

The Next Generation of Osia: Introducing the Osia[®] 3 Sound Processor

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The Next Generation of Osia: Introducing the Osia[®] 3 Sound Processor

Learning outcomes

1. After this course, participants will be able to describe the features of the Osia 3 System and counsel patients about its use.
2. After completing this course, participants will be able to describe the key findings of the SONUS study and explain the demonstrated clinical and patient-reported benefits associated with the Osia 3 Sound Processor compared with the Osia 2 Sound Processor.
3. After this course, participants will be able to identify the requirements for an Osia 2 to Osia 3 Sound Processor replacement order and apply the appropriate process for eligible patients.





Limitations/Risks

The applicability and accuracy of the course content may vary by the clinical, geographical, and cultural context; you should evaluate the course accordingly.

As healthcare is rapidly evolving, new findings may change the validity of the information presented in this course. Providers should always consult the latest research and guidelines from professional associations.

The interventions discussed in this course may be limited in generalizability, requiring practitioners to consider specific individual and population factors.

The course may not cover all possible risk factors, diagnostic methods, or treatment options, and complex cases may require additional considerations.

It is the responsibility of course participants to critically evaluate the evidence from multiple sources to guide professional practice.

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The Cochlear® Osia System

Channing Hughes
Acoustics Product Manager

The most powerful active implant system

Cochlear Osia OSI300 Implant

Monolithic design minimizes feedback¹⁻²

Piezo Power™ transducer

Power in the high frequencies¹

BI300 implant

Effective sound transmission

Cochlear Osia 3(I) Sound Processor

Advanced signal processing

Digital Link

Delivers a 100% consistent and strong signal

Most powerful
and only active
BC system with
a **65 dB HL**
fitting range³⁻⁵

1. Cochlear Limited. D1991788 V1 2023-06. Osia System R5 Datasheet.

2. Cochlear Limited. D2043008 V2 2023-03. Design Verification Report Osia System R5

3. Osia System R5 Datasheet. Cochlear Limited, Australia. 2023; D1991788

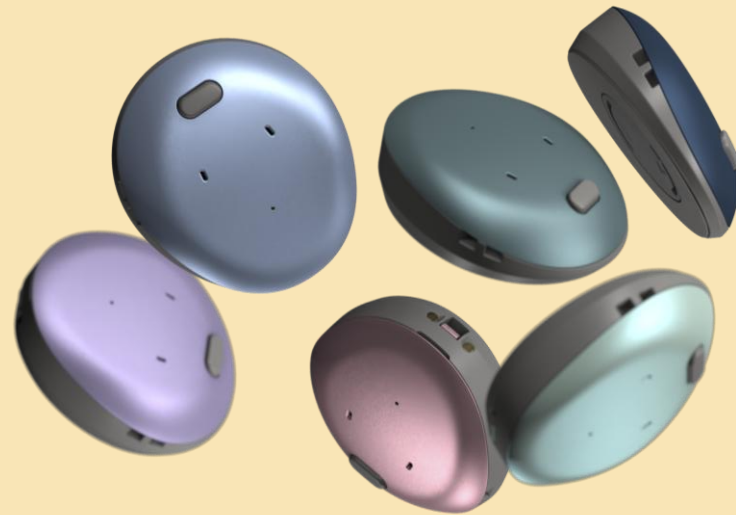
4. BCI602 BONEBRIDGE System Factsheet. Med-El. 29214 r4.0

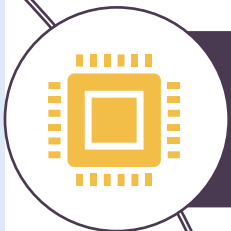
5. Sentio 1 Mini Product Information. Oticon Medical. 275144en – Version A / 2024.04

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Cochlear Osia 3 Sound Processor





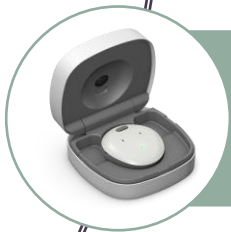
Zaphium™ Chip for improved sound quality



Powered for more performance to a fitting range of up to 65 dB HL*



ForwardFocus for the Osia System



First fully rechargeable active bone conduction sound processor^{1-2†}



Broadest range of streaming options

1. Cochlear Limited. D2304775-V1¹1. Cochlear Limited. D2304775-V1_EN Osia 3 SP and OSI200 PROF Datasheet2. Cochlear Limited. D2304776-V1_EN Osia 3(I) SP and OSI300 PROF Datasheet²_EN Osia 3 SP and OSI200 PROF Datasheet
2. Cochlear Limited. D2304776-V1_EN Osia 3(I) SP and OSI300 PROF Datasheet
*Refer to the relevant Osia System datasheet for additional fitting range information.
†Battery life varies for every user, according to the age of the battery, the programs used each day, your implant type, the thickness of skin covering your implant, and the size and type of battery used. Streaming may decrease sound processor battery life depending on how often

What is new with the Osia 3 Sound Processor?

