

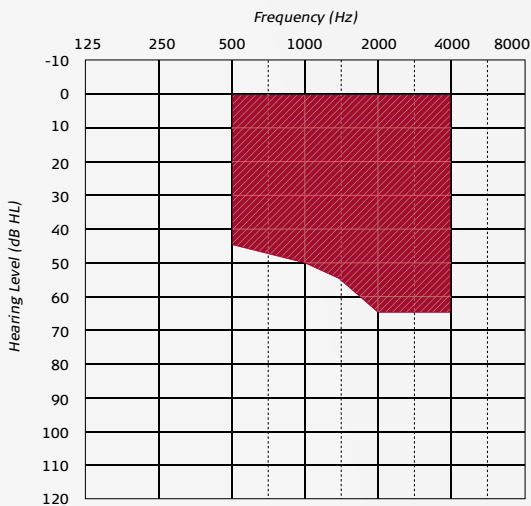
VIBRANT SOUNDBRIDGE[®] SYSTEM

Including the SAMBA[™] audio processor, the VORP 503 and the Vibroplasty Couplers.



Selection Criteria for the VIBRANT SOUNDBRIDGE

Conductive and mixed hearing loss with failed revision tympanoplasty or malformations (e.g. atresia)

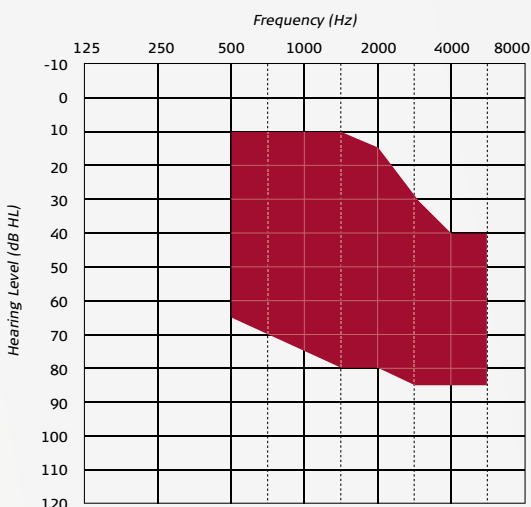


Treatment: RW Vibroplasty / Coupler Vibroplasty

Bone conduction

- Stable bone conduction thresholds within the shaded area
- Absence of active middle ear infections
- Ear anatomy allows the FMT to be positioned on a suitable vibratory structure
- Ability to get benefit from amplification
- Absence of retro-cochlear and central auditory disorders
- Adequate motivation and expectations

Sensorineural hearing loss with medical indications (e.g. chronic otitis externa)



