulation (EU) 2017/745 (MDR) and applicable regional or national regulatory requirements as well as any additional requirements imposed by Institutional Review boards and Ethical committees.

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Referenced documents:

[A] Doc-00064573 Intended purpose Ponto bone anchored hearing system (BAHS)
[B] Doc-00069507 PMCF plan for Ponto sound processors and accessories
[C] Doc-00065550 Medical background Oticon Medical BAHS

Appendix:

1. Part number for devices included in the study
2. The International Outcome Inventory of Hearing Aids (IOI-HA)

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1 SYNOPSIS

Clinical Study Title	Cross-sectional evaluation of the subjective performance and satisfaction with Oticon Medical's Ponto Sound Processors
Study Code	BC112
Device (s)	Ponto Sound Processors
Principal investigator(s):	NA Study carried out by sponsor through online survey
Sponsor:	Oticon Medical AB Datavägen 37 B 436 32 Askim Sweden
Methodology:	Observational Cross-sectional online survey
Inclusion/exclusion criteria:	Inclusion: • Online consent form filled out • Has been fitted with a Ponto Sound Processor
Objective(s):	Primary Objective • Evaluate subjectively assessed overall hearing performance and satisfaction with the Oticon Medical's Ponto sound processors. Secondary Objective (s) • Evaluate subjectively assessed hearing performance and satisfaction with the Oticon Medical's Ponto sound processors. • Evaluate non-usage among patients fitted with a Ponto sound processor
Endpoints	Primary Endpoint • Overall IOI-HA score Secondary Endpoint(s) • Factor 1, Factor 2 IOI-HA and per item IOI-HA score (Ponto 4 and Ponto 5 Mini) • Percentage of users fitted with a Ponto sound processor that have stopped using the Ponto sound processor and is unaided
Duration of study period:	10 months
Number of Participants	1000
Study plan prepared by:	Marianne Philipsson, Clinical Trial Manager, Oticon Medical AB

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2 TABLE OF CONTENTS

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3 LIST OF ABBREVIATIONS

AE	*Adverse Event*
BAHS	*Bone Anchored Hearing System*
BC	*Bone conduction*
CE	*Conformité Européenne*
CHL	*Conductive Hearing Loss*
CIP	*Clinical Investigation Plan*
dB	*Decibel*
EDC	*Electronic Data Capture*
FDA	*Food and Drug Administration*
GCP	*Good Clinical Practice*
GDPR	*General Data Protection Regulation*
HIPAA	*Health Insurance Portability and Accountability Act*
IRB	*Institutional Review Board*
IOI-HA	*International Outcome Inventory for Hearing Aids*
ISO	*International Organization for Standardization*
MDR	*Medical Device Regulation*
MHL	*Mixed Hearing loss*
OM	*Oticon Medical*
PMCF	*Post Market Clinical Follow-up*
PTA	*Pure Tone Average*
No	*Number*
SAE	*Severe Adverse Event*
SP	*Sound Processor*
SSD	*Single Sided Deafness*
US	*United States*

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4 INTRODUCTION

Bone conduction hearing systems use the body's natural ability to transfer sound through bone conduction. The bone conduction system picks up sound and converts it into vibrations that are transferred through the skull bone to the inner ear(s) (cochlea). A bone conduction system transmits sound directly to the cochlea independently of the function of the ear canal and middle ear. Thus, for patients with conductive hearing losses (CHL) or mixed hearing losses (MHL), patients 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 impairment in the ear canal or middle ear, stimulating the cochlea directly. For single-sided deaf (SSD) Participants, one utilizes that the vibrations are transmitted in the same manner via the skull bone to the (functioning) cochlea on the contralateral side [1].

Bone Anchored Hearing Systems (BAHS) have been used since the late 1970's and are divided into two types: direct drive and skin drive, both having two sub-types (see Figure 1). Direct drive denotes systems where the vibrations are transmitted directly to the bone (e.g. through an abutment connected to an osseointegrated implant), while in skin drive solution there is a layer of soft tissue between the transducer and the bone (e.g. when utilizing a Softband). Percutaneous direct drive, also referred to as BAHS, is the most common type with more than 150.000 users world-wide [1].

