Learning Objectives

- Explain to patients the benefits of Power bone anchored devices in everyday life.
- Describe the new surgical technique MIPS (Minimally Invasive Ponto Surgery).
- Explain how to connect wireless accessories to both Oticon Medical Ponto as well as Oticon Inc hearing aids.

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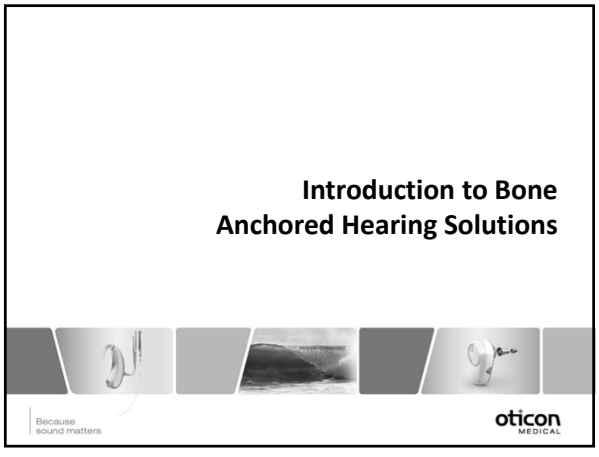
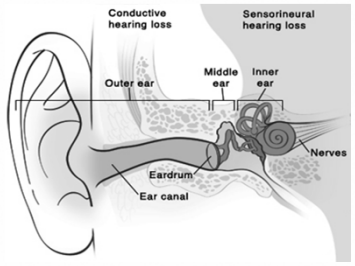


How We Hear



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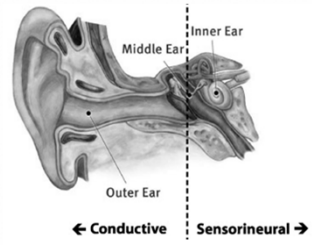
Conductive Hearing Loss



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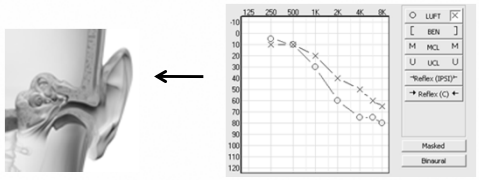
Audiometry, Measuring AC and BC

Measurement of Air-Conduction thresholds represent loss due to middle ear and outer ear



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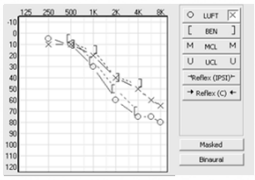
Audiometry, Measuring AC and BC

Measurement of Bone-Conduction thresholds represent loss due to inner ear



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Traditional Earphones/Headphones

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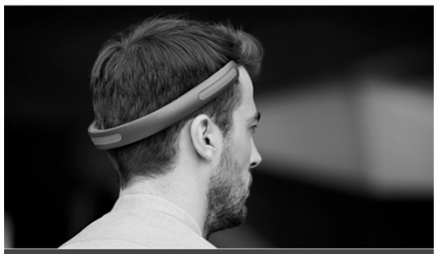

The Batband uses three transducers to relay sound waves to the wearer's inner ear via the bones of the skull

Image Gallery (4 images)

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Google Glass to use bone vibration instead of traditional headphones

TECHNOLOGY / 04 FEBRUARY 13 / by PHILIPPA WARR

Here are a few tips to help improve Glass' sound quality:

- Press the BCT against your head so that it is flush against your skull. This improves the conduction of sound through your bones and to your inner ear.
- Cup your right ear to reduce ambient sounds that might interfere with Glass' sound quality.
- Sometimes you may feel a tickling vibration from the BCT. That's normal, but if it's bugging you, turn down the volume.

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July 12, 2013 12.55am EDT

Bone conduction: the new front in guerilla advertising

Bone conduction technology enables commuters to hear advertisements via their skull – but how? Mr Fink's Finest Photos

The audio information of these ads is transmitted via the window of the train. When you rest your head against the glass the signal is heard inside your head, utilising a phenomenon known as bone conduction. See some reactions to the technology in

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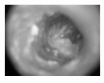
So What´s Wrong With Traditional Hearing Aids?

