
Bone conduction hearing solutions from **Sophono**

About Sophono, Inc.

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.

Sophono, Inc.

3022 Sterling Circle, Suite 100

Boulder, CO 80301

Toll-free: 1 877 604 9441

Tel: +1 720 407 5160

Fax: +1 720 407 5168

www.sophono.com



A new solution for conductive hearing loss

Listening to Life





About Bone Anchored Hearing Systems and Sophono, Inc.

Hearing everyday sounds is often taken for granted. However, there are many who are unable to experience the joy of sound due to hearing loss. With recent advances in technology, the wonder of sound is now possible for many millions of people.

For years, a subset of the hearing impaired were not accounted for: those with conductive hearing loss (outer or middle ear); mixed hearing loss (both middle and inner ear); and single-sided, sensorineural deafness (total deafness in one ear). Bone anchored hearing devices, a solution first introduced in Europe, provided a new option for over 100,000 adults and children.

Despite significant upgrades to the quality of sound processors, traditional bone anchored hearing aids (bahas) continued to be affixed to an abutment screwed into the skull that permanently protruded percutaneously (through the skin).

That is until now.

A German physician noted that many patients declined to use baha systems because of the abutment, even though they could benefit from the device. Potential candidates did not want to have a metal piece permanently protruding from their heads, and others could not accept the high complication rate due to postoperative infections and other issues. Still others were not willing to accept the daily process of cleaning the abutment and skin around it or that hair follicles would be removed, resulting in a permanent bald spot.

Introducing the Alpha 1 System

The Alpha 1 (M), a new abutment-free bone anchored hearing system, creates a secure fixation, using internal (implanted) and external magnets. There is no abutment and none of the common complications that occur with traditional bahas.

First implanted in 2006, and approved for release via a CE mark in 2010, hundreds of Alpha 1 (M) implants and sound processors have been placed, primarily in Germany and Western Europe.

Because of the far simpler surgical procedure, there have been no reported loss of implants, nor issues with post-surgical infections.

Otomag GmbH, the small German company created to manufacture the Alpha 1 System, was acquired and integrated into Sophono, Inc. in September 2010. Based in Boulder, Colorado, Sophono, Inc. is a medical device firm dedicated to improving the hearing and the quality of life of those it serves.





Listening to Life

You now have a choice.

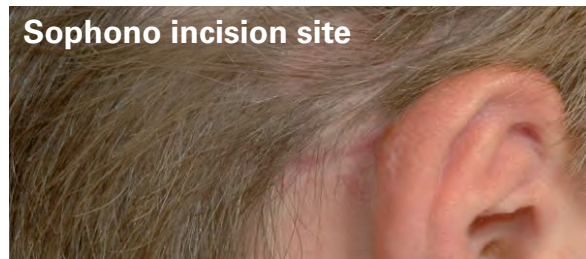
The Alpha 1 System offers convenience, cosmetic enhancement and freedom, with no sacrifice to performance. It delivers a fully digital solution for those with bone conduction hearing thresholds of 45 dB or less. Because the Alpha 1 (M) is abutment free, it eliminates the necessity of daily site cleansing. Your Alpha 1 device will be state of the art for years to come.

Surgery is simple and healing time is relatively short. Your Alpha 1 (M) is then fully functional.

The Alpha 1 (S), which functions without an implant, is an external sound processor used with a soft band or a headband for those not ready to commit to surgery, or for patients under 5 years old. Your audiologist or doctor can help you choose the right components for you.

Sphono, Inc. ensures our products are well researched, made with care, thoroughly tested and will give you the ability to clearly participate in Listening to Life.

Sophono incision site



Other BAHA incision site



Who should consider the Alpha 1?

Anyone with the types of hearing loss listed below is a candidate:

Conductive Hearing Loss

The damaged outer or middle ear is bypassed by placing sound reception directly onto the skull and to the inner ear.

Mixed Hearing Loss

The middle or inner ear may no longer process sound. The bone of the skull directs sound to the cochlea.

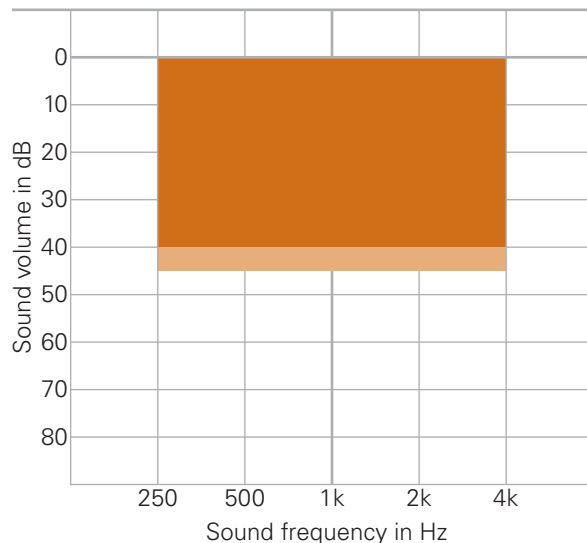
Single Sided Sensorineural Deafness

For total deafness in one ear, sound projected to the cochlea provides clarity and direction of sound better than hearing aids.

Alpha 1/Baha Comparison

	Alpha 1 (M)	Bahas
Implant lies completely under the skin	Yes	No
Hair follicles need to be removed	No	Yes
Healing time before use	1 month	2+ months
Digital Signal Processor	Yes	Yes

Candidacy Chart



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 bone conduction hearing thresholds better than 20 dB in the hearing ear.

Experience the SOUND of Sophono



Champagne



Anthracite



Silver



Brown

The Alpha 1 sound processor is offered in four colors: Champagne, Brown, Anthracite and Silver. It features eight channels, 16 frequency bands and four programmable memories (for easy change of program when surroundings change). The Alpha 1 sound processor provides superb digital capabilities comparable to other bone-anchored hearing aids.

Features

- Non-percutaneous, magnetically coupled bone anchored hearing aid
- 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 to match hair are available upon request

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

Frequently Asked Questions

Q. What special care must I give to my incision site?

A. Because there is no percutaneous protrusion, there are no daily routines for cleaning the skin once the incision line from surgery is healed.

Q. Will I have to have hair permanently removed?

A. No. In fact, after healing the hair will grow back over the incision site.

Q. Do children need to learn a daily routine or have to take special care with their Alpha 1?

A. No. Once the surgical incision is healed, there is no daily routine for them to learn. Additionally, there is no protruding abutment to catch on material or be disturbed by a playmate that can cause the need for a surgical revision.

Q. When can an Alpha 1 user return to normal activity post – surgically?

A. Because the implant is placed on an outpatient basis, patients routinely return home the same day. One day of rest is all that is usually required before returning to normal activity.

Q. Should the Alpha 1 be worn all the time?

A. Sleeping is easier without the device, and the processor should not be subjected to water from swimming, baths or showers. Other than that, wear it as much as you like. If you plan on strenuous physical activity where jarring might occur, Sophono offers a set of stronger magnets that will keep the unit securely in place when engaging in rigorous exercise or sports.



Q. What type of batteries are required, and where do I get them?

A. The Alpha 1 processor uses 675 type batteries. Many pharmacies and supermarkets carry these batteries, and they are available from your audiologist.

Q. How can I obtain an Alpha 1 for myself or my child?

A. Simply contact your physician or audiologist to see if Alpha 1 is right for you or your child. They need only to contact us, and Sophono and your healthcare provider will do the rest.