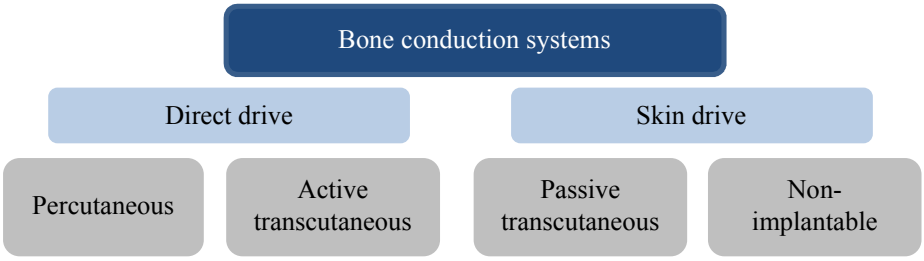

Figure 1 *Classification of bone conduction systems*

4.1 *The Ponto System*

The Ponto system is an osseointegrated, percutaneous (direct drive) bone conduction system, which replaces the function of the outer and middle ear. This replacement happens by providing mechanical energy to the cochlea from a transducer in the sound processor and via a percutaneous implant anchored in the temporal bone. Sound is picked up by the microphones in the external sound processor and converted to mechanical energy (vibrations) by the transducer in the sound processor and is then transmitted to a skin-penetrating abutment which is connected to the implant in the temporal bone of the skull (see Figure 2). The vibrations are conveyed from the implant by means of bone conduction to the cochlea. In the cochlea, the vibrations are converted to signals that are transmitted to the brain through the auditory nerve.

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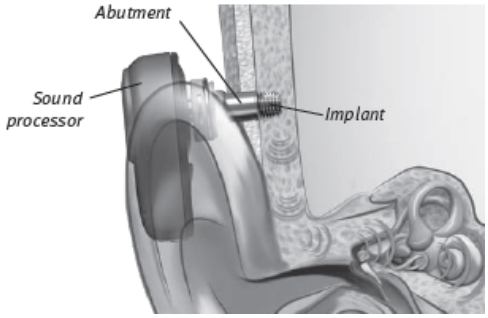

Figure 2 *Ponto sound processor connected to an abutment*

5 DESCRIPTION OF THE DEVICE

The devices investigated in the study will be the Ponto sound processors. Ponto sound processors are non-sterile devices containing a coupling, an electromagnetic transducer (vibrator), microphones, sound processor electronics and signal processing chip. The sound processors are powered by a zinc air hearing aid batteries accessible through a battery drawer. The Ponto sound processor are fitted and adapted to the patient's by a hearing care professional using a computer with a fitting software (Genie Medical) developed together with the sound processors.

5.1 Identification of the Device

The subjects included will have been fitted with a Ponto sound processor and they will evaluate the sound processor that they are currently fitted with. The study will focus on devices from the following Ponto families:

- Ponto
- Ponto Pro and Ponto Pro Power
- Ponto Plus and Ponto Plus Power
- Ponto 3, Ponto 3 Power and Ponto 3 SuperPower
- Ponto 4
- Ponto 5 Mini and Ponto 5 SuperPower

The Ponto sound processor comes in a range of different colors. Part number for each style and color that can be included in the study is listed in Appendix 1.

5.2 Manufacturer

The Ponto sound processors are 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.

5.3 Intended Purpose

The Ponto sound processors are intended for improvement of hearing for patients with conductive or mixed hearing losses, whether unilaterally or bilaterally fitted, or for those with single sided deafness[A].

5.4 Population and indications [A]

The study will include subjects that has been fitted with a Ponto Sound Processor. The Ponto system is

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intended for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of the sound. The pure tone average (PTA) bone conduction (BC) threshold (measured at 0.5, 1, 2 and 3 kHz) of the indicated ear should be better than or equal to 45 dB HL for use with the Ponto, Ponto Pro, Ponto Plus, Ponto 3, Ponto 4 and Ponto 5 Mini sound processors, 55 dB HL for use with the Ponto Pro Power, Ponto Plus Power and Ponto 3 Power sound processors and 65 dB HL for use with the Ponto 3 SuperPower and Ponto 5 SuperPower sound processors.

- Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10 dB on average measured at 0.5, 1, 2 and 4 kHz, 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 (i.e. single sided deafness or "SSD"). The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should then be better than or equal to 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).
- Also indicated for any patient who is indicated for an air-conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS.

6 JUSTIFICATION FOR THE DESIGN OF THE STUDY

The study is a non-interventional, observational, cross-sectional, study on users of Ponto sound processors. The purpose of this study is to evaluate subjectively assessed hearing performance and satisfaction with Oticon Medical's sound processors fitted with the Genie Medical fitting software.