Nothing - but for some people they just don´t work.

1. Conductive/mix loss due to chronic otitis



2. Conductive/mix loss due to atresia

3. Unilateral (single sided) loss

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What Exactly Are We Making?

The Ponto is an auditory osseointegrated bone conduction implant system

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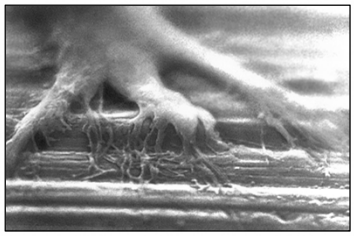
Osseointegration



Living Bone Tissue (Osseo)Integrating with Titanium

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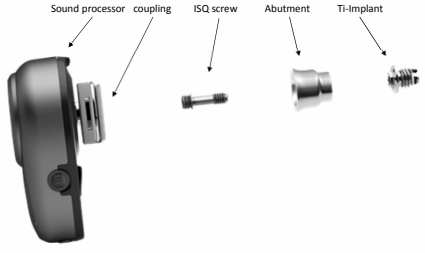
Osseointegration and Direct Bone Conduction Simulation



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Ponto Plus Sound Processors

Ponto Plus
Up to 45 dB BCHL

Ponto Plus Power
Up to 55 dB BCHL

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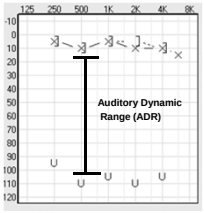
Normal Hearing

Hearing Threshold Level (HL)

Uncomfortable Level (UCL)



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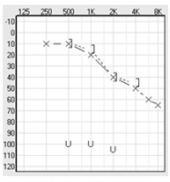
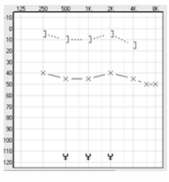
Type of Hearing Losses

Sensorineural
BC~= AC



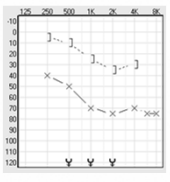
ADR is reduced

Conductive
BC~= 0dB HL



ADR is not reduced

Mixed
Sensori-neural and Conductive



ADR is somewhat reduced

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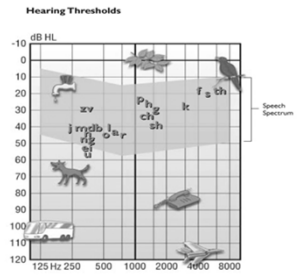
What Amount of Amplification is Needed?

1. Sounds should be amplified so they are within the Dynamic Range.



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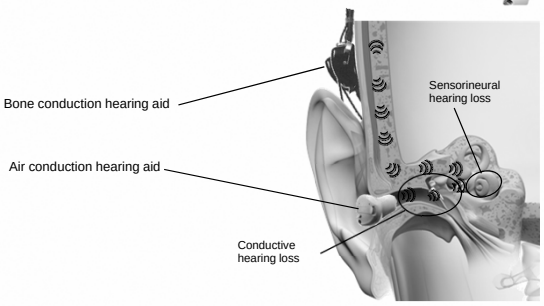
Hearing Loss and Traditional Hearing Aids



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What Amount of Amplification is Needed?

- People with sensorineural, conductive or mixed HL have different ADR; therefore they need different amount of amplification.
- Fitting rules (=rationale) tell how much amplification is needed to compensate for the HL. The needed gain is often expressed in Insertion Gain (dB IG).