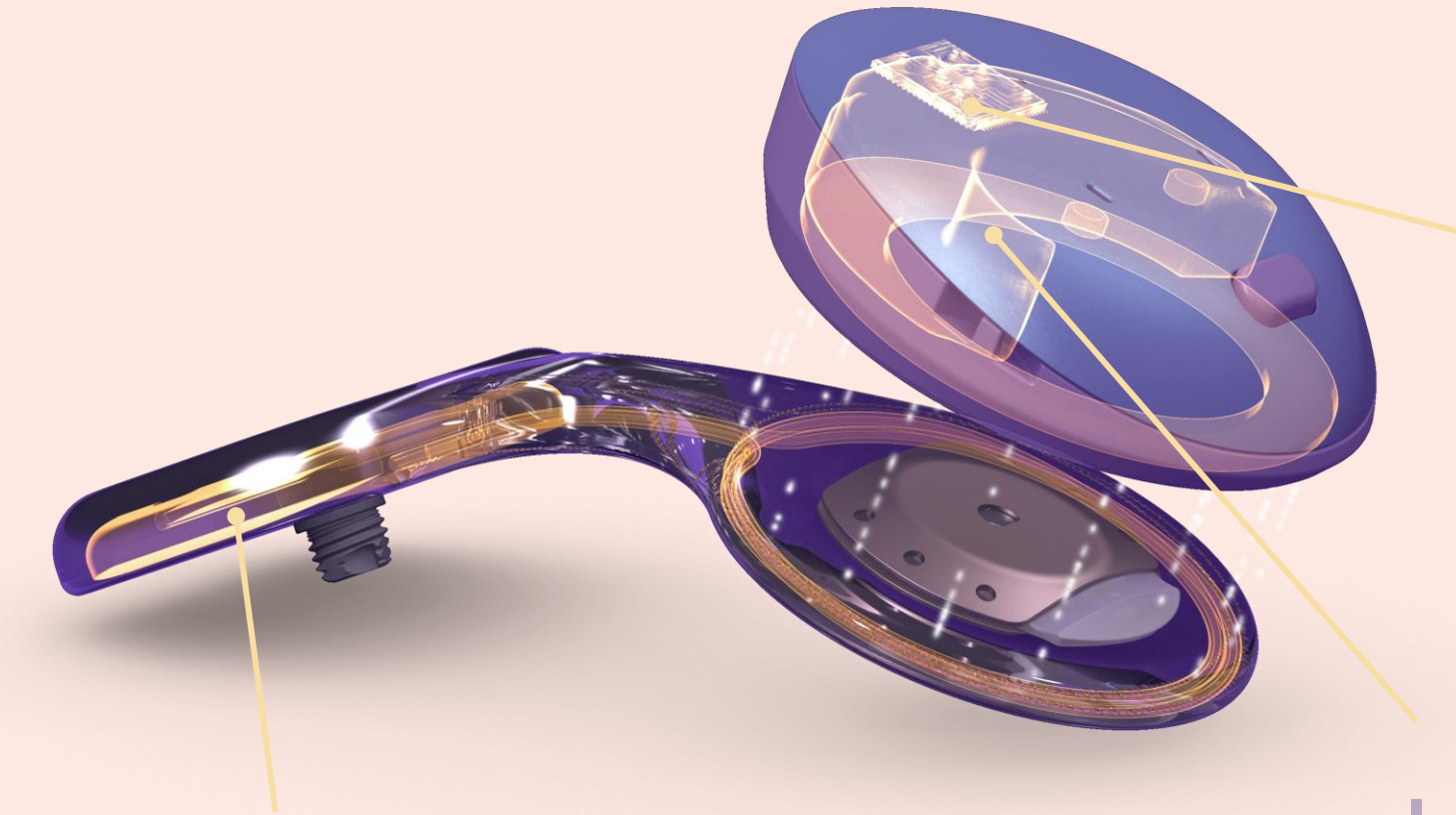


NEW: Enhanced by the Zaphium platform

Offers improved signal processing & industry-leading connectivity

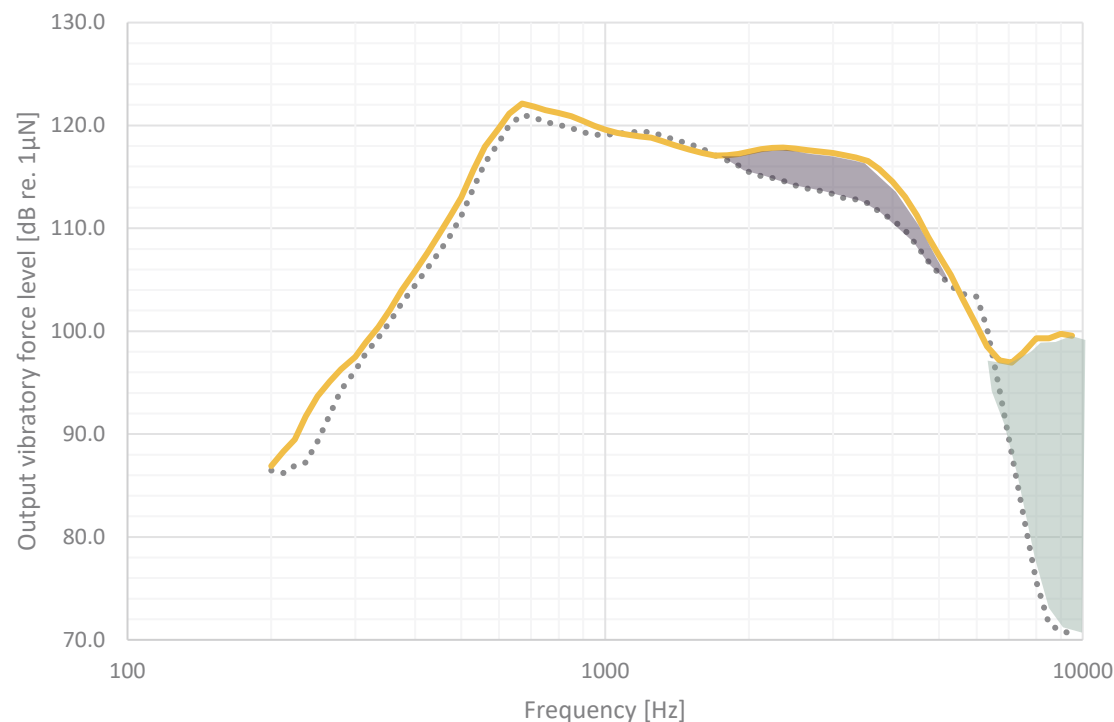
NEW: Powered by the lithium-ion battery

*Designed to help deliver **up to 65 dB HL*** and up to **30 hours of hearing** †*



Still driven by Piezo Power technology

Even more power in the mid to high frequencies



— Osia System with **Osia 3 Sound Processor**¹
..... Osia System with **Osia 2 Sound Processor**¹

Measured on: Head simulator

+4 dB¹
more
MPO

+2.5 kHz¹
new wider
bandwidth

The Zaphium platform and lithium-ion battery bring advanced signal processing and has increased power, to support higher MPO.

Hear now. And always

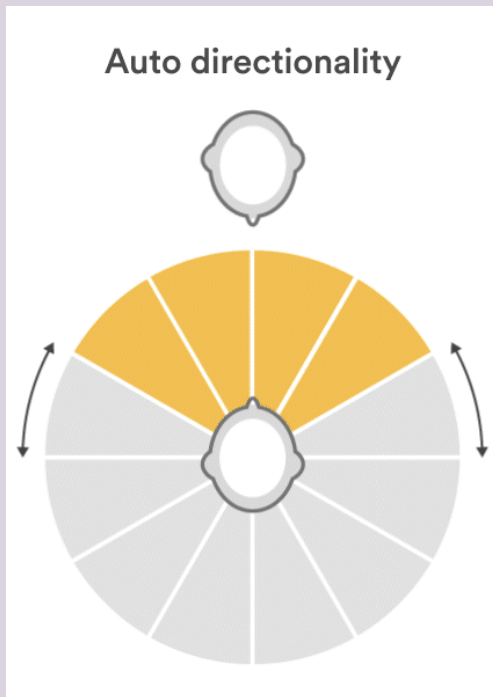


Introducing ForwardFocus for the Osia System

Differences between Auto Directionality and ForwardFocus

Auto Directionality in Everyday Program

- Noise reduction fluctuates between -3/-6/-9 dB, depending on AuD settings



ForwardFocus

- Use in very challenging environments
- Auto directional with beam width fixed
- Noise reduction is always set at -11dB



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Charging ahead with
confidence

First fully rechargeable active bone conduction sound processor



ON-THE-GO CHARGING CASE
with up to two full charge cycles



19 to 30 HOURS OF HEARING
on a single charge*



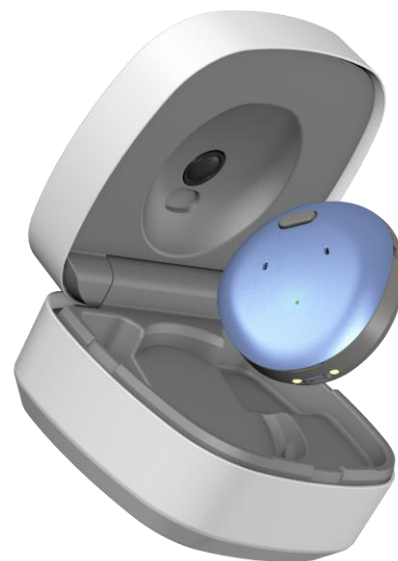
2 HOURS OF HEARING
after 15 minutes of charging

Powerful
performance that
fits patient
expectations





Charging BEFORE patient fitting



The Osia 3 Sound Processor and Osia 3 Charger must be charged prior to fitting. Charge both for a minimum of 3 hours before first use.

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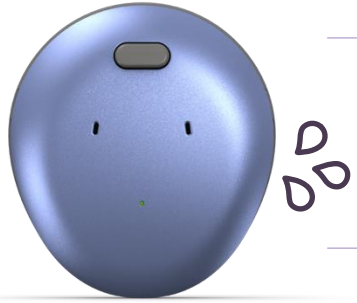
Adventure-ready design



IP68*
DOP

*The Cochlear Osia 3/3(i) Sound Processor is dust and water resistant to level of the International Standard IEC60529. Sound Processor is "water resistant" in fresh water down to 1metre for 60mins to level . The sound processor with Aqua+ is water resistant to level (tested to a depth of up to 3 metres for up to 2 hours). Refer to the relevant user guide for more information

Adventure-ready design



Best-in-class dust and water protection¹⁻³

**IP68
RATING**



AQUA+ ACCESSORY

Added protection for water activities



RETENTION ACCESSORIES

Added peace of mind for sports



*The Osia 3 Sound Processor meet the IP68 rating of the International Standard IEC60529 of freshwater waterproof. These processor configurations were tested by continuous submersion in freshwater for 60 minutes at a depth of 1 meter and functioned as intended. Cochlear offers the Aqua+ accessory for additional protection during extended water use, in salty or rushing water environments. For additional information, please refer to the appropriate user guide.^{1,2}

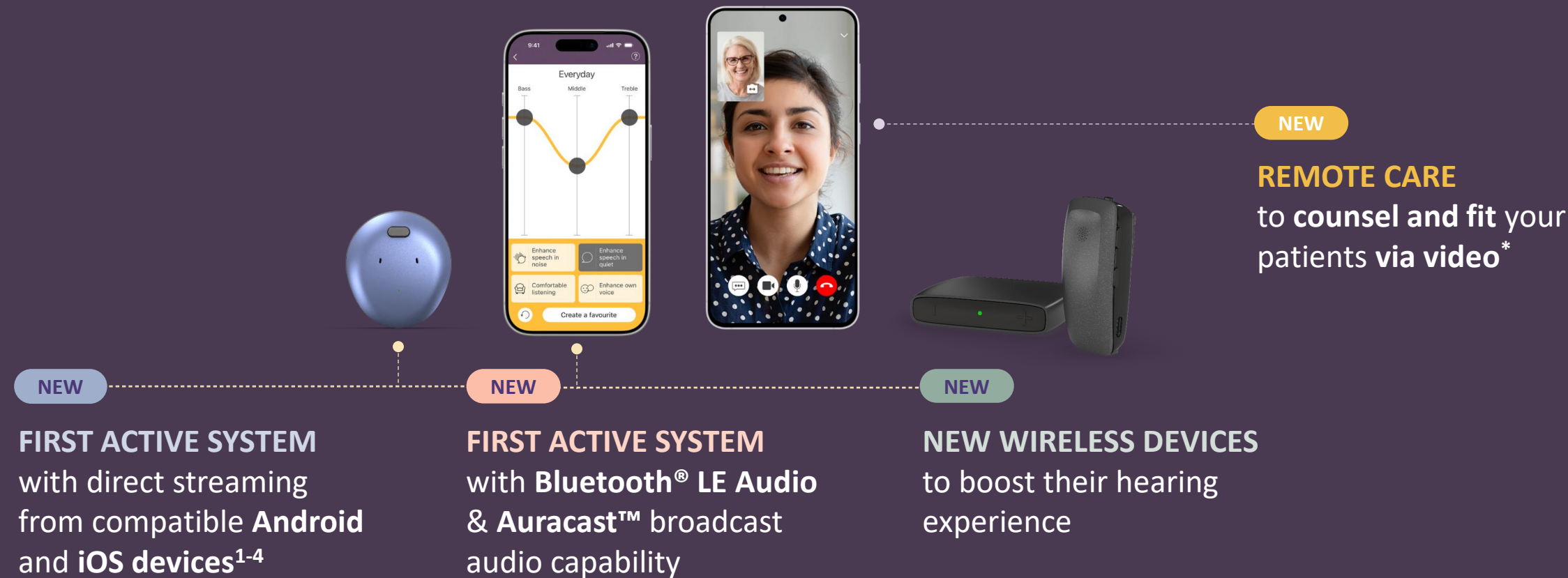
1. EN Osia 3 and 3(i) Sound Processor User Manual ROW. 2025; D2068700
2. EN Osia 3 SP and OSI200 PROF Datasheet. 2026; D2304775
3. EN Osia 3(i) SP and OSI300 PROF Datasheet. 2026; D2304776

