

# 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**<sup>™</sup>  
bone conduction hearing solutions



## A Simple Solution

**Sophono, Inc. has developed the world's first 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 solution to the percutaneous abutment was developed in Germany and the inventors have now joined forces with Sophono, Inc to bring the world of sound an abutment free solution 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.

The Alpha 1 devices are indicated for:

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

The Alpha 1 (M) system is 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 maxillo-facial 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 headband 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 30 minute surgical procedure reduces healing time and the time to fit the device. Your patient can begin using the processor with the implant within 4 weeks.
- Dramatically reduced post-surgical complications and revisions.
- Fewer patient follow-up visits required.

### 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

- Fewer surgical steps and improved patient emotional well-being.

### Simple wound care

- The simple incision requires no special care. Simple cleaning and changes of dressing are all that is required.

### No daily wound maintenance

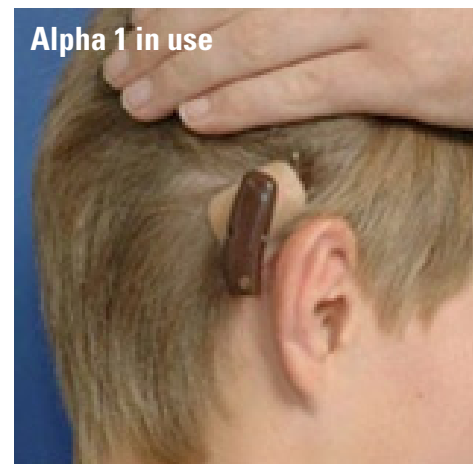
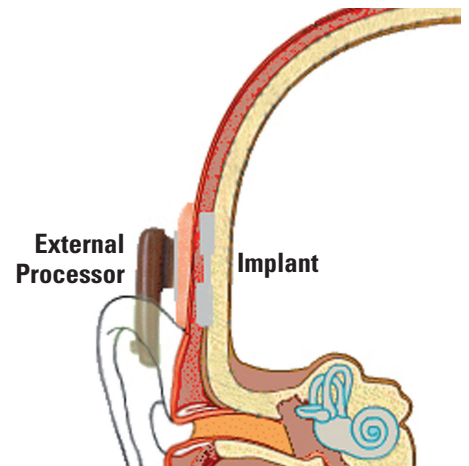
- Patients are free from the daily ordeal of abutment site care forever.

### Abutment-free hearing

- Having no external cosmetic impact improves user self-esteem.
- Eliminates painful accidental impact to and/or dislodging of implant.



Implant—actual size.



The Alpha 1 can be configured in two ways. The primary configuration is the Alpha 1(M) for use with an implanted magnet. The photos above show the device in use as well as the healed incision site for the implant.



## Features of the Alpha 1 System

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

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

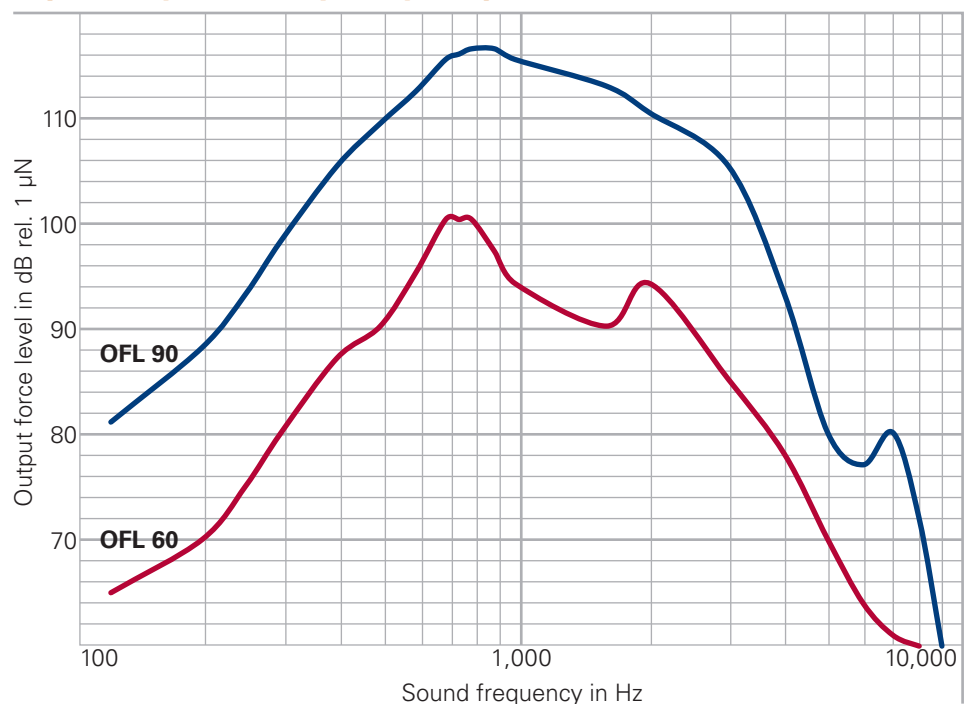
### The Alpha 1 System offers clear advantages:

- Implant lies completely under the skin
- No skin penetrating abutment
- Reliable implantation technique
- Fast healing time
- An alternative for those who said "no" to other devices

### Fitting of the Alpha 1 System is easy

The fitting software for the Alpha 1 processor is based upon traditional hearing device fitting software and is easily understood and adapted to by all professional Audiologists.