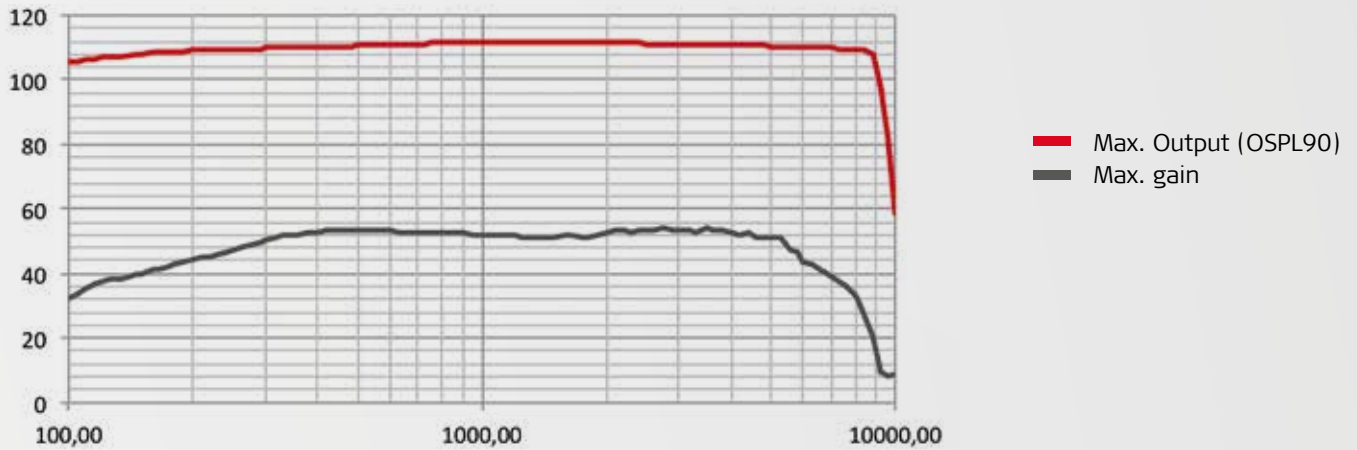
Treatment: Incus Vibroplasty

Air conduction

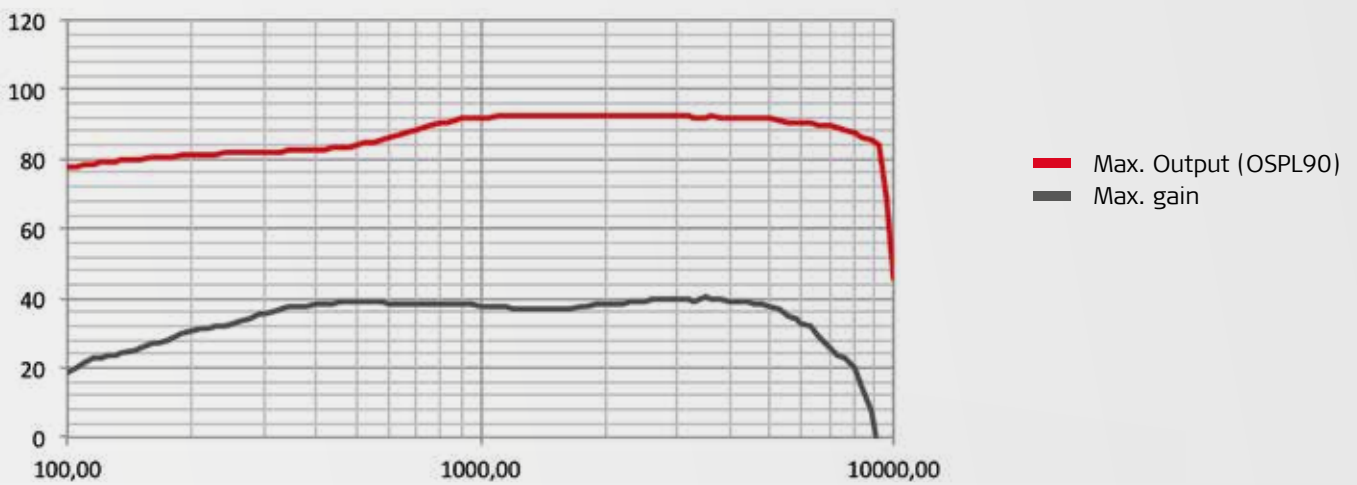
- Stable air conduction thresholds within the shaded area
- Normal middle ear function as shown by audiometric thresholds and impedance measurements
- Speech audiometry curve adequate to the respective PTA. Speech understanding of at least 50% on an open set word test, at the most comfortable listening level under headphones
- Ability to get benefit from amplification
- Absence of retro-cochlear and central auditory disorders
- Adequate motivation and expectations