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Connectivity and wireless technologies

Broadest range of streaming options



1. Cochlear Limited. D2304775-V1 Osia 3 SP and OSI200 PROF Datasheet. 2026. 2. Cochlear Limited. D2304776-V1 Osia 3(I) SP and OSI300 PROF Datasheet. 2026. 3. SAMBA 2 Factsheet 29305 r6.0. MED-EL Medical Electronics. <https://medel.pro/hearing-solutions/bc/bonebridge/samba24>. Sentio 1 Mini Product Information. 275144en - Version A / 2024.04. Oticon Medical. <https://sentio.oticonmedical.com>

^As Bluetooth LE Audio compatible devices become available, a sound processor firmware update will be required to use certain features. Auracast™ broadcast audio capability is subject to third party adoption of the Auracast protocol. The Bluetooth® and Auracast™ word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Cochlear is under license."

*Remote Assist for Osia for compatible Osia sound processors is intended for a follow-up adjustment or setup of a replacement or upgrade sound processor for suitable qualified patients based on clinical judgment. Only available at clinics that have enrolled in Remote Care.

Bluetooth LE Audio Accessories

TV-STREAMER+



MULTI-MIC+

- **Boosts hearing** in challenging environments
- **OneTouch Pairing**
- **AutoStreaming**
- **Supports Auracast™ broadcast audio**



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Osia System multi-center study insights

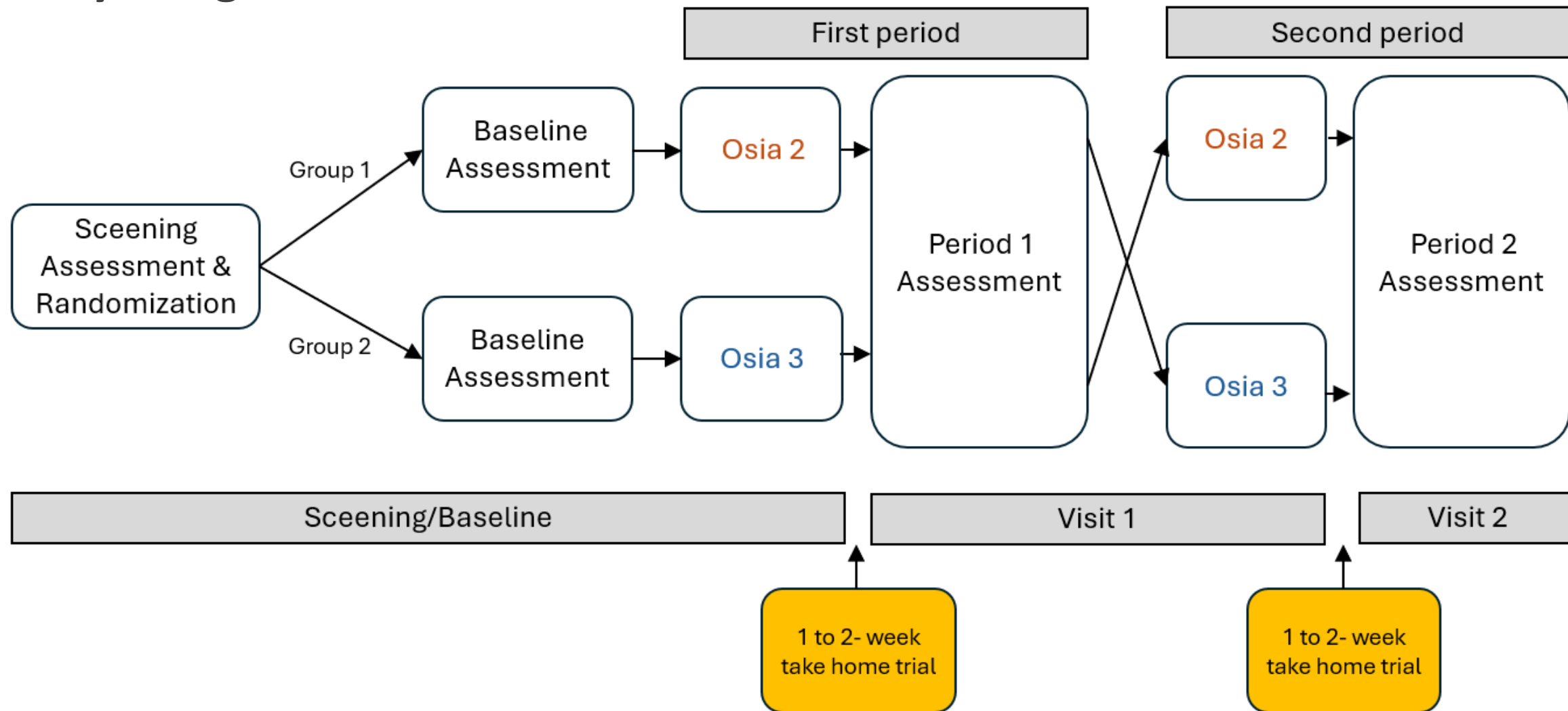
Bailey Harmon, Au.D., CCC-A
Clinical Research Audiologist

Study overview*

A pivotal, interventional, open-label, prospective, multi-center clinical investigation of hearing outcomes with the **Osia 3/3(I) Sound Processor** compared to the **Osia 2/2(I) Sound Processor** in **adult** Osia implant recipients (n = 29) with mixed hearing loss, conductive hearing loss, or single-sided deafness

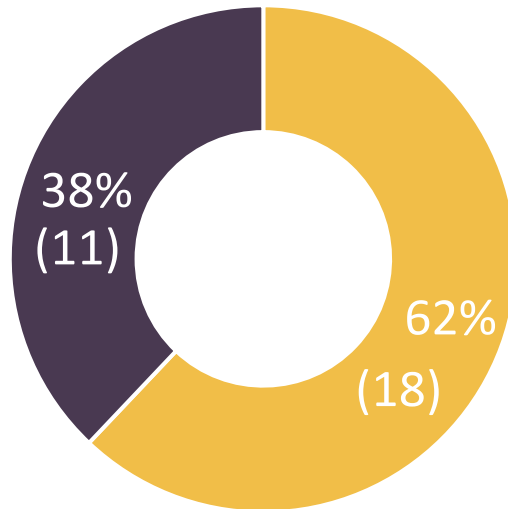
Inclusion Criteria	Sites	Investigators
✓ 18 years or older ✓ At least 1-month w/ Osia 2/2(I) ✓ Conductive or MHL (BC Thresholds up to 65 dB HL) <u>or</u> SSD (AC PTA $\leq$ 20 dB HL in contralateral ear)	USA, Denver Research and Technology Lab	Bailey Harmon
	AUS, Cochlear Macquarie	Esti Nel
	AUS, HEARnet	Karyn Galvin

Study design



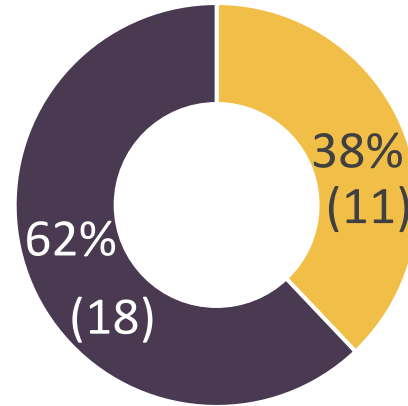
Participant demographics

Country



■ Australia ■ USA

Implant Ear

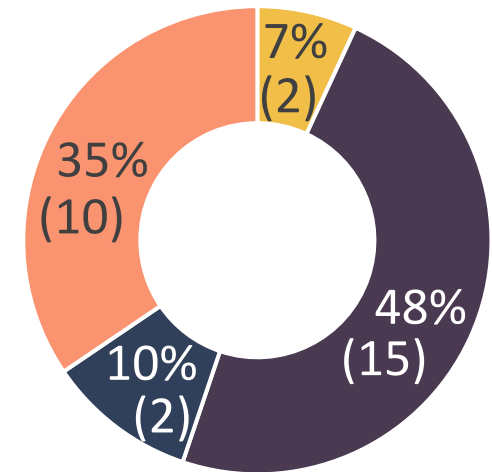


■ right ■ left



29 participants
Mean Age: 61.5 years (34-79 years)

