CONFIDENTIAL

Clinical Investigation Title	Pediatric Performance and Satisfaction of Oticon Medical Ponto on Softband
Investigation Code	BC117
Investigational Device (s)	Ponto on Softband
Sponsor	Oticon Medical AB Datavägen 37 B 436 32 Askim Sweden
Date	11 May 2023

Revision history:

Revision no	*Date*	*Description*
0.0	11 May 2023	First version - NITC
1.0	26 June 2023	After EC review, EC has requested that the inclusion criteria of 18 years of age be changed to "age of majority (AOM)" as the AOM is not 18 in all states.

STATEMENT OF COMPLIANCE

This clinical investigation is a survey study and therefore, as applicable, 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.

1 SYNOPSIS

Clinical Investigation Title	Pediatric Performance and Satisfaction of Oticon Medical Ponto on Softband
Investigation Code	BC117
Investigational Device (s)	Oticon Medical Ponto sound processor on Ponto Softband solution
Principal investigator(s):	N/A – online survey, Oticon Medical, LLC
Sponsor:	Oticon Medical AB Datavägen 37 B 436 32 Askim Sweden
Objective(s):	Primary Objective • Evaluate subjectively hearing performance of Oticon Medical Ponto sound processors on Ponto Softband • Evaluate subjectively overall satisfaction of Oticon Medical Ponto sound processors on Ponto Softband
Methodology:	Observational survey study
Inclusion/exclusion criteria:	1. Consent provided 2. Parent or primary caregiver of child (< 18 years) currently using a Ponto Softband for Ponto Sound Processor
Endpoints	Primary Endpoints • Overall PEACH scores • Overall GCBI scores • Outcomes of satisfaction questionnaire
Duration of study period:	24 months or when targeted number of participants (40) have been enrolled.
Number of participants targeted:	40
Investigation plan prepared by:	Nicole Amichetti, PhD, Clinical Project Manager, Oticon Medical, LLC Aren Bezdjian, PhD, Clinical Research Manager, Oticon Medical, LLC

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3 LIST OF ABBREVIATIONS

AOM	*Age of Majority*
BAHS	*Bone Anchored Hearing System*
CIP	*Clinical Investigation Plan*
EC	*Ethics Committee*
EDC	*Electronic Data Capture*
GCBI	*Glasgow Children's Benefit Inventory*
GDPR	*General Data Protection Regulation*
ICF	*Informed Consent Form*
IRB	*Institutional Review Board*
ISO	*International Organization for Standardization*
OM	*Oticon Medical*
PEACH	*Parent's Evaluation of Aural/Oral Performance of Children*
SIN	*Subject Identification Number*

4 INTRODUCTION

4.1 Background

There are two pathways by which physical sound waves can be transformed into mechanical vibrations that stimulate the cochlea in the inner ear: air conduction and bone conduction. In air conduction, an acoustic signal travels through the outer and middle ear and arrives at the cochlea. In bone conduction, an acoustic signal bypasses the outer/middle ear and vibrates the bones of the skull to stimulate the cochlea. Both air and bone conduction support the same conversion mechanism in the cochlea where mechanical vibrations are converted into neural impulses to produce the perception of hearing.

Thus, for patients who are unable to reliably transmit acoustic signals through air conduction, e.g., those with conductive hearing losses (CHL) or mixed hearing losses (MHL), hearing loss following a middle ear disease (e.g., chronic otitis media, cholesteatoma, otosclerosis or other ossicular diseases), or malformations such as aural atresia and/or microtia, bone conduction hearing systems can be sued to bypass conductive impairment in the ear canal or middle ear, and stimulating the cochlea directly via skull bone vibrations. For single-sided deafness (SSD), one utilizes the vibrations that are transmitted in the same manner via the skull bone to the (functioning) cochlea on the contralateral side.

