Rev	Issue	Description of Change	Originator	Effective Date	TW#
0	1	Initial draft	D. Buschmann	15. Feb. 2017	TW138726
0	2	FCC Compliance information added	D. Buschmann	21. Feb. 2017	TW139413
0	3	FCC Compliance information modified	P. Lampacher		

Bonebridge
Samba audio processor
Model BB Left (51559) and BB Right (51560)

Instructions for use

Table of contents

Contents of the package

- Samba audio processor
- Remote control
- Instructions for use
- Audio processor Registration Card and envelope
- Audio processor batteries (Type 675 zinc-air button cell) in 1 dial card package
- Remote control batteries (Type AAA), 2 pieces
- Attachments: Hair clip (large and small)
- Activity Clip
- 8 additional interchangeable design covers
- Samba case

Introduction

This user manual covers operation and maintenance of the Samba audio processor for the Bonebridge System.

You should read this manual carefully and completely so that you are familiar with the operation and maintenance of your audio processor. Please do not hesitate to contact your audiologist, clinic or MED-EL representative with any additional questions you may have.

Part One – General information gives information on indications, contraindications, maintenance and storing of the audio processor.

Part Two – User information is intended to complement information provided by your doctor or audiologist. This includes basic information of how to use, maintain and troubleshoot your device.

Part Three – Audiologist information is intended for audiologists and provides additional detailed instructions on fitting, adapting and programming the Samba audio processor. An advanced troubleshooting-section in the end of part three will help to detect the causes of malfunctions and give instructions to resolve them.

Part Four - Warnings and precautions contains all relevant warnings and precautions, as well as information on the warranty and the registration card.

Part Five – Clinical trial description describes the clinical trial and gives details on clinical studies and their results.

Part Six – Samba technical data includes technical data, explanation to symbols used in this manual and manufacturer‘s declaration.

Part Seven – The remote control contains information on the remote control.

Read carefully the section “Part Four – Warnings and precautions”!

Information particularly relevant for parents of implanted children is added, wherever necessary, in this font and with this symbol.

Caution

The Samba audio processor is only to be used with a Bonebridge Bone Conduction Implant (BCI 601)!

Part One – General information

Device description

The Bonebridge is an osseointegrated bone conduction implant system intended to provide a level of useful sound perception to individuals with hearing loss.

The Bonebridge System consists of two major components: The Bone Conduction Implant, called the BCI, and the external audio processor, e.g. the Samba.

The externally worn audio processor is attached to the patient’s head, behind the ear. A magnet in the audio processor is attracted to an opposing magnet within the implant. The audio processor includes two microphones to pick up sound from the environment, a sound processing circuitry to modify the output signal to the customer’s specific requirements, and a digital compression processor. The device is powered by a single standard battery. The Bonebridge System is activated by simply fitting the audio processor.

The implanted part of the Bonebridge System consists of the internal coil and the Bone Conduction Floating Mass Transducer™ (BC-FMT). A signal from the audio processor is transferred across the skin to the internal coil. The internal coil then relays the signal to the BC-FMT. The BC-FMT converts the signal to vibrations, which are interpreted by the customer as sound. The implanted portion of the Bonebridge System is not operated directly by the user and has no specific maintenance requirements. The user does, however, have operation and maintenance responsibilities for the Samba audio processor and its accessories.