### Alpha 1 System Frequency Response Curve



## You have questions, we have answers.

### Q. Who should I consider a candidate for the Alpha1 (M)?

**A.** Adults and children above the age of 5 with bone condition thresholds better than or equal to 45 dB HL. This relates to most patients with conductive, mixed hearing and single sided deafness.

### Q. Basically, how does the system work?

**A.** The Alpha 1 (M) requires no percutaneous abutment or permanent opening 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.

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

**A.** The same physics involved when using a softband are true when using the Alpha 1 with the magnetic implant. 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?

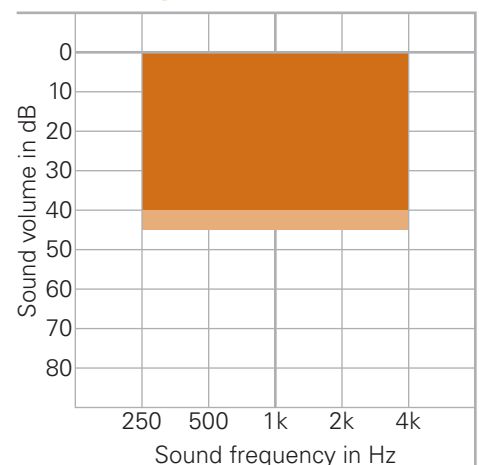
**A.** Patients followed over time were given the choices of magnet strength and on average preferred a magnet strength equivalent to, or less than, the pressure exerted in use of a soft band. Should skin irritation occur, the retention force can be reduced by use of a weaker external magnet, and skin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

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

**A.** Data collected on the first 84 implants (57 patients) implanted demonstrates significant improvement in sound field thresholds and word recognitions scores. BC thresholds were between 5 – 43dB and air bone gaps between 18 – 75 dB. Average gain was 38 +/-8db. Average word recognition scores were 2% pre-operatively and 77% post-operatively at 65dB SPL.<sup>†</sup>

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

### Candidacy



The Alpha 1 (M) is designed for patients 5 years of age and older 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 telecoil and/or FM receiver
- 4 Colors—Champagne, Anthracite, Silver and Brown
- Custom colors to match hair are available upon request



Champagne



Brown



Anthracite



Silver

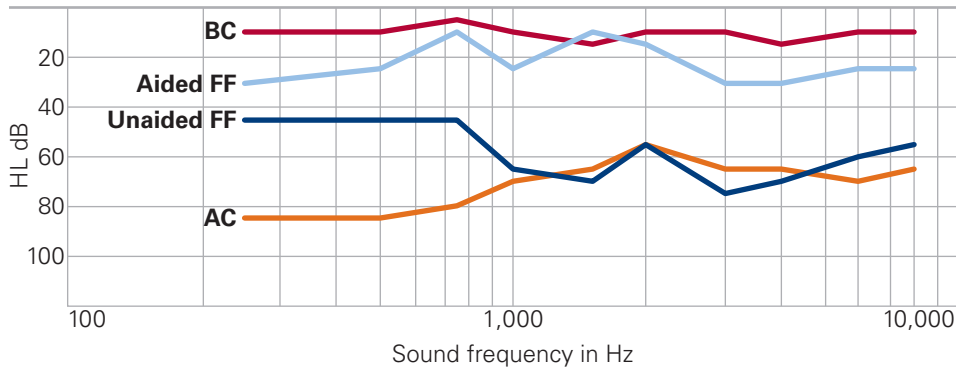
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## Technical Data

Gain	At 1600Hz	29dB
	Maximum	38 dB
Peak Output		115 dB
Frequency Range		280 – 5400Hz
Equivalent Input Noise		17 dB
Battery Current Drain		0.95 mA
Power Supply		1.3 V
Battery Size		675
Expected Battery Life		200 – 240 hours

## Case Studies

### Conductive Loss: Patient VT, Right Ear



The Alpha 1 (S) can be used by any age patient. This graph shows examples of results typical with the Alpha 1 magnetic 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
Averaged 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

This table outlines typical results for patients with monaural and binaural conductive loss as well as mixed loss. Averages are computed from 500, 1000, 2000, 3000 and 4000 Hz.