Bone Anchored Hearing Systems (BAHS) have been used since the late 1970s and can be divided into two types: 1) direct drive and 2) skin drive. Direct drive denotes systems where the vibrations are transmitted directly to the bone (e.g., through an abutment connected to an osseo-integrated implant), while in a skin drive solution there is a layer of soft tissue between the transducer and the bone (e.g., when utilizing a softband).

A softband solution, in this investigation, the Ponto Softband solution is suitable for children with conductive/mixed hearing loss and single-sided deafness. It can also be used by adults who don't benefit from conventional hearing aids, or those who have temporary ear problems such as blockages or infections. Worn around the head, with an attachment for Ponto Sound Processor, the softband comes in assorted colors, is adjustable for a snug and tailored fit.

5 IDENTIFICATION AND DESCRIPTION OF THE DEVICE

5.1 Device description

The Ponto Softband device is part of a skin-drive bone conduction, wherein a Ponto sound processor is attached to the band which allows for circumlocution of the function of the outer and middle ear. Acoustic sound pressure waves are picked up by the microphones in the externally mounted sound processor and this signal is converted to mechanical energy (vibrations) by the transducer in the sound processor. This signal is then transmitted through the skin to the temporal bone of the skull The mechanical energy vibrates the temporal bones of the skull which are picked up by the hair cells within the cochlea in the inner ear where the mechanical energy is converted to electrical neural impulses and transmitted to the primary auditory cortex in brain via the auditory nerve.

The survey will focus on Softband 5 but will also allow for feedback from parents whose children previously or currently use any of the Softband generation models:

- Softband/Softband bilateral (initial CE 2010)

- Ponto Softband (initial CE 2016)
- Ponto Softband bilateral (initial CE 2017)
- Softband 5 (initial CE 2022)

Parents whose children have been fitted with a Ponto sound processor on a Ponto Softband will be surveyed. The study will focus on devices from the following Ponto families:

- Ponto 3, Ponto 3 Power, Ponto 3 SuperPower
- Ponto 4
- Ponto 5 Mini, Ponto 5 SuperPower

5.2 Manufacturer

The Ponto sound processors as well as Oticon Medical Softbands 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.

5.3 Population and indications

The study population of interest is children below the age of 18 who are currently wearing a softband coupled to a Ponto sound processor. Parents or primary caregivers will be the surveyed population.

The softband solution is intended for children with conductive/mixed hearing loss and single-sided deafness who cannot be fitted or are waiting to be fitted with a surgically placed bone anchored hearing implant. It can often be recommended for individuals who do not benefit from conventional hearing aids who have ear problems such as blockages or infections, who present with a high likelihood of implant extrusions or skin care related burdens or who have thin or irregular skull bone (i.e. syndromic children).

6 JUSTIFICATION FOR THE INVESTIGATION

The study is a non-interventional, observational, study on users of Ponto sound processors who use their sound processors on a softband solution. The purpose of this study is to assess subjective benefit by evaluating performance and overall satisfaction of the Ponto on a Ponto Softband in pediatric users.

This study will utilize responses from survey questions of parents or primary caregivers of children fitted with a softband solution. The survey will collect responses relating to reported hearing improvements and quality of life.

The study will use the PEACH questionnaire[1] to evaluate performance. The PEACH is a measure used by hearing health professionals to evaluate the effectiveness of a child's use of hearing in real-world environments. PEACH is validated with norms scale (English). This study will also use the GCBI questionnaire[2], modified to specifically query a child's quality of life after receiving their Ponto sound processor on softband. Additionally, a specialized questionnaire is constructed to gather feedback on wear and general comfort of Oticon Medical Softband.

7 RISKS AND BENEFITS OF THE INVESTIGATIONAL DEVICE AND CLINICAL INVESTIGATION

Participants will be asked to complete a survey. No additional treatments or procedures will be utilized for this study. Therefore, only risks associated to data capture and data privacy have been identified and these

are mitigated by strict data management procedures (see Section 12).