Samba audio processor overview

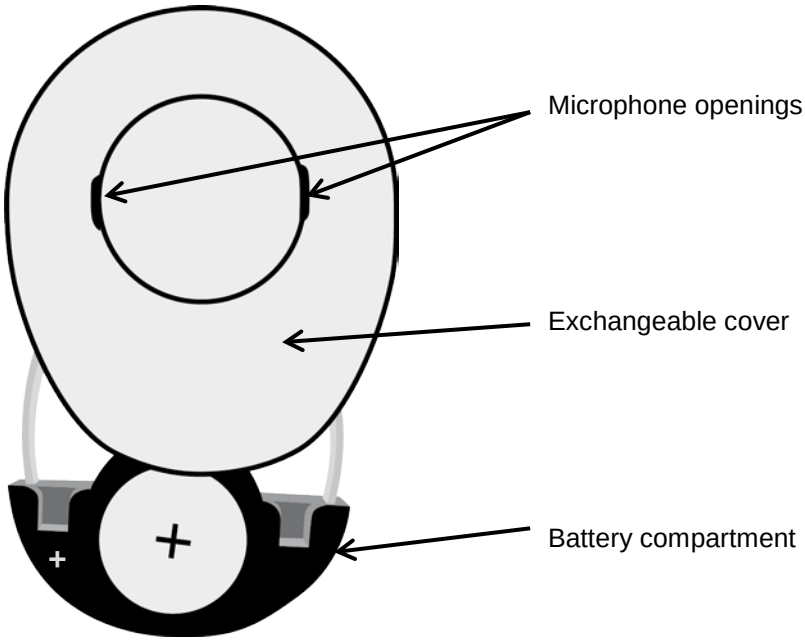


Figure 1: Samba audio processor overview (opened position)

Intended use – Indications – Contraindications

Intended use

The Samba audio processor is an external part of the Bonebridge. The Bonebridge is intended to improve hearing for patients with conductive or mixed hearing losses, bilateral fitting, and single sided deafness.

The Bonebridge augments hearing by providing acoustic information to the inner ear via bone conduction. This is achieved by actuating a vibratory transducer, which is implanted in the mastoid bone.

Indications

Patients who have received a BCI 601 are indicated to use the Samba audio processor.

Because the Samba is a component of the Bonebridge System, all indications for the Bonebridge are applicable.

Contraindications

Because the Samba is a component of the Bonebridge System, all contraindications for the Bonebridge are applicable.

NOTE *Important information related to indications, contraindications, warnings and risks for your implant are shipped in a separate document (instructions for use of the implant) to your clinic together with the implant. If you want to review this information, please contact your clinic or MED-EL.*

Intolerances

Persons known to be intolerant of the materials used in the implant or the audio processor should not receive a Bonebridge System. Please refer to **Part Five – Samba technical data** of this manual for materials of the Bonebridge System in tissue contact.

Maintenance

Your Samba audio processor is designed for durability and reliability. When handled with sufficient care, it will function for a long time. The expected service life of your audio processor is 5 years.

Other than replacing the battery, there are no serviceable features on the audio processor. If your device does not work properly, check the section **Troubleshooting** in **Part Two – User information**. If you cannot solve the problem following the recommended actions in the troubleshooting section, please return to your audiologist for advice.

Please have your Samba checked by your audiologist at least every two years.

Cleaning

MED-EL recommends to clean the Samba weekly for hygienic reasons. Only clean the outside of the device. Do not clean the Samba in or under water. Use a damp cloth to gently clean your audio processor. If necessary, use nonabrasive household soap together with a damp cloth. Do not use aggressive cleaning agents. Prevent water from running into the Samba via the microphone openings or the battery compartment.

Storage, handling and disposal

When not in use, the Samba should be kept in the Samba case provided. You can remove the battery from the Samba for storage to extend battery life and you can store the battery in the Samba case. For doing this, place the battery in the recess of the Samba case. The positive (+) pole (i.e. the flat side of the battery) must face downward (see Figure 2).

Figure 2: Samba case with Samba audio processor and its battery (with positive pole (+) in downward position)

If you live in a humid climate or perspire heavily, the audio processor should be placed in a drying container instead of in the Samba case when it is not worn. Drying containers are effective for a limited period of time, depending on the humidity in your area. Follow the instructions provided with the drying container.

NOTE *Please store the Samba in a dry place and protect it from direct sunlight.*

The external components of your Bonebridge System must not be disposed of with your other household waste. You are responsible for disposing all external components of your Bonebridge System by returning them to MED-EL or a local representative.

Part Two – User information

This section is intended for users of Samba audio processors and contains important information on handling and operation.