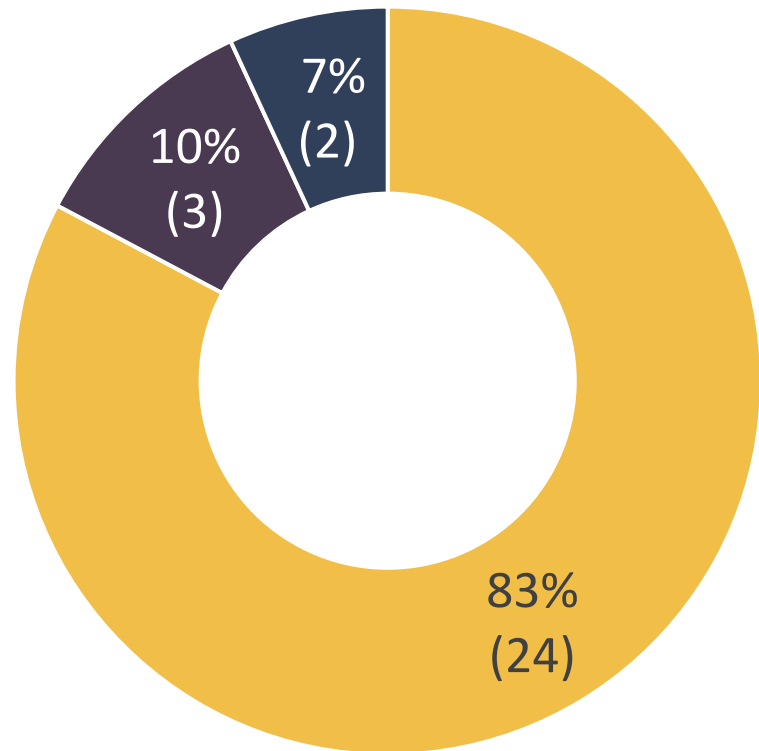
Implant Generation



■ OSI100 ■ OSI200 HwV1 ■ OSI200 HwV2 ■ OSI300

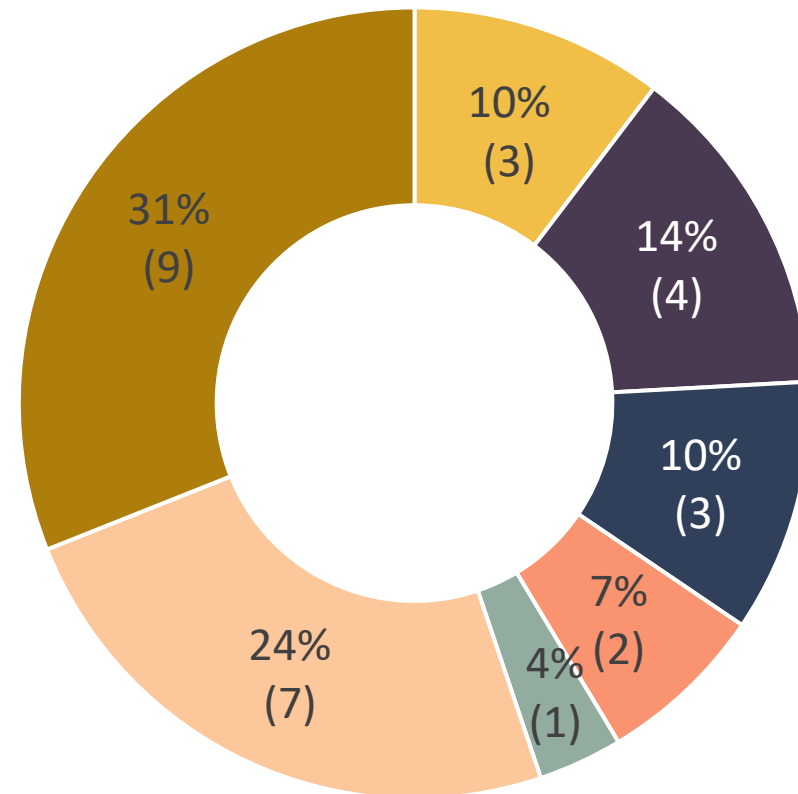
Participant hearing history

Type of hearing loss



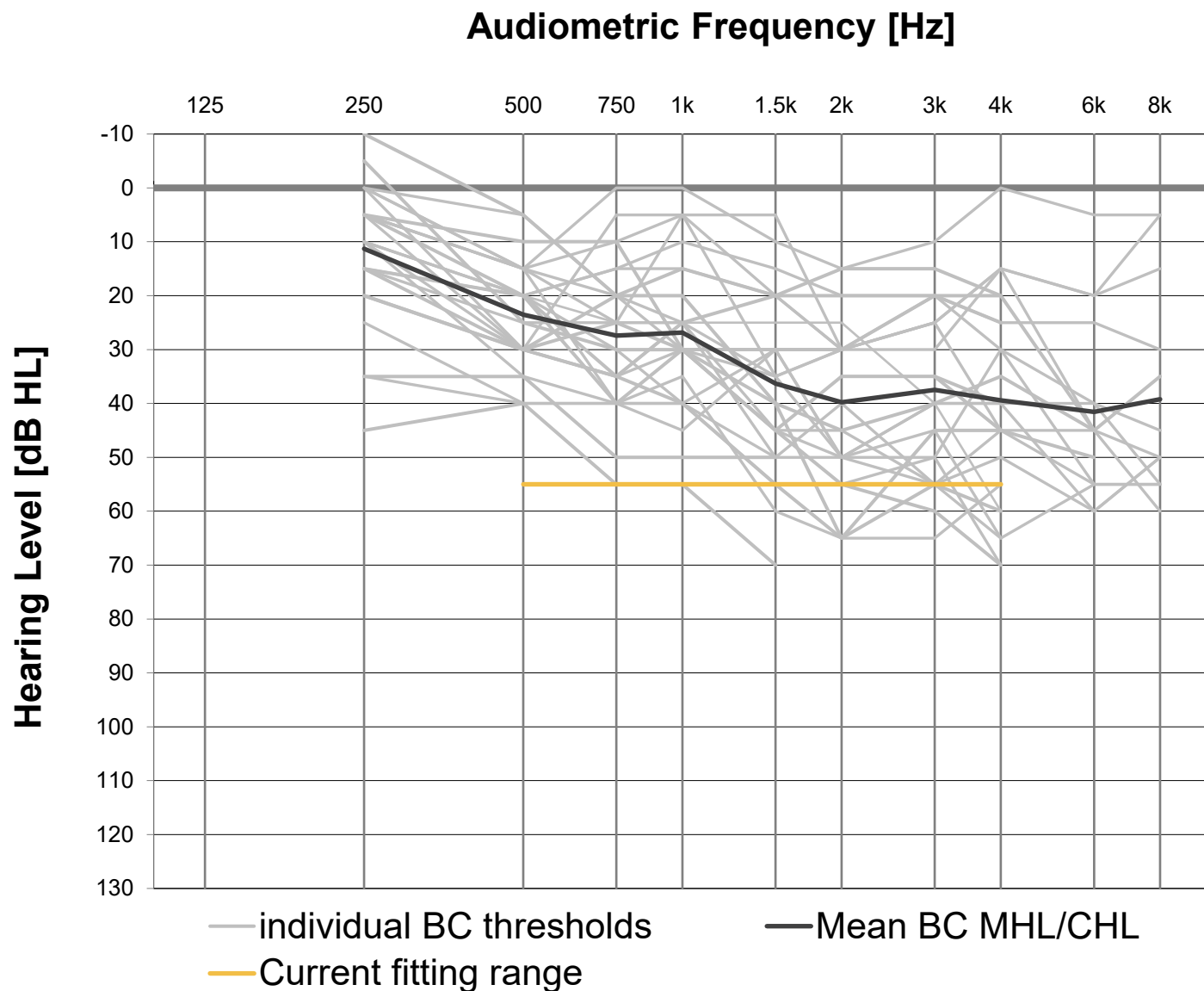