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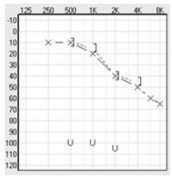
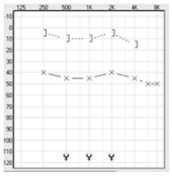
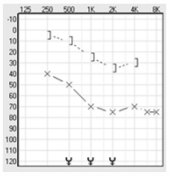
Need For Gain in Traditional HI

- is determined by AC and BC thresholds

Sensori-neural	Conductive	Mixed
		
AC = 40 @2k Hz	AC = 40 @2k Hz	Combination of what's is needed for sensori-neural and conductive part of the HL
1/3 - 1/2 of the hearing loss, ~ 16 dB IG	1:1 of the hearing loss, 40 dB IG	

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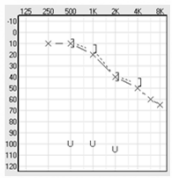
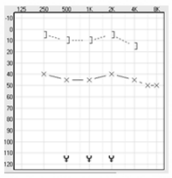
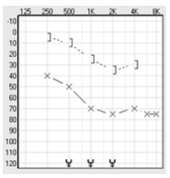
Need For Gain in Bone Anchored Solutions

- is determined by BC thresholds

Sensori-neural	Conductive	Mixed
		
AC=BC = 40 @2k Hz	BC = 0 @2k Hz	Determined by BC
~ 16 dB IG	0 dB IG	

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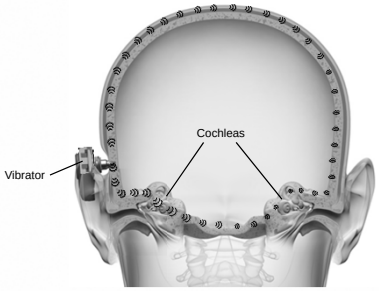
Bone Anchored Hearing Aids

How does it work?



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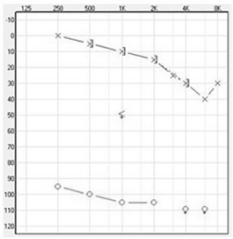
Unilateral Hearing Loss AKA: Single Sided Deafness



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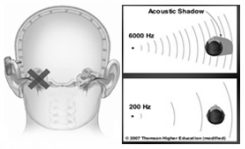
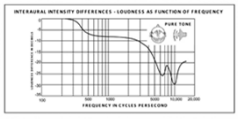
Emphasis on HF Amplification For SSD Patients

- The goal is to lift the head shadow effect:
  - The head shadow effect exists above 1500Hz, therefore only high frequencies need to be amplified
  - Amplifying the low frequencies might disturb the natural hearing of the contralateral ear, leading to poorer hearing in background noise





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Bone Anchored Solutions

Sound always travels to both cochlea.

There is a transcranial attenuation (damping) when sound travels from one side to another.

It varies from person to person, though always largest in the high frequencies.

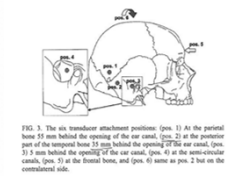
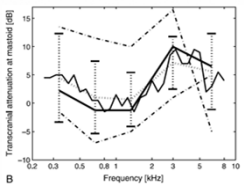


FIG. 3. The six transducer attachment positions: (pos. 1) At the parietal bone 55 mm behind the opening of the ear canal, (pos. 2) at the posterior part of the temporal bone 55 mm behind the opening of the ear canal, (pos. 3) 5 mm behind the opening of the ear canal, (pos. 4) at the semi-circular canals, (pos. 5) at the frontal bone, and (pos. 6) same as pos. 2 but on the contralateral side.



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Power Across the Frequency Spectrum

- BAHS are inherently weak because the vibrator has to vibrate the whole skull
- More power means more audibility of everyday sounds
- Lower power means:
  - Reduced audibility
  - Poorer reproduction of own voice because of saturation issues
  - Tinny sound quality
  - Poorer result for patients with mixed hearing losses – the 45 dB HL fitting range may certainly be a stretch
  - Poorer general acceptance by patients

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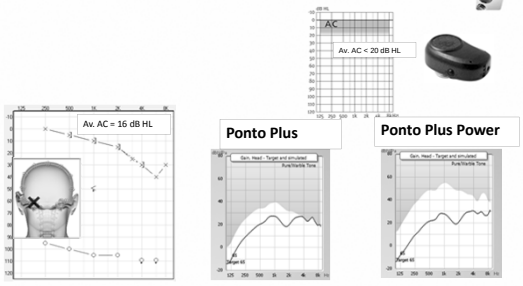
Ponto Plus Power and Single-Sided Deafness