Although participants included in this study might not receive any benefit from the study itself, the research project will promote a better understanding of satisfaction of the Ponto Softband solution which will be shared within the field of BAHS and may lead to improvements in future iterations of the oftband design.

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 the study is to evaluate subjectively reported hearing performance and overall satisfaction of Oticon Medical Ponto sound processors on softband.

8.1 Primary objective

Primary objective	Corresponding primary endpoint/outcome variable(s)	Section
A. ***To investigate hearing performance of children wearing Oticon Medical Ponto sound processors on Softband***	*PEACH questionnaire evaluating Aural/Oral performance of children in quiet, noise and overall.*	*9.2.1*
B. To investigate overall satisfaction of Oticon Medical Ponto sound processors on Softband	*GCBI questionnaire evaluating health related benefit after hearing intervention for children.* *By answering specialized questionnaire to gather feedback on wear and general comfort of the Oticon Medical Softband.*	

9 DESIGN OF THE CLINICAL INVESTIGATION

9.1 Subject population

The population for this study will be children who use a Ponto Sound Processors on a Ponto Softband in the United States. Parents or caregivers of users (hereforth referred for as “participants” who are part of Oticon Medical’s US user database, who signed up for inclusion in the database when fitted with a Ponto Sound Processor will be approached through email out-reach. When signing up for the database participants give their consent to be contacted by Oticon Medical. In all cases, study awareness and enrollment in this study will occur only after being fitted with Ponto sound processor(s) on a softband solution.

9.1.1 Inclusion criteria

The following participants will be included in the study:

- Individuals who are a parent or guardian of a softband user who are at or above the age of majority (AOM). AOM is 21 in Mississippi, 19 in Nebraska and Alabama, and 18 in all other US states.
- Participants provided study-specific consent before completing the survey.
- Users fitted with at least one Ponto Sound Processor on a softband at the time of the survey.

9.1.2 Exclusion criteria

The following participants will be excluded from the study:

- Participants who did not provide consent or later revoked consent.
- Under the the AOM

9.1.3 Number of Subjects

The aim is to enroll 40 participants within 24 months.

9.2 Investigation Procedures

Out-reach will be made through email to registered participants, parents or primary caregivers of children, fitted with a Ponto device on a softband in the US Salesforce database. The participants in the US Salesforce database had previously consented to being contacted by Oticon Medical in the future. The email will be sent through the Salesforce database and contain general information about the study as well as a link to the study landing page, created and hosted in SMART-TRIAL. On the landing page more information about the survey is provided and participants are asked to proceed with sign-up by providing their email address. At this point the participant is assigned a unique identification number. Following providing consent, the participant will be provided with access to the survey in SMART-TRIAL. Periodic reminders, one after one week, another after four weeks, and after five weeks will be sent from SMART-TRIAL if consent has been provided by survey not completed.

Out-reach efforts will also be made through Oticon Medical's social media accounts (such as linked-in, facebook, etc). Additionally, clinics and providers in the US who have active pediatric populations fitted with Ponto sound processors on softband who have expressed interest in assisting recruitment efforts may also be included in reach out efforts. Interested clinics will be provided with a one-page informational flyer to provide to parents of children who meet the inclusion criteria. The flyer will have the same information as the social media postings as well as emails sent to the users in the Salesforce database.

9.2.1 Surveys

<u>PEACH</u>

The Parent's Evaluation of Aural/Oral Performance of Children (PEACH) was developed to evaluate the effectiveness of amplification for infants and children with hearing impairment by a systematic use of parents' observations. The PEACH questionnaire is composed of 13 questions that examines a child's auditory performance in quiet and noisy listening conditions and has been shown to have good internal consistency and high test-retest reliability. The PEACH can be used with infants as young as one month old and with school-aged children who have hearing loss ranging from mild to profound degree.