■ Mixed ■ Conductive ■ Sensorineural

Primary cause of hearing loss



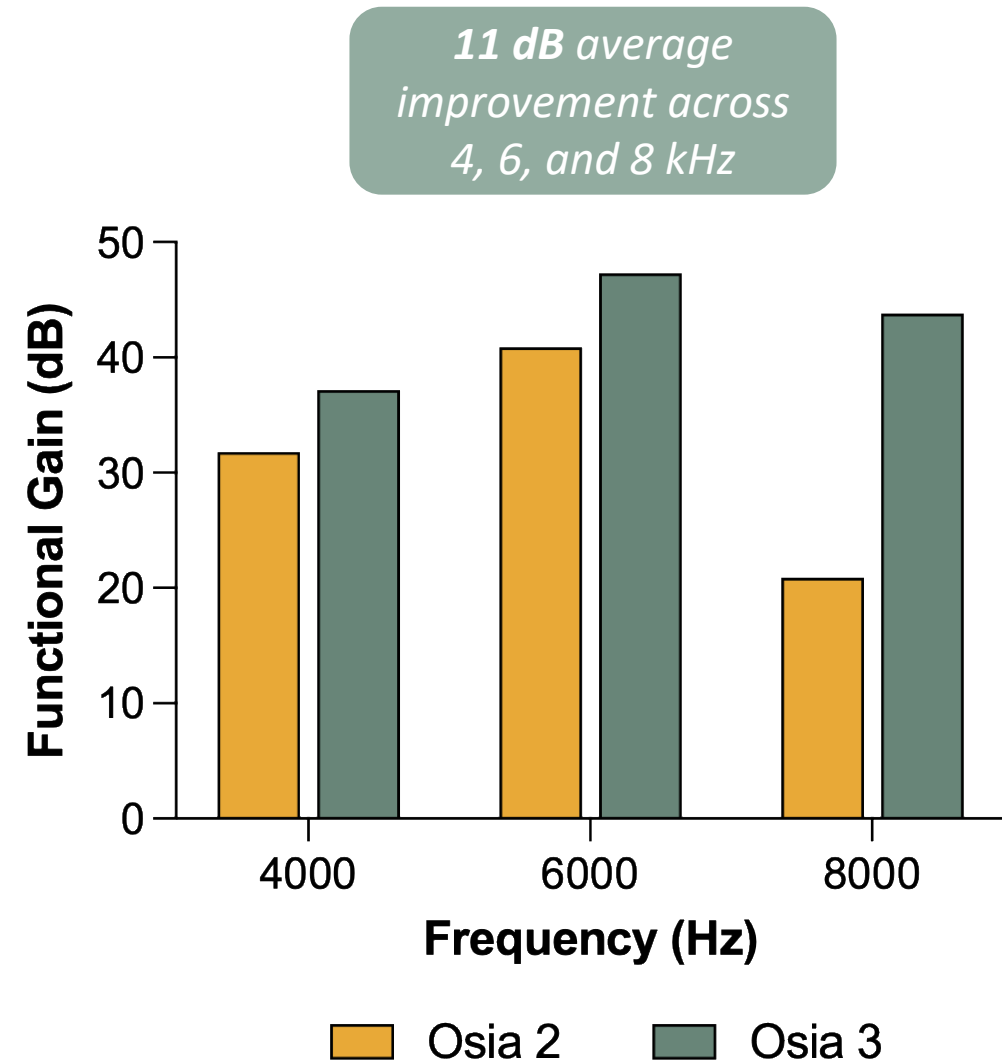
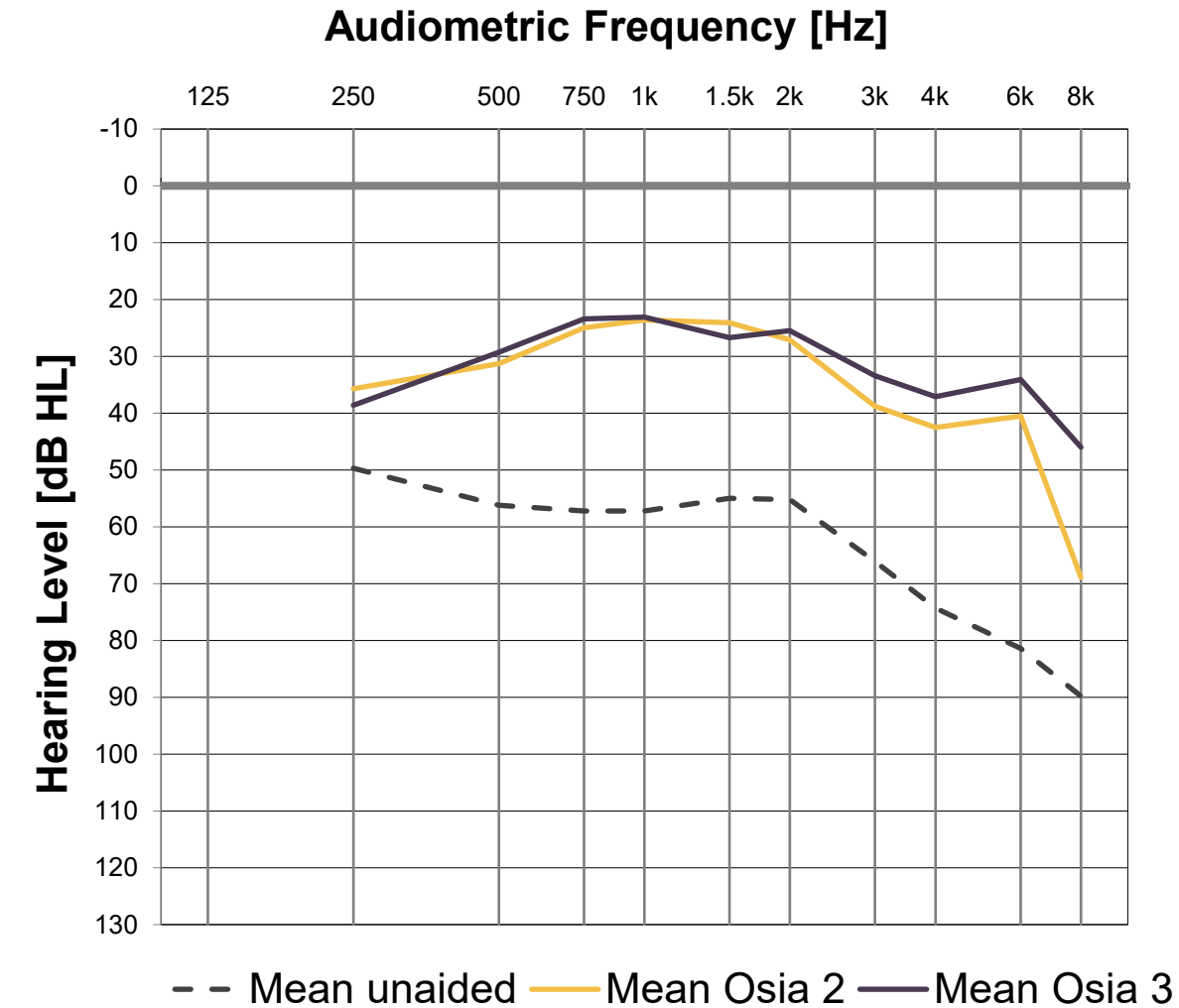
■ Atresia
■ Cholesteatoma
■ COM
■ Radical Mastoidectomy
■ Tumor
■ Unknown
■ Other