Output curves

Output curves for the SAMBA Hi

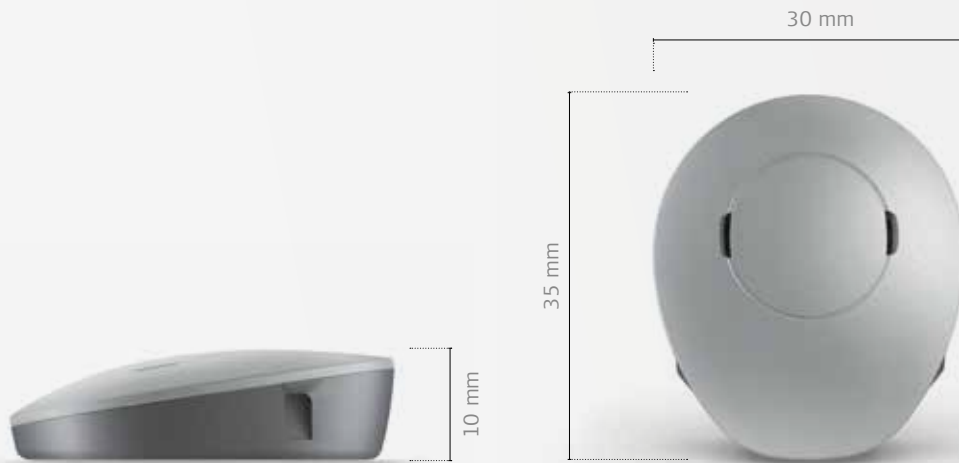


Output curves for the SAMBA Lo



SAMBA™ audio processor

Design meets technology



reddot award 2014
winner

Intelligent Hearing System

- Intelligent Sound Adapter
- Adaptive directional microphones
- Speech Tracking

Wireless connectivity*

- Wireless connectivity options via bluetooth or telecoil to external devices such as mobile phones, FM-systems, ALDs etc. This function is possible by using the Siemens miniTEK™.

Programs

- Up to 5 individual programs

Remote Control

- Easy adjustment of the volume and change between the programs of the SAMBA



Optimized fitting procedure

- Fitting via battery pill or wireless fitting
- Vibrogram for Vibrant Soundbridge and Bonebridge
- Data-logging providing information about the usage of the SAMBA

Simplified logistics

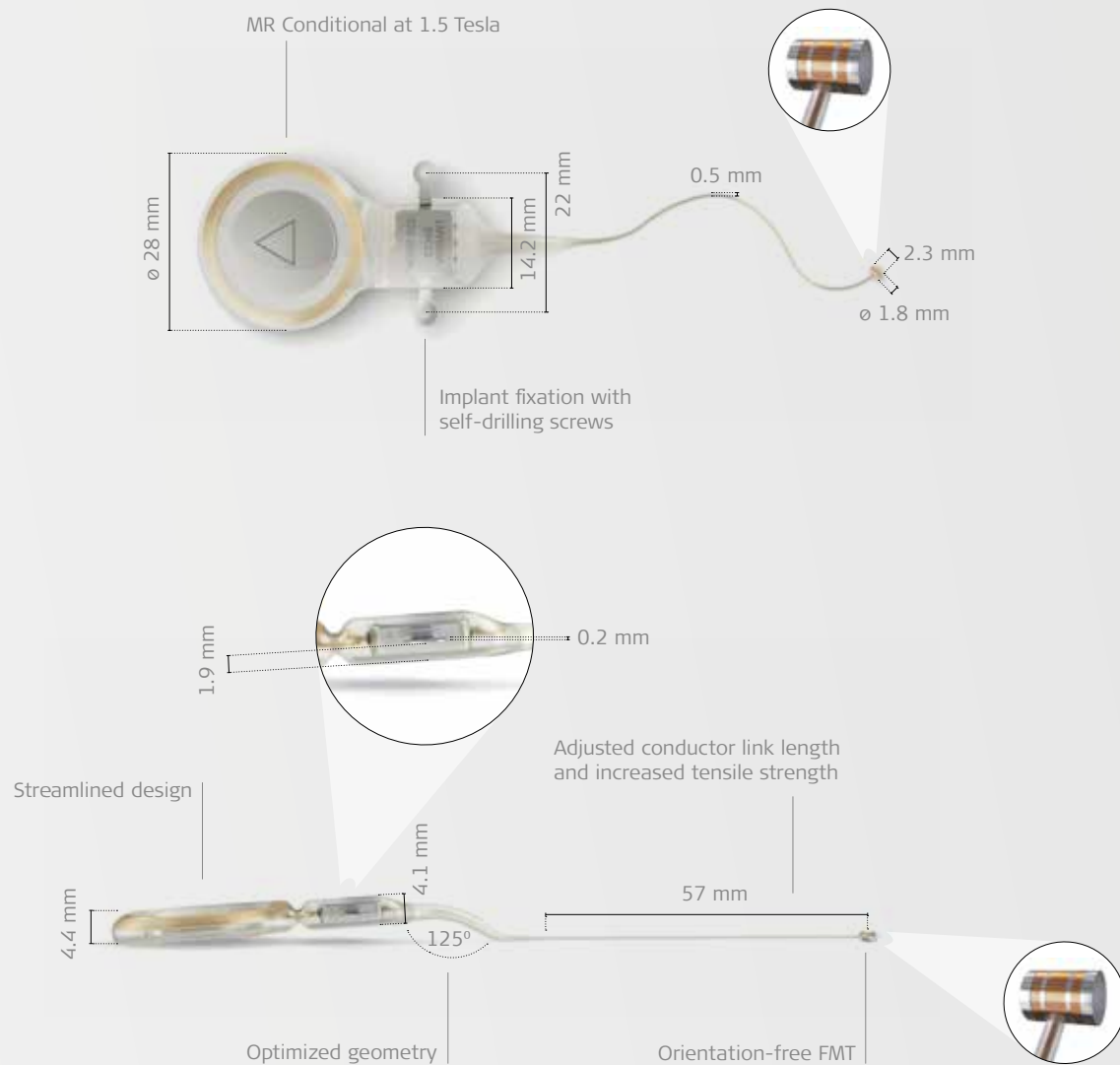
- Fewer audio processor variants which optimizes logistics
- Basic package of 9 covers shipped with the SAMBA; users can individually adapt colour and design