<u>GCBI</u>

The Glasgow Children's Benefit Inventory (GCBI) was designed to retrospectively assess quality of life benefits

after a healthcare intervention. The GCBI is a parent-completed questionnaire comprised of 24 questions that query various aspects of a child's daily life and is worded to apply to children of any age. The GCBI is commonly modified to be used in any area of paediatric medicine. For this study, "operation" will be adapted to "Ponto sound processor on Softband", (Appendix B).

Softband specific questionnaire

The softband-specific questionnaire was developed by Oticon Medical and consists of questions designed to be completed by parents or other caregivers of children who are currently fitted with a Ponto sound processor on a softband.

10 MONITORING

Not applicable.

11 STATISTICAL DESIGN AND ANALYSIS

The results of the questionnaires will be analyzed and presented using descriptive statistics including the mean, standard deviation, median, and range.

The sample size in the investigation is not hypothesis-driven, but rather based on the number of users in the database which fit the inclusion criteria as well as estimations derived from previous survey study response rates from social media and other Oticon Medical reach out efforts.

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

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 a secure, password protected electronic data capture (EDC) system. Only relevant study personnel will be given a password to access the EDC. A two-factor authentication system will also be in place when logging into the EDC and an automatic logout in place if the user in the EDC has been idle for more than ten minutes.

In the EDC system all subjects enrolled in the study will be assigned a three-digit Subject Identification Number (SIN) with a link to their personal identification (email address), which will not be stored in the EDC, but on a secure, password protected Oticon Medical Server.

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.

13 AMENDMENTS TO THE CIP

Substantial amendments will be approved by the IRB/EC, before incorporated. For non-substantial

amendments, local regulations regarding notifications to IRB/EC will be followed, if applicable.

If the study is to be deemed exempt via IRB/EC approval, non-substantial amendments to this protocol and accompanying material will be made without notifying the IRB/EC. Only on the occurrence wherein amendments to the protocol are made that might affect the exemption, the IRB/EC will be notified.

14 DEVIATIONS FROM CLINICAL INVESTIGATION PLAN

All protocol deviations will be documented stating the reason, date, the action(s) taken, and the impact for the participants/users and/or the study. At the end of the study, protocol deviations will be categorized as minor or major and their consequence on analysis and study conclusions will be determined.

15 DEVICE ACCOUNTABILITY

Not applicable.

16 STATEMENTS OF COMPLIANCE

The CIP, the Subject Information, the Online Informed Consent Form (ICF) and other required documents will be submitted to an IRB/EC Documentation will be reviewed and approved, or deemed exempt, in writing, by IRB/EC before enrolment of subjects into the study can be initiated. Any additional requirements imposed by IRB/EC shall be followed.

17 INFORMED CONSENT PROCESS

Participants will be given full and adequate written information about the nature and purpose of the investigation, including data handling privacy procedures and possible risks involved. Potential participants will also be notified that they are free to decline participation in the investigation, and that they are free to discontinue at any time, without any consequences to their future care. Sufficient time will be given for consideration to participate and the opportunity to ask questions will be provided. Contact details for research personnel who are available to answer any questions will be provided to potential participants. Subject consent will be obtained electronically, documented, and stored in the secure EDC system.

If any new information becomes available during the investigation that possibly could influence the participant's willingness to participate, they will be informed and asked to provide electronic consent for a revised informed consent document, if applicable.

18 ADVERSE EVENTS, ADVERSE DEVICE EFFECTS, AND DEVICE DEFICIENCIES

Adverse events, adverse device effects, and device deficiencies will be covered by normal post-market complaints handling, including unexpected findings from primary and secondary objectives, i.e., participant reported outcomes on the subjective performance and satisfaction of their softband device.

19 SUSPENSION OR EARLY TERMINATION OF THE INVESTIGATION

The sponsor may prematurely terminate the study at any time. If the investigation is suspended or terminated prematurely, any applicable regulatory authorities and ECs/IRBs concerned will be informed promptly in writing.

20 PUBLICATION POLICY

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

When the 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.