Audiogram – bone conduction threshold MHL/CHL

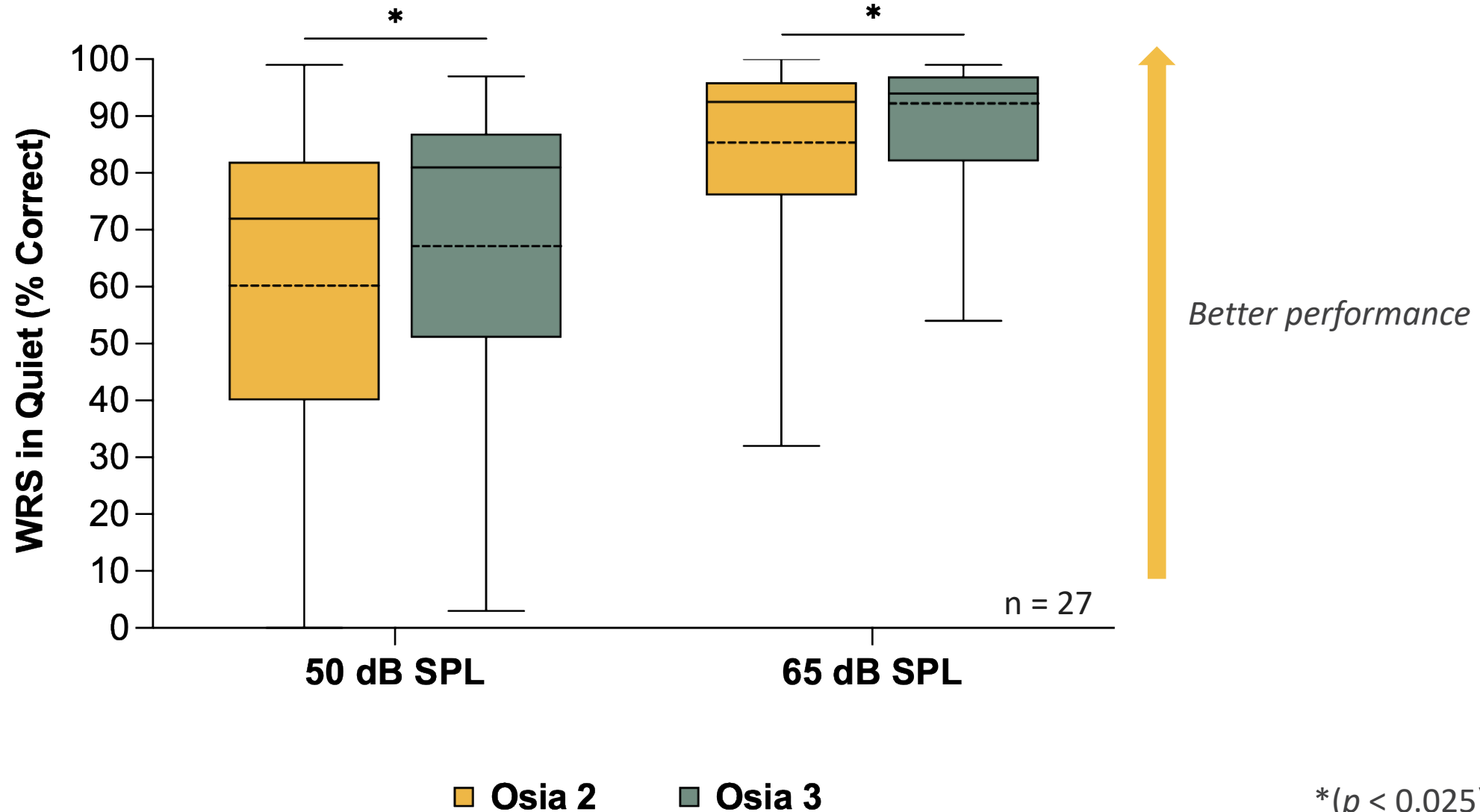


*Study inclusion
criteria of up to
65 dB HL*

Significant improvement of high-frequency aided thresholds

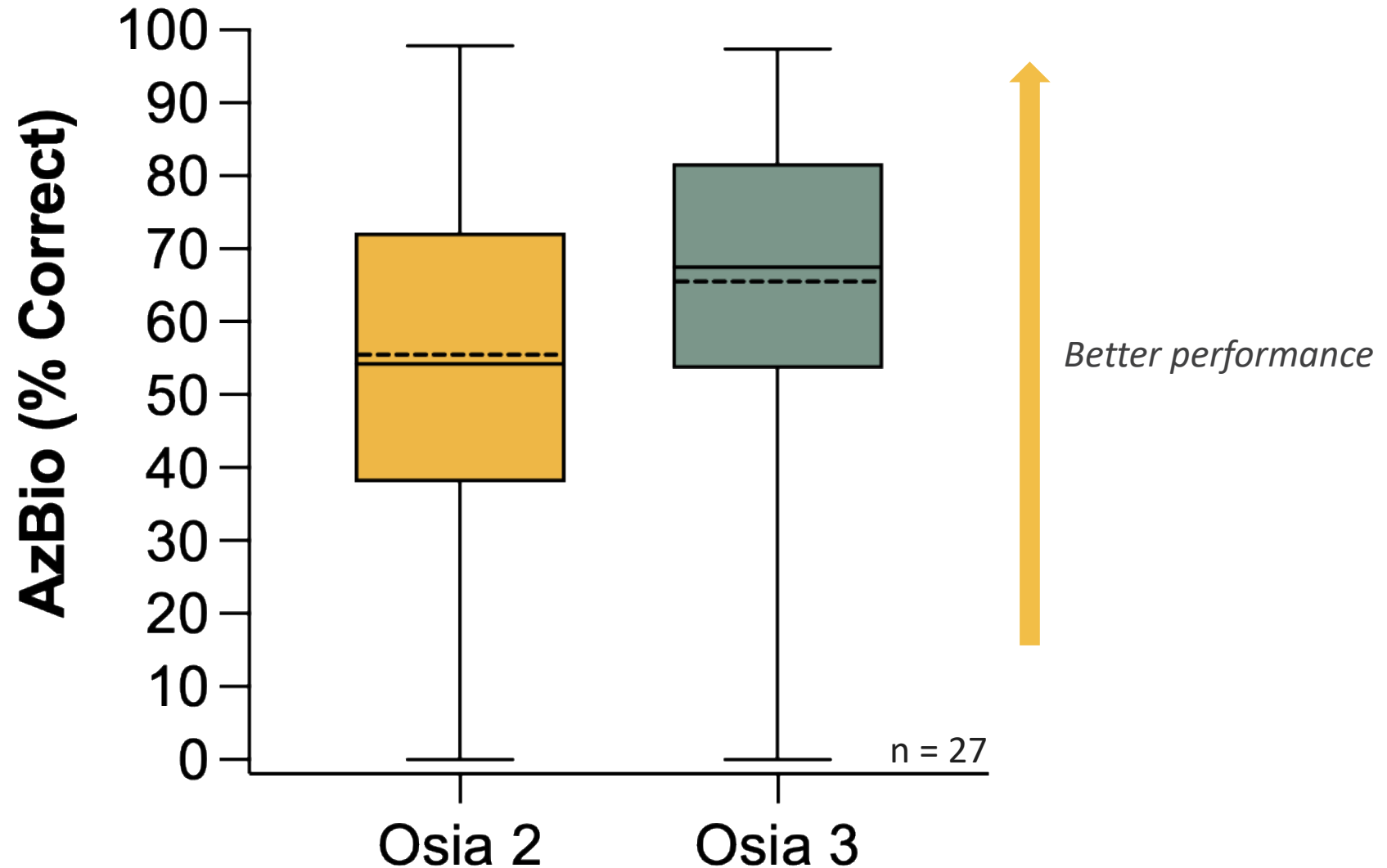


Speech perception in quiet (CNC) at 50 dB and 65 dB SPL was ***significantly better*** with Osia 3/3(I) compared to Osia 2/2(I) in Everyday program



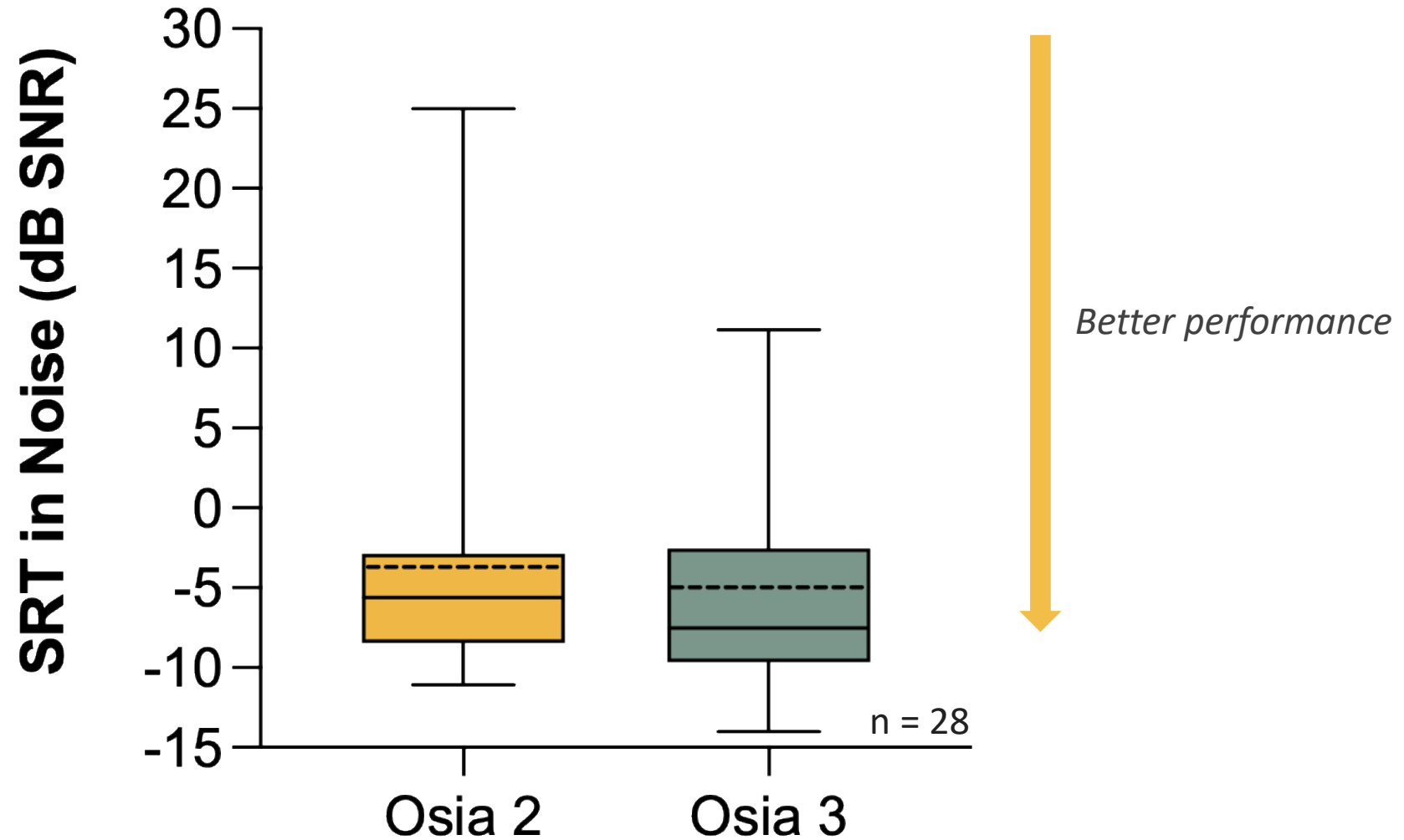
Speech in noise improvement between Osia 2/2(I) in Noise program and Osia 3/3(I) in new Noise program (fixed SNR) at S0N180