- Single-sided deaf patients with slight cochlea loss will get more HF amplification when fitted with Ponto Plus Power

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Known Consequences of Low MFO

- BAHS are inherently weak because the vibrator has to vibrate the whole skull – focus ought to be on making them stronger – not weaker

- What are the potential issues?
  - Poor reproduction of own voice because of saturation issues
  - Reduction of patient's ability to hear speech at a distance
  - Tinny sound quality
  - Poor general acceptance by patients – especially upgrades
  - Poor result with patients with mixed hearing losses – the 45 dB HL fitting range may certainly be a stretch

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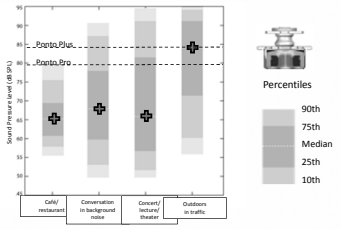
Powerful Transducer = More of Everyday Sounds

Sound levels in different everyday situations*



Percentiles

90th
75th
Median
25th
10th

*Based on recordings of users' everyday situations and a typical Ponto user. The exact effect for a user will depend on the situation, hearing loss and choice of sound processor.
Ref: Wagener et al. (2008)

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Known Consequences of Reduced Bandwidth

- Good high frequency performance is very important as patients with BAHS normally have good cochlear function and therefore can benefit from hearing the high frequencies
- What are the potential issues?
  - Reduced general sound quality
  - For patients with good cochlear function a reduction in speech understanding in certain background noise situations
  - A harder and less balanced sound experience as the reduced bandwidth might force audiologists to provide more gain in the mid frequencies

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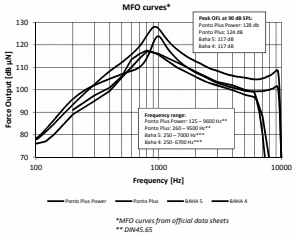
Ponto Plus – Provides More Output

BAHS are inherently weak because the transducer has to vibrate the whole skull.
Make sure never to compromise on sound!

- Increased low frequencies helps to provide better loudness sensation and voice quality.
- More high frequency gain delivers important speech cues.
- Wider bandwidth helps with speech perception, sound quality and understanding speech in noise.



*MFO curves from official data sheets
** DIN45.65
***ANSI 3.22

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Considerations For Mixed HL

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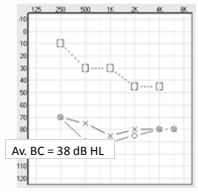
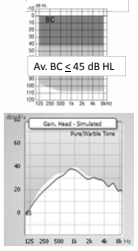
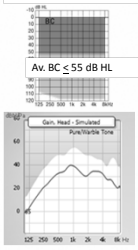
Mixed Hearing losses

Ponto Plus

Ponto Plus Power







- More gain and headroom with Ponto Plus Power – benefits a wide range of mixed HL

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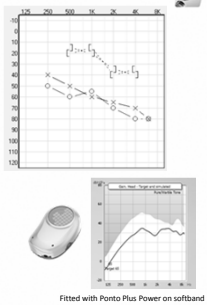
Mixed Hearing Losses

- The need for amplification is high because:
  - Compensation for the sensori-neural hearing loss
  - Additional amplification is needed in a softband / skin drive solution to compensate for the skin attenuation
- Only a **Power** bone anchored hearing device can provide the needed gain



Fitted with Ponto Plus Power on softband

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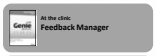
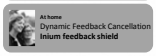
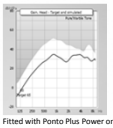
Mixed Hearing Losses

- The power sound processor needs to have an effective feedback management system, to ensure that:
  - The prescribed gain will not be limited by the feedback limit
  - The patients are not bothered by feedback
- A power sound processor is also needed in order to provide the patient with the possibility to turn up the volume.