21 SIGNED AGREEMENTS

On behalf of Oticon Medical I approve this clinical investigation plan.

Date and signature:

Name and title

22 REFERENCES

1. Ching, T. Y., & Hill, M. (2007). The parents' evaluation of aural/oral performance of children (PEACH) scale: Normative data. *Journal of the American Academy of Audiology*, *18*(03), 220-235.
2. Kubba, H., Swan, I. R., & Gatehouse, S. (2004). The Glasgow Children's Benefit Inventory: a new instrument for assessing health-related benefit after an intervention. *Annals of Otology, Rhinology & Laryngology*, *113*(12), 980-986.

23 APPENDICES

A. PEACH

	Question	Never 0%	Seldom 1 - 25%	Sometimes 26 - 50%	Often 51 - 75%	Always 75-100%
1.	How often has your child worn his/her hearing aids and/or cochlear implant?	0	1	2	3	4
2.	How often has your child complained or been upset by **loud** sounds?	4	3	2	1	0
3.	When you call, does your child respond to his/her name in a **quiet** situation?	0	1	2	3	4
4.	When asked, does your child follow simple instructions or do a simple task in a **quiet** situation?	0	1	2	3	4
5.	When you call does your child respond to his/her name in a **noisy** situation when he/she can't see your face? (examples of responses include looks up, turns, answers verbally)	0	1	2	3	4
6.	When asked, does your child follow simple instructions or do a simple task in a **noisy** situation?	0	1	2	3	4
7.	When you are in a **quiet** place reading with your child, how often does he/she pay close attention to what you are saying? OR if your child is listening to stories/songs on the TV or CD when there is no other background noise how often can he/she follow what is being said?	0	1	2	3	4
8.	How often does your child initiate/ participate in conversation in a **quiet** situation?	0	1	2	3	4
9.	How often does your child initiate/ participate in conversation in a **noisy** situation?	0	1	2	3	4
10.	How often does your child understand what you say in the car/bus/train?	0	1	2	3	4

11.	How often does your child recognize peoples' voices without seeing who was talking?	0	1	2	3	4
12.	How often does your child successfully use a phone?	0	1	2	3	4
13.	How often does your child respond to sounds other than voices?	0	1	2	3	4

B. GCBI questionnaire

1. Has your child's Ponto sound processor on softband made his/her overall life better or worse?
a) much better b) a little better c) no change d) a little worse e) much worse
2. Has your child's Ponto sound processor on softband affected the things he/she does?
a) much better b) a little better c) no change d) a little worse e) much worse
3. Has your child's Ponto sound processor on softband made his/her behaviour better or worse?
a) much better b) a little better c) no change d) a little worse e) much worse
4. Has your child's Ponto sound processor on softband affected his/her progress or development?
a) much better b) a little better c) no change d) a little worse e) much worse
5. Has your child's Ponto sound processor on softband affected how lively he/she is during the day?
a) much better b) a little better c) no change d) a little worse e) much worse
6. Has your child's Ponto sound processor on softband affected how well he/she sleeps at night?
a) much better b) a little better c) no change d) a little worse e) much worse
7. Has your child's Ponto sound processor on softband affected his/her enjoyment of food?
a) much better b) a little better c) no change d) a little worse e) much worse
8. Has your child's Ponto sound processor on softband affected how self-conscious