The overall study purpose aims to study long-term use of Oticon Medical's sound processor Ponto (fitted with the Genie Medical fitting software) and how it impacts patient reported hearing improvements and quality of life.

The study is making use of subjective self-reported outcomes to evaluate hearing performance. Subjectively self-reported outcomes are commonly used to quantify how the patients subjectively perceive the device in their everyday life [C] and is considered to provide representative measurements of hearing improvement [2] One such subjectively self-reported outcome measure is the IOI-HA [3]. The IOI-HA contains generally applicable items for self-assessment of hearing aid fitting outcomes. It covers a minimal set of seven core outcome items targeting a different outcome domain. The domains are: daily use, benefit, residual activity limitations, satisfaction, residual participation restrictions, impact on others and quality of life. Each item has five response choices proceeding from the worst outcome to the best outcome. In terms of construction and wording, the items of the IOI-HA have been designed to be easy to read and understand. In addition it is designed to be self-explanatory and without any need for formal instructions [3]. The IOI-HA was originally designed to be distributed in paper form, but Thorén, Andersson and Lunner [4] found that the questionnaire can be distributed also in an online format without compromising reliability of the outcome. Based on the short self-explanatory design [3] together with data supporting the use of the questionnaire for online use [4] the IOI-HA has been chosen to be the questionnaire used in this study.

7 POTENTIAL BENEFITS AND RISKS OF THE STUDY

No additional treatments or procedures will be utilized for this study, although participants will be asked to complete a survey. Therefore, only risks associated to data capture and data privacy have been identified and these are mitigated by strict data management procedures (see Section12).

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Although participants included in this study might not receive any benefit from the study, the study will promote a better understanding of satisfaction of the Ponto Sound Processors which will be shared within the field of BAHS and may lead more efficient BAHS for others. Prior to enrollment into the study the participants will receive information about potential benefits and risks. Electronically signed consent based on this information will be required from all participants prior to collecting any study specific data.

8 OBJECTIVES AND HYPOTHESES

The purpose of this study is to evaluate subjectively assessed hearing performance and satisfaction with Oticon Medical's Ponto sound processors (fitted with the Genie Medical fitting software).

8.1 Primary objective

Primary objective	Corresponding primary endpoint/outcome variable(s)	Section
A. Evaluate the subjectively assessed overall performance and satisfaction with Oticon Medical's Ponto sound processors	1. Overall IOI-HA score	*9.2.1.2*

8.2 Secondary Objective(s)

Secondary objective(s)	Corresponding primary endpoint/outcome variable(s)	Section
A. Evaluate the subjectively assessed performance and satisfaction with Oticon Medical's Ponto sound processors	1. Factor 1 IOI-HA score 2. Factor 2 IOI-HA score 3. Per item IOI-HA score	*9.2.1.2*
B. Evaluate non-usage among patients fitted with a Ponto sound processor	1. Percentage of users fitted with a Ponto sound processor that have stopped using the Ponto sound processor and is unaided	
C. Evaluate Ponto sound processor upgrade rate	1. Percentage of users who have been refitted with a Ponto sound processor	

9 DESIGN OF THE STUDY

This is a non-interventional, observational, cross-sectional, study on subjects fitted with Ponto sound processors. Subjects fitted with one or two Ponto sound processors will be invited to participate in an online survey. The survey contains questions about the subjectively experienced performance and satisfaction of the device. The survey can be filled out on computer, tablet or mobile phone and should take the participants about 10 minutes to fill out.

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9.1 Subjects

The population for this study will be users of Ponto Sound Processors in the US. User who are a part of Oticon Medical's US user database where the users are signing up in relation to being fitted with a Ponto Sound Processor will be approached through email out-reach. When signing up for the database the users give their consent for being contacted by Oticon Medical. In addition, out-reach through social media and Oticon Medical US website will be considered to increase numbers of subjects. In all both cases, study awareness and enrollment of the participants for this study will occur after being fitted with one or two Ponto sound processor.

9.1.1 Inclusion criteria

Following users will be included in the study:

- Online consent form filled out
- Has been fitted with at least one Ponto Sound Processor

9.1.2 Exclusion criteria

There are no exclusion criteria for this study.

9.1.3 Number of subjects

The aim is to recruit in total approx. 1000 subject. The subjects will be split into sub-groups based on which sound processor they are using.