Fitted with Ponto Plus Power on softband

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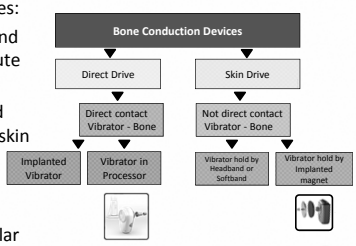
Bone Conduction
Direct Drive vs Skin Drive systems

- There are two types of bone conduction devices:
- **Direct Drive** devices send vibrations via direct route to bone
- **Skin Drive** devices send vibrations through the skin to bone



- Softband and magnet solutions provide similar performance[1]

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1) Briggs (2015) Clinical Performance of a New Magnetic Bone Conduction Hearing Implant System: Results from a Prospective, Multicenter, Clinical Investigation. Otol Neurotol. 2015 Jun;36(5):834-41.

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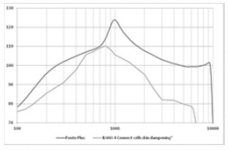
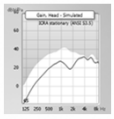
Avoiding Poor Results For SSD Patients

- Only direct drive solutions can amplify the needed frequencies.
- Fitting a skin drive solution to an SSD patient may lead to poor results.
- Thanks to the Feedback Shield, Ponto Plus provides more high frequency amplification than other bone conduction devices, and without feedback.





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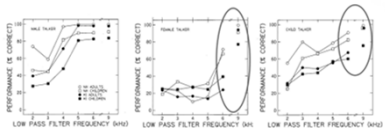
On The Importance of Bandwidth For Children

- Stelmakowich et al. (2001)
  - Recognition of high-frequency consonants
  - Difference between *speakers*



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Conclusion

Medwetsky, 1992; Boothroyd, Erickson, and Medwetsky, 1994; Jongman, Wayland, and Wong, 2000), these results suggest that, when fitting hearing aids to young children, audible energy through 5 kHz is needed to maximize perception of /s/ produced by a male talker and that a 9-kHz upper limit is needed for /s/ produced by a female. From a clinical perspective, it is important to distinguish between cases where performance *cannot be improved* by high-frequency

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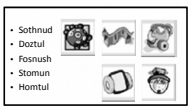
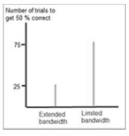
The Importance of High Frequencies For Language Development in Children

Clinical study

- Purpose: Determine learning rate for words presented with 4 kHz and 9 kHz bandwidths
- Method: Five nonsense words, paired with 5 novel pictures
- Outcome: Children need **3 times as many trials with limited bandwidth** to learn new words as compared to the children who listen to extended bandwidth.[7]





7) Pittman (2008) Short-term word-learning rate in children with normal hearing and children with hearing loss in limited and extended high-frequency bandwidths. Journal of Speech, Language and Hearing Research. Vol5, 785-797

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The Importance of /S/

- 3rd or 4th most frequently occurring phoneme in the English language
- Makes a word plural
- Shows tense
- Shows possession

- Is that Mary? vs Is that Mary's?
- She put it on vs. she puts it on
- Keep Vs. Keeps
- Bring the Chair Vs. Bring the chairs

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Daily Usage And Comfort

Ponto

- Minimal physical sensation of the device
- Device stays attached to abutment
- Nothing prevents the user from wearing it during all waking hours (> 8 hours)

PONTO

Magnetic solution

Wearing a processor		
Usage/day	BAHS [3]	Magnetic solution [4]
< 4 h	2 %	14%
4 – 8 h	7 %	64%
> 8 h	**90 %**	22%

Magnetic solution

- Low avg. usage: 7.0 h/day
- 22 % of patients had numbness 9 months post-surgery.

