

Bone conduction hearing solutions from Sophono

Sophono, Inc. was launched in October 2009, following five years of research and with a vision and dedication to improving the bone anchored hearing device experience. The Alpha 1 System was developed in Germany, released in 2006 and used primarily in Germany and Western Europe. It is now produced in our facility in Boulder, Colorado. Sophono, Inc. products provide a high-quality hearing solution with distinct advantages to traditional bone anchored devices. We are also committed to using green materials for the packaging of the sound processor, as well as our marketing and sales materials.

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A **new solution** for conductive hearing loss



 **Sophono**[™]
bone conduction hearing solutions



A Simple Solution

Sophono, Inc. has developed an innovative new non-percutaneous, implantable bone anchored hearing device. The Alpha 1 System eliminates the problematic abutment of other devices by using magnets to securely affix the external sound processor to a titanium implant.

This long-awaited alternative for the elimination of the percutaneous abutment was developed in Germany. Sophono, Inc. offers an abutment-free device for patients who suffer from hearing disorders, where traditional air-conduction hearing aids fail to have an impact due to canal and middle ear malfunction.

Indications:

- Mixed Hearing Loss
- Conductive Hearing Loss
- Single Sided Deafness

The Alpha 1 (M) system is designed for use by patients 5 years of age and older. The audio processor is affixed without hair removal and without a permanent opening through the skin. The external processor is connected magnetically to the surgically implanted internal device that houses hermetically sealed magnets in a titanium case. This implant component is secured to the mastoid bone behind the ear with maxillofacial screws.



Alpha 1 (M) processor—actual size.

The Alpha 1 (S) product designation is for use of the sound processor with a soft band or head band for patients that prefer not to have an implant or who do not meet the minimum age requirements for implantation. The digital sound processor is coupled to the patient's choice of bands and vibrates the bone through the skin without the use of magnetic coupling. The Alpha 1 (S) can be used by patients of any age.

The advantages of the Alpha 1 (M) technology are exceptional. The benefits are many.

Simple, single-stage surgery

A simple surgical procedure reduces healing time and the time to fit the device. Dramatically reduced post-surgical complications and revisions result in fewer patient follow-up visits.

No implant revision

The implant is completely passive with no electronic or moving parts and should never need to be replaced.

No permanent hair follicle removal

Hair removed for surgery will grow back.

Simple wound care

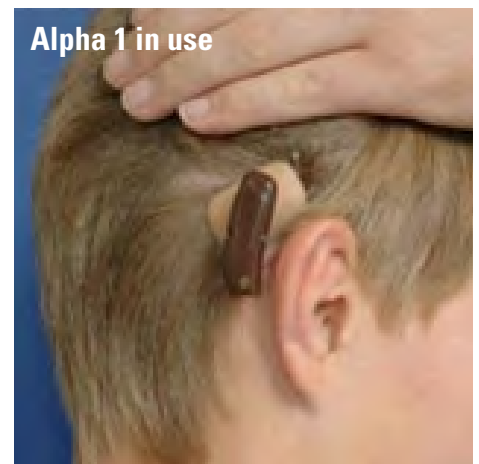
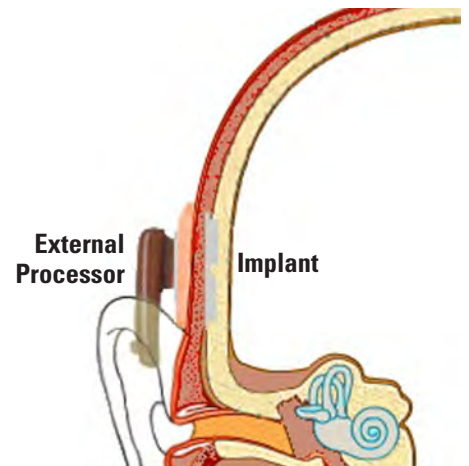
The incision requires no special care. Cleaning and changes of the dressing are all that is required.

No daily maintenance

No percutaneous abutment frees patients from the ordeal of daily site care.

Abutment-free hearing

Having no external cosmetic impact can improve user self-esteem. Eliminates opportunity for painful, accidental impact to and/or dislodging of implant.



The photos above show the device in use as well as the healed implant incision site.