9.2 Study flow

Primarily out-reach will be made through an email. The email will contain overall information about the study and a link to the study landing page. In addition, posts might be made in social media or at Oticon Medical US website with information and a link to the same landing page. On the landing page the participants can get more information about the survey and also provide their informed consent. Following consent, the users will get access to the survey that should be completed within one month. To maximize data collection, e-mail and/or text message reminders to complete the survey will be 7 days after the initial email and 5 days prior to the survey completion deadline. In Figure 3 an overview of the study flow is visualized.

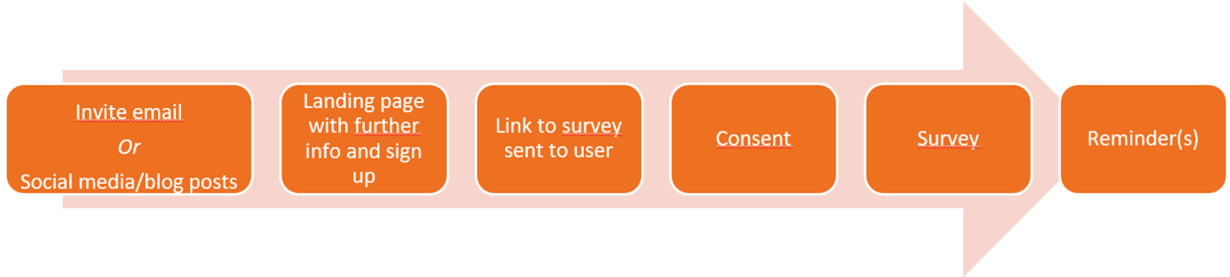

Figure 3 Scematic overview of the flow of the study

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9.2.1 Survey

The study will consist of an online survey distributed to the subjects The survey consists of two parts:

1. Overall information about the subject and the device
2. A validated questionnaire focusing on subjective performance using a hearing device. For adult participants the questionnaire IOI-HA will be used.

9.2.1.1 Part 1 Overall information

Following overall information will be gathered from the participants:

- Gender
- Age
- Usage of device
- Unilateral or bilateral user
- Softband or Abutment fitting
- Time of fitting (for how long they have used the device)

9.2.1.2 Part 2 International Outcome Inventory Hearing Aids (IOI-HA)

The IOI-HA is a short questionnaire with generally applicable items used as self-assessment of hearing aid fitting outcomes. The questionnaire consists of seven items: daily use, benefit, residual activity limitation, satisfaction, residual participation restrictions, impact on other and quality of life. Each item has five response choices proceeding from worst to best. Analysis of the results can be done per item or total score. The items can be grouped in two subscales: Factor 1 (daily use, benefit, satisfaction and quality of life) and Factor 2: (residual activity limitation, residual participation restrictions and impact on others) [3].

10 MONITORING

Due to the nature of this study, with users reporting data directly into the electronic system, monitoring is not applicable.

11 STATISTICAL DESIGN AND ANALYSIS

The results of the IOI-HA (ranging from 1-5, 1=worst and 5= best) will be analyzed and presented using descriptive statistics. The values of the Overall, Factor 1, Factor 2 and per item IOI-HA score will be given as Mean, standard deviation (SD), Median, Minimum and Maximum.

11.1 Sample size

The user database currently consists of approx. 3000 users and we expect an initial response-rate of 50%, i.e. that approximately half of the users will respond to the survey invite. As the database continuously increases and outreach through social media and website also is planned additional outreach can be made to fulfill the sample size estimated below.

The IOI-HA have been used for many studies on different number of subjects. The original paper the sample size was 172 [3] and the for the online validation [4] the sample size was 53. However, the IOI-HA has also been used for bigger populations, in [5] the IOI-HA was used on 1649 subjects. For the two studies [3] and [4] the response rate were high and reported drop-out rates were 20% and 34%, respectively. Drop-out is in

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this study defined as the participants not finalizing the survey after filling out the digital consent form. Drop-out rate for this study is expected to be low based on previous reported literature and as the study only consist of one assessment (i.e. the subject filling out one survey at a single point of time). The drop-out rate is estimated to a 30%, aiming for answers from in total 1000 subjects, with minimum 50 subjects from each sub-group 1, 2 and 3.

11.2 Subgroups for analysis

Subgroup primary endpoint analysis will be made based on the type of Ponto sound processor. The following subgroups will be analysed:

- Subgroup 1: Ponto, Ponto Pro and Ponto Plus (Ponto, Ponto Pro, Ponto Pro Power, Ponto Plus and Ponto Plus Power)
- Subgroup 2: Ponto 3 SuperPower
- Subgroup 3: Ponto 3 (Ponto 3, Ponto 3 Power)
- Subgroup 4: Ponto 4
- Subgroup 5: Ponto 5 Mini
- Subgroup 6: Ponto 5 SuperPower

11.3 Missing data handling

No imputations or estimations will be made to replace missing data.