SYMFIT 7.0

Optimized workflow due to standardized fitting procedure for the new Vibrant Soundbridge and the Bonebridge. With the new SYMFIT 7.0 software fitting can be carried out either wirelessly or via the battery pill. Additionally, Vibrograms can be created for the new Vibrant Soundbridge as well as for the Bonebridge.

VORP 503

The new standard in middle ear implants



MR Conditional at 1.5 Tesla

- Gives users the possibility to still benefit from MRI scans, if required in the future.

Implant fixation with self-drilling screws

- Easier, quicker implant fixation

Adjusted conductor link length

- Easier conductor link handling

Increased tensile strength of the conductor link

- Optimized handling

Attachment clip-free and orientation-free FMT

- Same implant for left and right ear
- Various Couplers for every indication available

Streamlined design and optimized geometry

- Thinner implant design

Vibroplasty Couplers

New coupling possibilities offering more surgical flexibility

FOR SENSORINEURAL HEARING LOSS

Incus-SP-Coupler

- For FMT fixation on short process of the incus
- New coupling without posterior tympanotomy, away from facial nerve and corda tympani
- Fewer steps required in SNHL surgery



Incus-LP-Coupler

- For FMT fixation on long process of the incus
- Easier coupling without crimping



FOR CONDUCTIVE & MIXED HEARING LOSS

RW-Soft-Coupler

- Round Window Vibroplasty with less drilling
- More standardized round window coupling
- Easier handling, anatomically optimized
- Dimensions: 1.5x1mm



Vibroplasty-Clip-Coupler

- Standardized stapes-head coupling



Additionally available Vibroplasty Couplers:

FOR SNHL

Incus-Symphonix-Coupler



FOR CONDUCTIVE AND MIXED HL



Vibroplasty-Bell-Coupler



Vibroplasty-OW-Coupler



Vibroplasty-RW-Coupler

Technical data

SAMBA™ audio processor

Dimensions

see figure on page 4

Weight

< 9 g (incl. battery)

Material in tissue contact

Eastman Tritan Copolyester MX731

Power supply

- Power supply of the audio processor:
One non-rechargeable 675 zinc-air button cell with a nominal 1.4-Volt supply and 600mA-Hrs of capacity
- Power supply of the remote control:
Two AAA batteries