Numbness [4]			
4 wk	6 wk	3 mo	9 mo
62.9 %	44.4 %	25.9 %	22.2 %

3) Dutt et al. Day to day use and service related issues with bone anchored hearing aids: The Entific medical systems questionnaire. Journal of Laryngology and Otology 2002; 116: 20-28
4) Briggs et al (2015) Clinical performance of a new magnetic bone conduction hearing implant system: Results from a prospective, multicenter, clinical investigation. Otology & Neurotology. Jun;36(5):834-41

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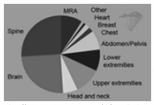
Surgical Considerations Pertinent to Patients with SSD Due to Acoustic Neuroma

- MRI
- A big artifact causes shadowing. Nothing in the shadow is visible
- MRI is widely used. There is a high likelihood patients will undergo MRI examination during their lifetime



http://www.magnetic-resonance.org/ch/21-01.html

- Acoustic neuroma patients undergo a number of MRI´s post surgery in follow up program

Ponto [5]
- 3 Tesla
- 10 mm artifact

Magnetic system[6]
- 1,5 Tesla
- 115 mm artifact

Note! The illustrations are not exact. Just a schematic view of the artifact effect

5) Oticon Medical MRI Security card
6) Surgery guide, Cochlear Nucleus 4 Attract System, Surgical procedure

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Many BAHS Options Available

Some important considerations:

- Does the solution provide enough amplification / output?
- Is it comfortable enough to wear for a full day?
- Cosmetically, how does it compare?




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Wireless

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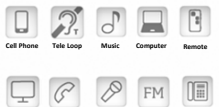
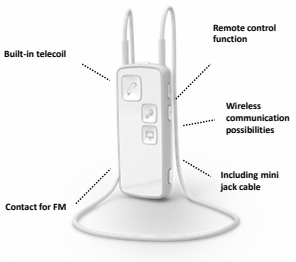
Wireless Connectivity

- Ponto Steamer





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Bimodal Use Of Oticon Medical Streamer

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Which Oticon Hearing Aids Can Be Used in a Bimodal Setup?

- Currently, there are six models that can be used bimodally with OM Streamer*:

- ***Dynamo:***
  - Dynamo SP4
  - Dynamo SP6
  - Dynamo SP8
  - Dynamo SP10

- ***Sensei SP:***
  - Sensei SP
  - Sensei SP Pro

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* Find the full list of Oticon Medical Streamer-compatible hearing aids at www.oticonmedical.com/OMStreamerHA

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How Do We Recommend That Oticon Medical Streamer is Used in Bimodal Fitting Cases?

- Leave Oticon Medical Streamer **OPEN**.
  - The wireless Ponto sound processor and the Oticon hearing aid can both be used with the Oticon Medical Streamer without linking, right out of the box, in the **OPEN** condition

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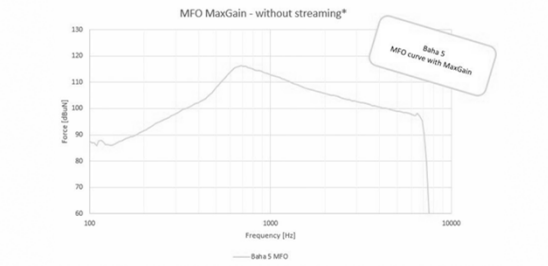
Wireless Possibilities Should Never Compromise on the Power Which Users Need!



*The MaxGain (max audiology gain) setting was used for all devices during testing - with and without iPhone audio streaming link active - The MFO MaxGain curves shows results without actively streaming a sound file through the wireless link.

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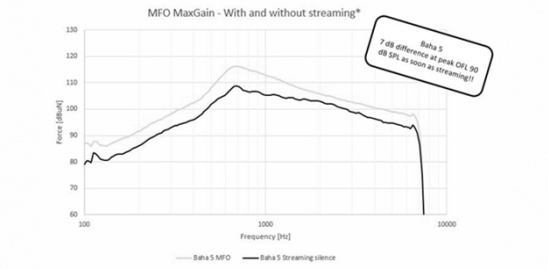
Wireless Possibilities Should Never Compromise on the Power Which Users Need!