11.4 Timing for data analysis

Data analyses will be performed in three steps. First data analysis will focus on subgroup 1-3. Second data analysis will focus on subgroup 4-5. Third analysis will focus on Subgroup 6. Out-reach to the users will be made according to timing of the analysis, also in three steps. Additional outreaches can be performed to increase the number of participants.

Data cleaning and database lock of the applicable data will be performed before each of the three data analysis.

12 DATA MANAGEMENT

All data collected and processed concerning the subjects participating in the study are protected under the Regulation (EU) 2016/679 (GDPR) and Health Insurance Portability and Accountability Act (HIPAA) and will be handled accordingly. Further, professional secrecy regarding subject information and data applies to all involved personnel.

The data from the online survey will be recorded into an electronic data capture (EDC) system. In the EDC system all subjects enrolled in the study will be assigned a Subject Identification Number with a link to their personal identification (email address). The personal identification information will used for sending out emails with the surveys. The subject can at any time ask to get their personal identification information removed. The access to the EDC system is restricted and will be limited to a couple of users with administrational rights.

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12.1 *Data Management Plan*

Data management-related activities, e.g. data cleaning, will be performed by the data manager.
Once all data has been captured, reviewed and declared clean the database will be locked before any data analysis.

13 AMENDMENTS TO THE CIP

Substantial amendments should be approved by the IRB as applicable, before incorporated. In addition, substantial amendments to the Study Information and Consent Form and/or other applicable documents previously approved by the IRB must be approved by the IRB before they will come into effect. For non-substantial amendments, local regulations regarding notifications to IRB should be followed.

If study deemed exempt IRB approval amendments to this protocol and accompanying material will be made without notifying the IRB. Only if amendments to the protocol are made that might affect the exemption, IRB will be notified.

14 DEVIATIONS FROM THE PROTOCOL

A deviation is an intentional or unintentional failure to follow the requirements of the protocol. Every effort should be made to comply with the requirements of the protocol. If deviations occur a record should be made in a deviation log. The implications of the deviation must be reviewed and discussed as soon as possible after detection. All protocol deviations must be documented stating the reason, date, the action(s) taken, and the impact for the subjects and/or the study. At the end of the study, protocol deviations will be categorized as minor or major and their consequence on analysis populations will be determined.

15 DEVICE ACCOUNTABILITY

Not applicable. Participants will evaluate their own devices.

16 STATEMENTS OF COMPLIANCE

Applicable parts of ISO 14155, Regulation (EU) 2017/745 (MDR) as specified in this CIP will be adhered to. The CIP, the Subject Information, the Online Informed Consent Form and other required documents will be submitted to an Institutional Reivew Board (IRB). Documentation will be reviewed and approved, or deemed exempt, in writing, by IRB before enrollment of subjects into the study can be initiated. Any additional requirements imposed by IRB shall be followed.

17 INFORMED CONSENT

Prior to providing the subjects with the survey they will be provided with written information in an electronical form. The information will contain detailed information about the study including the purpose, procedures and how the subject's data will be handled in the study. The information will contain contact details to sponsor in case of any questions. Subject consent will be obtained electronically and documented. No study-specific data collection will occur prior to subject consent.

18 ADVERSE EVENTS, ADVERSE DEVICE EFFECTS AND DEVICE DEFICIENCIES

As the study has patient reported outcomes with focus on subjective performance and satisfaction, there will be no adverse events, adverse device effects, or device deficiencies collected.

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19 VULNERABLE POPULATION (IF APPLICABLE)

No vulnerable population to be included in the study.

20 SUSPENSION OR EARLY TERMINATION OF THE CLINICAL STUDY

The sponsor may at any time terminate the study. If the study is terminated prematurely the concerned IRB will be informed promptly in writing by the sponsor.

21 PUBLICATION POLICY

A description of this study will be available, throughout the whole duration and onwards, on www.ClinicalTrials.gov.

When the clinical Study is completed, even if prematurely terminated, a final report will be compiled, and the results will be made publicly available. The results obtained in the study might be submitted for publication in scientific journals by the sponsor. Privacy and confidentiality of information about each subject will be preserved in any reports and any publications of the clinical Study data.