he/she is with other people?				
a) much better	b) a little better	c) no change	d) a little worse	e) much worse
9. Has your child's Ponto sound processor on softband affected how well he/she gets on with the rest of the family?				
a) much better	b) a little better	c) no change	d) a little worse	e) much worse
10. Has your child's Ponto sound processor on softband affected his/her ability to spend time and have fun with friends?				
a) much better	b) a little better	c) no change	d) a little worse	e) much worse
11. Has your child's Ponto sound processor on softband affected how embarrassed he/she is with other people?				
a) much better	b) a little better	c) no change	d) a little worse	e) much worse
12. Has your child's Ponto sound processor on softband affected how easily distracted he/she has been?				
a) much better	b) a little better	c) no change	d) a little worse	e) much worse
13. Has your child's Ponto sound processor on softband affected his/her learning?				
a) much better	b) a little better	c) no change	d) a little worse	e) much worse
14. Has your child's Ponto sound processor on softband affected the amount of time he/she has had to be off nursery, playgroup or school?				
a) much better	b) a little better	c) no change	d) a little worse	e) much worse
15. Has your child's Ponto sound processor on softband affected his/her ability to concentrate on a task?				
a) much better	b) a little better	c) no change	d) a little worse	e) much worse
16. Has your child's Ponto sound processor on softband affected how frustrated and irritable he/she is?				
a) much better	b) a little better	c) no change	d) a little worse	e) much worse
17. Has your child's Ponto sound processor on softband affected how he/she feels about him/herself?				
a) much better	b) a little better	c) no change	d) a little worse	e) much worse
18. Has your child's Ponto sound processor on softband affected how happy and content he/she is?				

a) much better	b) a little better	c) no change	d) a little worse	e) much worse
19. Has your child's Ponto sound processor on softband affected his/her confidence?				
a) much better	b) a little better	c) no change	d) a little worse	e) much worse
20. Has your child's Ponto sound processor on softband affected his/her ability to care for him/herself as well as you think he/she should, such as washing, dressing, and using the toilet?				
a) much better	b) a little better	c) no change	d) a little worse	e) much worse
21. Has your child's Ponto sound processor on softband affected his/her ability to enjoy leisure activities such as swimming and sports and general play?				
a) much better	b) a little better	c) no change	d) a little worse	e) much worse
22. Has your child's Ponto sound processor on softband affected how often he/she needs to visit a doctor?				
a) much better	b) a little better	c) no change	d) a little worse	e) much worse
23. Has your child's Ponto sound processor on softband affected how prone he/she is to catch colds or infections?				
a) much better	b) a little better	c) no change	d) a little worse	e) much worse
24. Has your child's Ponto sound processor on softband affected how much medication he/she has needed to take?				
a) much better	b) a little better	c) no change	d) a little worse	e) much worse

C. Softband specific questionnaire

1. Is your child currently using a Ponto sound processor on a softband?
Yes
No

2. What is your child's date of birth? (Please use MM/DD/YYYY format)
_____/_____/_____

3. What is your child's gender?
Male
Female
Other

Do not wish to disclose

4. Approximately how long has your child experienced hearing problems?
Less than a year
1 to 3 years
3 to 6 years
6 to 9 years
more than 9 years
I'm not certain
Since birth

5. How long has your child been using a Ponto sound processor on softband?
Less than a year
1 to 3 years
3 to 6 years
6 to 9 years
more than 9 years
I'm not certain
Since birth

6. Is your child using one or two Ponto sound processor(s)?
1 – One sound processor
2 - Two sound processors (one on the left, one on the right)

7. Is your child currently using a Softband 5 or other softband?
Softband 5
Other softband
I'm not sure

8. Is this your child's first softband?
Yes, this is the first
No, they used a different generation softband in the past
I'm not sure

9. Which Ponto sound processor does your child currently use?
Ponto 3
Ponto 3 Power
Ponto 3 SuperPower
Ponto 4
Ponto 5 Mini
Ponto 5 SuperPower
I don't know / other model

10. Think about how much your child used their sound processor(s) over the past two weeks. On an average day, how many hours did they use the sound processor(s)?

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

11. Think about a situation where your child wanted to hear better, before receiving their sound processor. Over the past two weeks, how much has the sound processor(s) helped in that situation?

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

12. How satisfied overall are you with your child's Ponto experience?

very much
quite a lot
moderately
slightly
not at all

13. How satisfied overall are you with your child's softband?

very much
quite a lot
moderately
slightly
not at all