Features of the Alpha 1 System

The Alpha 1 audio processor is a completely programmable digital hearing system including:

- 8 channels
- 16 frequency bands
- 4 programs
- Customizable program switching
- Low battery warning tones
- Automatic noise reduction and feedback suppression

The Alpha 1 System offers clear advantages:

- Implant lies completely under the skin
- No skin penetrating abutment
- Reliable implantation technique
- Shorter time from implantation to full use
- An excellent option for those who said “no” to other devices and painful procedures

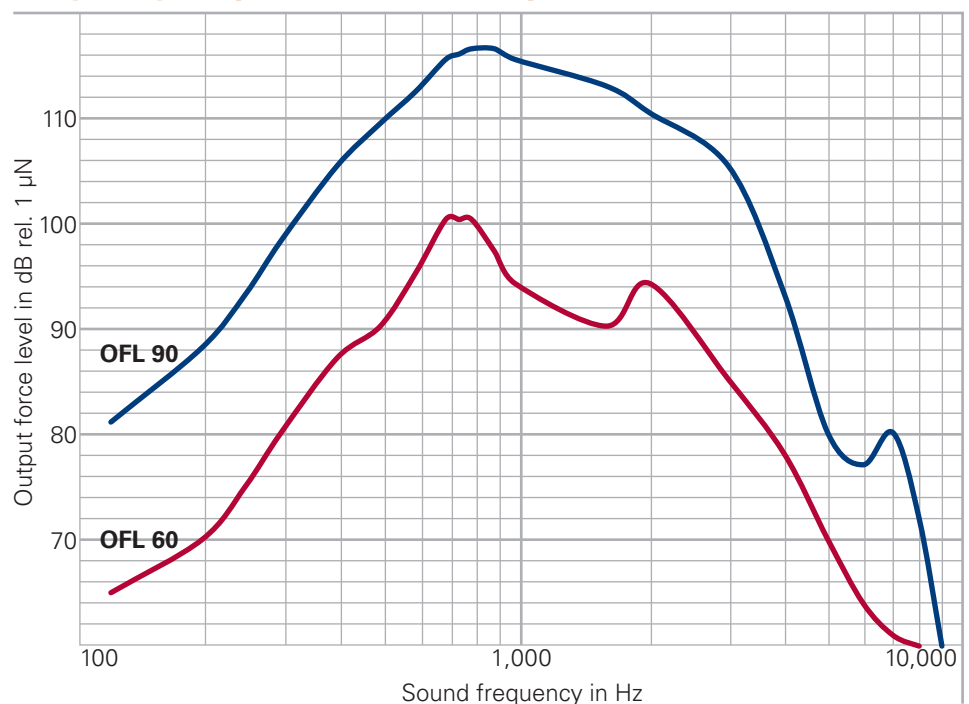


Implant—actual size.

Fitting of the Alpha 1 System is easy:

The fitting software for the Alpha 1 processor is based on traditional hearing device fitting software. Professional audiologists find it easy to understand and implement.

Frequency Response Table with Alpha 1 (M)



You have questions. Sophono has the answers.

Q. Who is a candidate for the Alpha 1 (M) or (S)?

A. Adults and children above the age of 5 with bone conduction thresholds better than or equal to 45 dB HL are candidates. This relates to most patients with conductive, mixed hearing and single sided deafness. The (S) system is available for use by any age patient.

Q. Basically, how does the system work?

A. The Alpha 1 (M) requires no percutaneous abutment or permanent opening of the skin. It is comprised of a surgically implanted internal plate that houses two magnets hermetically sealed in a titanium case. The external sound processor houses a bone oscillator and uses a metal disc and spacer shim to magnetically couple to the internal component and deliver auditory stimulation through the closed skin. The Alpha 1 (S) uses a softband attachment to deliver the same performance without an implant.

Q. Is there an attenuation of the vibration through the skin?

A. The patient receives the same vibrational amplitude through the skin with the magnetic implant as they do with the softband or headband.

Q. Is the magnet sufficient to secure the processor to the implant?

A. Sophono produces a number of external magnets with varying strengths to ensure firm contact and protection from skin irritation. The magnetic retention of the external processor is more than adequate for normal activity levels.

Q. Will the strength of the magnetic attraction be significant enough to cause discomfort and/or skin breakdown?

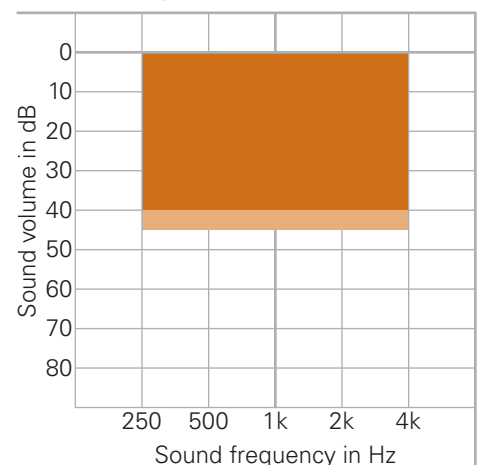
A. Patients followed over time were given the choices of magnet strength and on average preferred a magnet strength equivalent to, or less than, the pressure exerted in use of a soft band. Should skin irritation occur, the retention force can be reduced by use of a weaker external magnet.