Audio frequency range

250 Hz to 8 kHz

Signal processing

16-band Digital Equalizer
16 independent Compression Channels
Sound Smoothing
Speech and Noise Management
Adaptive directional microphones
Intelligent Sound Adapter
Classifier
5 different programs
Wind Noise Reduction

Controls

MED-EL Remote Control
Turn off the system by opening the battery case

Wireless technology (from Remote Control to audio processor)

Type: NFMI (near field magnetic induction)
Frequency: 3.26 MHz
Modulation type: FM
Wireless range: 1 m

Microphone features

Ambient Sound
Adaptive directional microphones
Speech Tracking
Omnidirectional microphones

Basic package of covers (shipped with the SAMBA)

Simply Black
Glossy Black
Chocolate Brown
Mahogany
Terra Brown
Golden Sand
Light Blond
Silver Grey
Tweed

Different design covers additionally available

VORP 503

Dimensions

see figure on page 5

Weight

10.6 g

Materials

medical grade silicone elastomer, Titanium, medical grade epoxy

Housing design

- Screw fixation
- Recommended flattening depth for the demodulator: 1.9 mm

Safety features

Overvoltage Protection Circuit

MRI Conditions

MR Conditional at 1.5 Tesla

Implant fixation with self-drilling cortical screws

Dimensions:

Overall length: 4 mm
Diameter: 1.6 mm
Material: Titanium alloy Ti 6Al 7Nb

Screw penetration in bone

3.5 mm (max.)

Screwdriver

Used for tightening cross-head cortical screws

Content of implant kit

- 1 VORP 503
- 3 self-drilling cortical screws
- 1 screwdriver

Vibroplasty Couplers

Materials

Incus-LP-Coupler:

Titanium Grade 5 ELI (ASTM F136), Titanium Grade 2 (ASTM F67)

Incus-SP-Coupler:

Titanium Grade 5 ELI (ASTM F136)

RW-Soft-Coupler:

Implant Grade Silicone Rubber and Gel

Vibroplasty-CiP-Coupler:

Titanium Grade 2, Titanium Grade 1

Additionally available Couplers

Vibroplasty-SMPX-Coupler:

Titanium Grade 1 (ASTM F67, Titanium Grade 5 ELI (ASTM F136)

Vibroplasty-Bell-Coupler:

Titanium Grade 1, Titanium Grade 2

Vibroplasty-OW-Coupler:

Titanium Grade 1, Titanium Grade 2

Vibroplasty-RW-Coupler:

Titanium Grade 1, Titanium Grade 2

Content of each Coupler package

Incus-LP-Coupler and Incus-SP-Coupler:

1 holding frame, 1 retainer, 1 Coupler

RW-Soft-Coupler:

1 holding frame, 2 retainers, 2 Couplers

Vibroplasty-CiP-Coupler: 1 Coupler

Additionally available Couplers

Incus-Symphonix-Coupler: 1 holding frame, 1 retainer, 1 Coupler

Vibroplasty-Bell-Coupler: 1 Coupler

Vibroplasty-OW-Coupler: 1 Coupler

Vibroplasty-RW-Coupler: 1 Coupler

SYMFIT 7.0

System Requirements

- Windows XP, Windows Vista, Windows 7, Windows 8
- Required hard disk space: 300 MB free storage (2 GB free storage recommended)
- 512 MB RAM (1 GB recommended)
- Graphics Display 1024 × 768 resolution (1280 × 1024 recommended)
- Programming Interface: HI-PRO / NOAH-Link / CONNEXX Link
- CD-ROM drive
- CONNEXX 6.5.5
- USB interface 1.1 (2.0 recommended)



More information on medel.com/soundbridge

* Wireless connectivity feature is available with the Siemens miniTEK™. Sivantos is not responsible for the operation with the SAMBA or its compliance with safety and regulatory standards in operation with the SAMBA.

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