Mean paired
difference of
7.3%



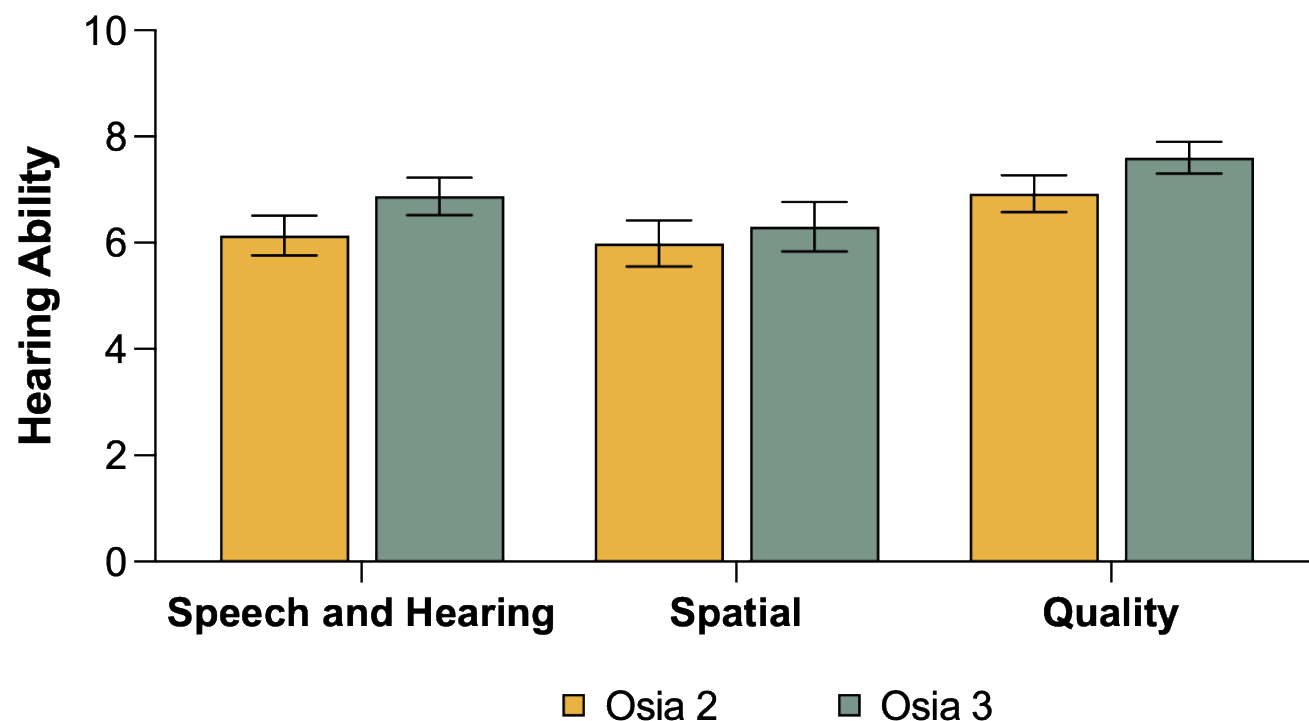
Speech performance in adaptive noise was better with the Osia 3/3(I) compared to Osia 2/2(I)

Clinically
meaningful
average
improvement of
1.1 dB

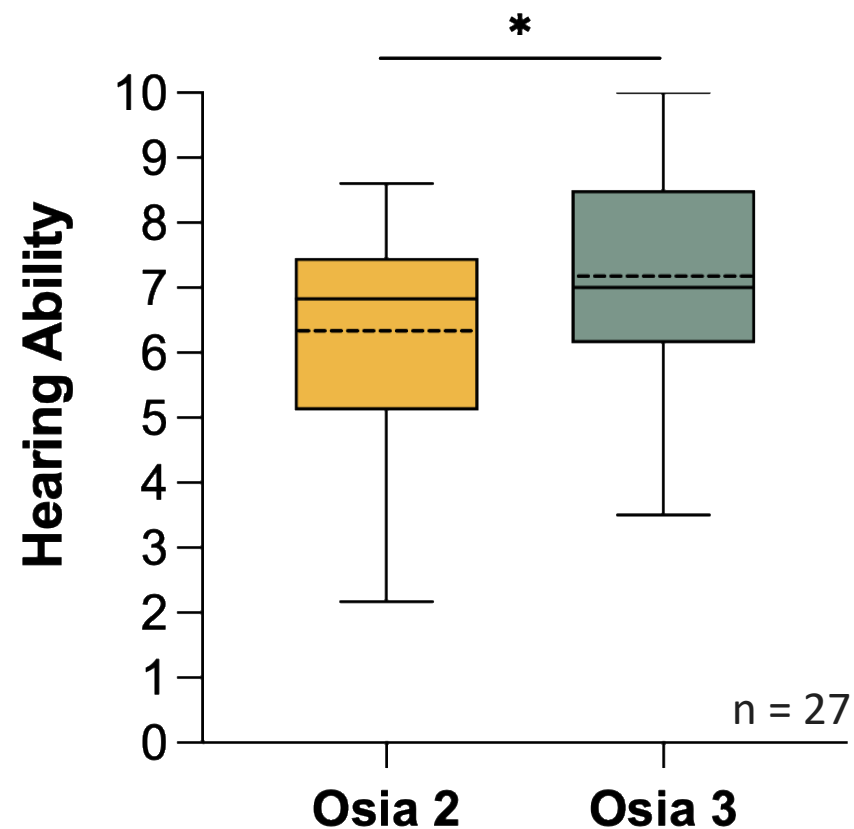


Participants reported *significantly improved functional hearing* with the Osia 3/3(I) compared to the Osia 2/2(I)

Mean paired
differences of **0.74**



SSQ-12 Global Score



*($p < 0.025$)

Participants reported *higher satisfaction* when using the Osia 3/3(I)

Osia 2/2(I)

Osia 3/3(I)



HEARING PERFORMANCE

Satisfied or Very Satisfied

86%

+3

89%



Hearing in background noise

64%

+22

86%



Overall sound quality

71%

+25

96%



Hearing in wind

32%

+29

61%



Listening to Music

32%

+61

93%

All study participants (100%) would recommend the Osia 3/3(I) to other Osia users

Key study findings



Speech perception improved in quiet and in noise



Significant improvements in self-reported hearing ability (SSQ-12)



90% of participants were satisfied or very satisfied with the overall hearing performance with the Osia 3 Sound Processor



100% of participants would recommend the Osia 3 Sound Processor

Guiding recipients through their replacement sound processor journey

Hannah Lynott

Recipient Services Product Manager

Coverage criteria and eligibility requirements

Typical coverage for replacement sound processors

Medicare^{*^}

End of useful life (5 years)

Commercial/ Medicare Advantage^{*^}

Based on the plan's medical necessity policy

Medicaid^{**}

State specific criteria

^{*}Contact your insurance company or local Hearing Implant Specialist to determine your eligibility for coverage.

^{**}Coverage for adult Medicaid Recipients varies according to state specific guidelines.

[^]Covered for Medicare beneficiaries who meet CMS criteria for coverage



When is a recipient considered eligible?

A recipient is typically considered eligible* for a medically necessary replacement sound processor when the current device is out of warranty, and one or more of the following criteria are met:

- The sound processor no longer meets the patient's needs, including support for activities of daily living (ADLs).
- The device is broken and no longer supported by Cochlear. If the device is broken, describe how the sound processor is broken.
- The device has been lost or stolen.

Using Noah[®]* to identify eligible patients

The screenshot displays the Noah 4 software interface. On the left, the 'Patient Browser' panel shows the 'Advanced search' option selected. The main window features a 'Devices' tab with search criteria: Serial number, Aid name, Fitting start date (MM/dd/yyyy), Fitting end date (MM/dd/yyyy), and a dropdown menu for '< Select a manufacturer >'. The 'Journals' tab is also visible. Below the search criteria, a table lists patient names:

First name	Last name
B	M
H	B
T	T
J	P
T	G

On the right, an audiogram grid is shown with frequencies from 20 to 80 Hz. The text 'No Audiogram' is displayed across the grid.

Use the advanced search function to select your fitting range and device manufacturer, then generate a list of recipients who may be eligible.