22 SIGNED AGREEMENTS

22.1 Sponsor

On behalf of Oticon Medical AB I approve this clinical Study plan.

Date and signature:

Name and title

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2. Cox, R.M., *Assessment of subjective outcome of hearing aid fitting: getting the client's point of view.* International Journal of Audiology, 2003. **42**: p. 90-96.
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5. Houmoller, S.S., et al., *Prediction of successful hearing aid treatment in first-time and experienced hearing aid users: Using the International Outcome Inventory for Hearing Aids.* Int J Audiol, 2021: p. 1-11.

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23 APPENDICES

Appendix 1. Part number for devices included in the study

Style/side / Colour	Ponto		Ponto Pro		Ponto Pro Power	
	Left	Right	Left	Right	Left	Right
White Silver	130-00-113-00	130-00-123-00	130-00-213-00	130-00-223-00	M50903	M50902
Chroma Beige	130-00-110-00	130-00-120-00	130-00-210-00	130-00-220-00	M50875	M50874
Mocca Brown	130-00-111-00	130-00-121-00	130-00-211-00	130-00-221-00	M50873	M50872
Diamond Black	130-00-112-00	130-00-122-00	130-00-212-00	130-00-222-00	M50677	M50676

Style/side / Colour	Ponto Plus		Ponto Plus Power	
	Left	Right	Left	Right
White Silver	M51706	M51707	M51736	M51737
Chroma Beige	M51704	M51705	M51734	M51735
Mocca Brown	M51702	M51703	M51732	M51733
Diamond Black	M51700	M51701	M51730	M51730

Style/side / Colour	Ponto 3		Ponto 3 Power		Ponto 3 SuperPower	
	Left	Right	Left	Right	Left	Right
Pure White	M52630	M52631	M52644	M52645	M52658	M52659
White Silver	M52626	M52627	M52640	M52641	M52654	M52655
Chroma Beige	M52624	M52625	M52638	M52639	M52652	M52653
Mocca Brown	M52622	M52623	M52636	M52637	M52650	M52651
Steel Grey	M52628	M52629	M52642	M52643	M52656	M52657
Diamond Black	M52620	M52621	M52634	M52635	M52648	M52648

Style / Colour	Ponto 4	Ponto 5	Ponto 5 SuperPower
CBE Chroma Beige CO90	186777	223156	223162
TC Terracotta CO94	186778	223157	223163
SIL Silver CO44	186779	223155	223161
STG Steel Grey CO92	186780	223159	223165
CNB Chestnut Brown CO93	186781	223158	223164
DBL Diamond Black CO63	867821	223160	223166

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Appendix 2 The International Outcome Inventory of hearing aids

INTERNATIONAL OUTCOME INVENTORY – HEARING AIDS (IOI-HA)

1. Think about how much you used your present hearing aid(s) over the past two weeks. On an average day, how many hours did you use the hearing aid(s)?

none	less than 1 hours a day	1 to 4 hours a day	4 to 8 hours a day	more than 8 hours a day
❑	❑	❑	❑	❑

2. Think about the situation where you most wanted to hear better, before you got your present hearing aid(s). Over the past two weeks, how much has the hearing aid helped in that situation?

helped not at all	helped slightly	helped moderately	helped quite a lot	helped very much
❑	❑	❑	❑	❑

3. Think again about the situation where you most wanted to hear better. When you use your present hearing aid(s), how much difficulty do you STILL have in that situation?

very much difficulty	quite a lot of difficulty	moderate difficulty	slight difficulty	no difficulty
❑	❑	❑	❑	❑

4. Considering everything, do you think your present hearing aid(s) is worth the trouble?

not at all worth it	slightly worth it	moderately worth it	quite a lot worth it	very much worth it
❑	❑	❑	❑	❑

5. Over the past two weeks, with your present hearing aid(s), how much have your hearing difficulties affected the things you can do?

affected very much	affected quite a lot	affected moderately	affected slightly	affected not at all
❑	❑	❑	❑	❑

6. Over the past two weeks, with your present hearing aid(s), how much do you think other people were bothered by your hearing difficulties?

bothered very much	bothered quite a lot	bothered moderately	bothered slightly	bothered not at all
❑	❑	❑	❑	❑

7. Considering everything, how much has your present hearing aid(s) changed your enjoyment of life?

worse	no change	slightly better	quite a lot better	very much better
❑	❑	❑	❑	❑

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