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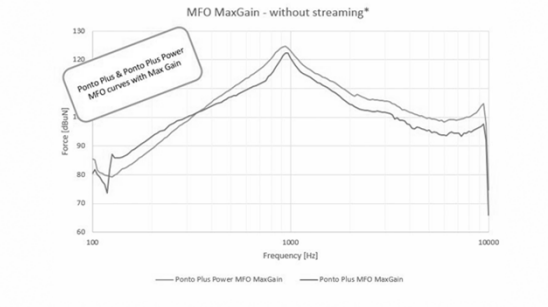
Ponto Plus - Wireless Possibilities Does Not Affect the Power Users Need!



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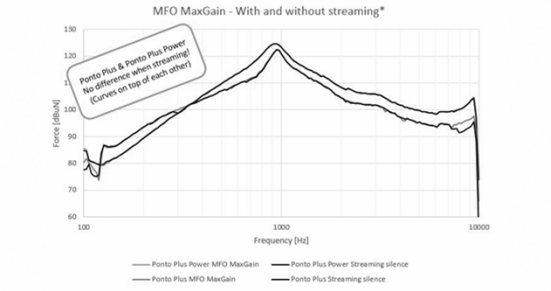
Ponto Plus - Wireless Possibilities Does Not Affect the Power Users Need!



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Minimally Invasive Ponto Surgery (MIPS)

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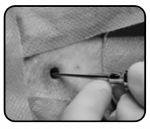
Suture Free Surgery - No Scarring

Tissue preservation surgery with linear incision



MIPS Surgery

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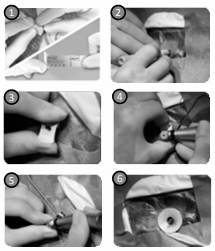
MIPS Procedure, Summary

1. Decide position and measure skin thickness
2. Punch
3. Insert Cannula
4. Drill. Guide- and widening drilling
5. Insert implant
6. Fit Soft Healing cap



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A Truly New Perspective on Tissue Preservation

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MIPS Procedure, Summary

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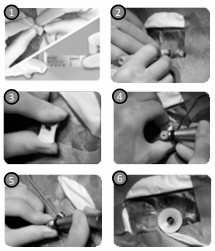

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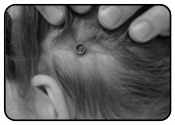
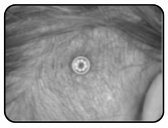
Minimizing Post-op Complications



Tissue preservation surgery
3 months post- op



MIPS surgery 1 week post-op

*Johansson M, Holmberg M, Hultcrantz M, "Bone anchored hearing implant surgery with tissue preservation – A systematic literature review," Oticon Medical white paper, MS2107, 2014

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Patient Outcomes 7 Days Post-op

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Abutment Extension

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Small Change. Big Difference

- No surgery
  - The Abutment extension is connected on the existing abutment without any surgery involved.
  - It is delivered non-sterile.
  - Placement can take place outside the surgical theatre.
  - The Abutment extension does not work with BAHA processors. It must be removed if a BAHA is fitted.

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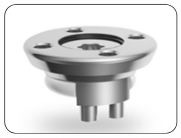
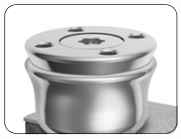
Small Change. Big Difference

- Seamless fit on existing abutment
  - The Abutment extension has full compatibility to most bone anchored hearing aid abutments available on the market*.





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*Please read the Abutment extension IFU for further instructions

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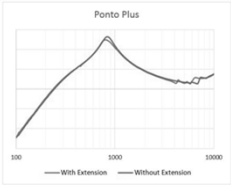
Is the Sound Transmission Affected by the Abutment Extension?

- No
- The graph shows the output as measured with accelerometer on counterweight mounted on patient's abutment; with and without abutment extension.
- The curves show that they are on par with no major difference.



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*When normal Genie Medical fitting flow is followed.

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Abutment Extension

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Future Technologies

- More powerful sound processor*

- Requires FDA clearance to commercially market in the United States
- Not currently available.

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