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Documentation requirements

Documentation best practices

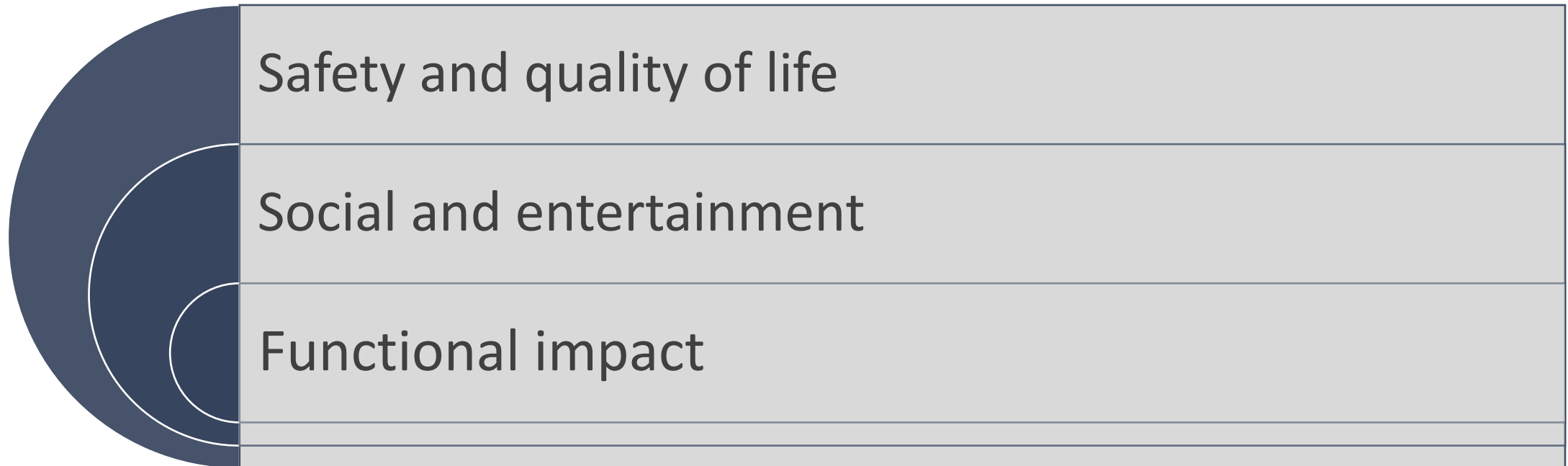


Refer	Refer to “replacement sound processor”
Specify	Specify you are ordering the device
Enforce	Enforce the benefit to the patient including activities of daily living
Provide	Provide robust clinical notes including audiograms, product claims, booth testing and imaging

Activities of daily living: documentation foundation

Insurance payers evaluate medical necessity based on functional impact, not just device age or technological advancement.

Documenting how the current sound processor limitations affect your patient's ability to perform essential daily activities creates the strongest justification for replacement approval.



Example: in-person interaction for clinician placed order

Patient is listening in challenging environments on a daily basis in significant background noise. Today, they report a poor sound quality and difficulty hearing in noise that is not improved by cleaning or reprogramming of their device. The current sound processor can no longer meet the needs of their daily life.

We discussed replacement of their device with an Osia 3 Sound Processor from Cochlear North Americas, the sole provider for this device that is compatible with the internal implant. The Osia 3 Sound Processor demonstrates 7% improvement in speech understanding in noisy environments compared to the current Osia 2 sound processor.¹ This is medically necessary for reliable access to sound for daily communication and safety.

1. Hearing Outcomes With the Osia 3 Sound Processor Compared to the Osia 2 Sound Processor in Adult Osia Implant Recipients (SONUS). Clinicaltrials.gov NCT07156461. Available at: <https://clinicaltrials.gov/study/NCT07156461?term=Osia%203%20Sound%20Processor&rank=2>

Example: phone interaction following recipient placed order

Communication: Cochlear North America is asking for a status update on the left processor. Patient was last seen October 2025. Called mother to inquire about child's processor functionality. Left processor has been cutting in and out and patient is without consistent access to sound. This is impacting her ability to focus at school and understand the content.

It is recommended the processor should be replaced with an Osia 3 Sound Processor - sound quality and battery performance on the Osia 3 Sound Processor are significantly better.¹⁻⁵ Abby is a senior in high school and has high listening demands, the Osia 3 Sound Processor would ensure she has highest quality of sound.

1. Gawliczek T, Wimmer W, Caversaccio M, Kompis M. Influence of maximum power output on speech understanding with bone anchored hearing systems. *Acta Otolaryngol.* 2020;140(3):225-229.

2. Tejani, V. D., Stevens, S., Meyer, A., Bartoshuk, M., Berry, S., Aubuchon, P., Cismas, M., Doolittle, S., Drob, J., Flores, N., Hill, L. M., Levy, E. M., Litton, H., Maher, R., Marchegiani, A., Mauro, L., Moyer, C., Novak, J. L. S., Purdy, J., . . . Murray, G. (2025). Audiological outcomes of the Cochlear Osia 2 bone conduction system implanted under expanded indications in a pediatric population. *International Journal of Audiology*, 1–10. <https://doi.org/10.1080/14992027.2025.2550530>

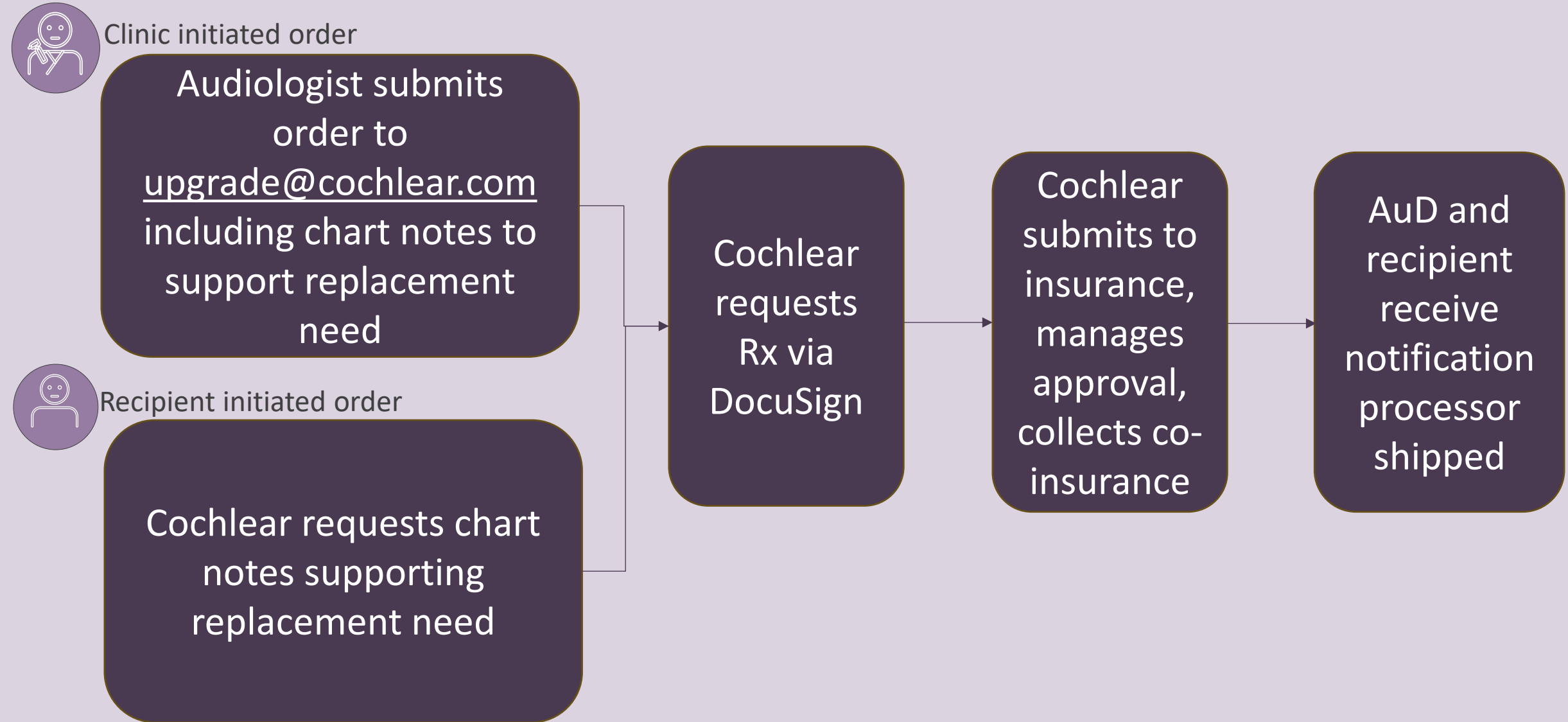
3. Holder, J. T., Sheffield, S. W., & Gifford, R. H. (2016). Speech Understanding in Children With Normal Hearing: Sound Field Normative Data for BabyBio, BKB-SIN, and QuickSIN. *Otology & neurotology* : official publication of the American Otological Society, American Neurotology Society [and] European Academy of Otolology and Neurotology, 37(2), e50–e55. <https://doi.org/10.1097/MAO.0000000000000907>

4. Cochlear Limited. D2304775-V1_EN Osia 3 SP and OSI200 PROF Datasheet

5. Cochlear Limited. D2304776-V1_EN Osia 3(I) SP and OSI300 PROF Datasheet

Submitting a sound processor replacement order

The documentation process for replacement sound processors



Preparing a sound processor replacement order

Required materials should be submitted to upgrade@cochlear.com and must:

- Clearly justify the medical necessity for replacement
- Document that replacement technology was discussed and deemed appropriate
- Include chart notes from visits with an audiologist, physician, or physician assistant
- Include provider signature (handwritten or electronic) with a date/time stamp



www.cochlear.com

This material is intended for health professionals. If you are a consumer, please seek advice from your health professional about treatments for hearing loss. Outcomes may vary, and your health professional will advise you about the factors which could affect your outcome. Always read the instructions for use. Not all products are available in all countries. Please contact your local Cochlear representative for product information.

The content of this guideline is intended as a guide for information purposes only and does not replace or remove clinical judgment or the professional care and duty necessary for each specific recipient case. Clinical care carried out in accordance with this guideline should be provided within the context of locally available resources, expertise, and standards of care and practice.

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CAM-MKTP-1452 SEP26