Q. What clinical data is available on the Alpha 1 System?

A. Data collected on the first 86 implants (57 patients) implanted demonstrates significant improvement in sound field thresholds and word recognition scores. BC thresholds were between 5 – 43 dB and air bone gaps between 18 – 75 dB. Average gain was 38 +/-8 db. Average word recognition scores were 2% pre-operatively and 77% post operatively at 65 dB SPL.¹

¹Siegert, R. (2010). Magnetic Coupling of Partially Implantable Bone Conduction Hearing Aids Without Open Implants, Laryngo-Rhino-Otol, 89, 1-6.

Candidacy



The Alpha 1 System is designed for patients with conductive loss or mixed loss with bone conduction hearing thresholds better than 45 dB. The Alpha 1 can also be used for single sided deafness when the hearing ear has better bone conduction hearing thresholds better than 20 dB in the hearing ear.



Sophono Alpha 1 Technical Specifications

Features

- Non-percutaneous magnetically coupled bone anchored hearing device
- 8 channels
- 16 frequency bands
- 4 programs
- Customizable program switching and low battery warning tones
- Automatic noise reduction and feedback suppression
- Volume Control
- Available with direct audio input for use with FM receiver, telecoil and other external accessories
- 4 Colors—Champagne, Anthracite, Silver and Brown
- Custom colors are available



Champagne



Brown



Anthracite



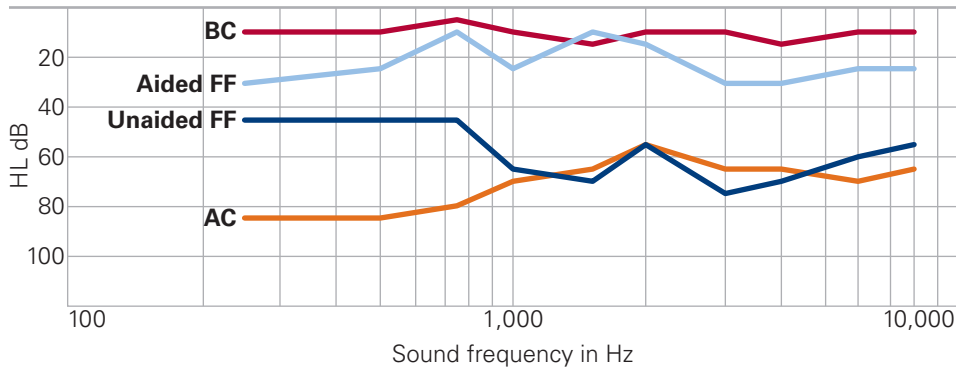
Silver

Technical Data

Gain	At 1600Hz	29 dB
	Maximum	38 dB
Peak Output		115 dB
Frequency Range		280 – 5400 Hz
Equivalent Input Noise		17 dB
Battery Current Drain		0.95 mA
Power Supply		1.3 V
Battery Size		675
Expected Battery Life		> 450 hours

Case Studies

Conductive Loss: Patient VT, Right Ear



These graphs show examples of results typical with the Alpha 1 (M) hearing system. Note that the unaided free field thresholds are better than the air conduction thresholds as these patients had normal hearing in the non-implanted ear and the masking was not perfect.

Typical Results

	Monaural		Binaural	
	Conductive Loss		Conductive Loss	
Patient ID	LD	VT	RB	ME
Age at Implant (years)	13	13	17	10
Time Implanted (months) as of February 1, 2010	3	16	29	27
Gender	F	F	F	M
Implant Ear	Right	Right	Binaural	Binaural
Average Bone Conduction Thresholds (dB HL)	10	11	11	11
Average Air Conduction Thresholds (dB HL)	67	68	69	69
Average Unaided Free Field Thresholds (dB HL)	71	62	71	49
Average Aided Free Field Thresholds (dB HL)	30	25	23	23
Unaided Speech at 65 dB (% correct)	10	15	0	10
Aided Speech at 65 dB (% correct)	75	75	100	90

Typical results are outlined in this table for patients with monaural and binaural conductive loss. Averages are computed from 500, 1000, 2000, 3000 and 4000 Hz.