Switching the Samba on/off

To switch the Samba on, insert a battery and close the battery compartment completely. To switch the Samba off, open the battery compartment. It is sufficient to open the battery compartment about 5 mm (1/4 in.).

The Samba audio processor transmits sound information even when it is not attached to the head. To extend battery life, the battery compartment should be opened whenever the audio processor is not in use. This disconnects the battery and thus switches the audio processor off.

Activating the Bonebridge System

The Bonebridge System is activated when the Samba is switched on and placed over the internal coil of the implant.

Fitting the Samba to the implant

The Samba audio processor is kept in position over the implant by magnetic force. Magnets of different strength can be used to offer best comfort for every individual.

If wearing the audio processor causes redness or discomfort to your skin, or if the audio processor seems to fall off frequently, return to your audiologist to have the magnet exchanged.

NOTE *Please check your skin over the implant regularly during the first month of use.*

Make sure the audio processor marked with the symbol L is used on the left side, and the audio processor marked with the symbol R on the right side. The mark can be found on the bottom of the Samba audio processor (see Figure 3).

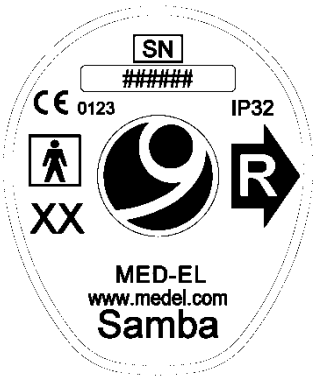


Figure 3: Bottom of the Samba audio processor (marked for the right side)

NOTE *The functionality of the audio processor is influenced by its orientation.*

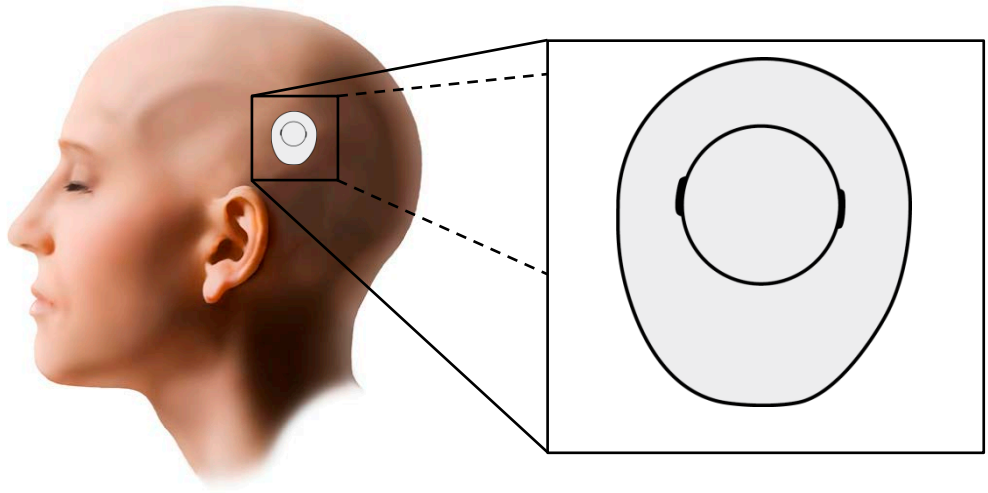


Figure 4: Placing the Samba on the head

The best results are achieved when the Samba is placed with the microphone openings facing towards the top (as shown in Figure 4).

Hair trimming

Occasionally you may need to trim or shave your hair to about 6 mm (1/4 in.) in the area directly over the implant. In most cases the patch of trimmed hair can be easily concealed by the remainder of your hair.

Using the Activity Clip

The Activity Clip is an optional magnetic accessory that can be used for additional fixation of the audio processor (also named Single-Unit Processor) to the hair. Improved fixation may be desirable for example during sports activities. The instructions for use for the Activity Clip are included in the clip's packaging.

Changing the program

The Samba audio processor offers up to five programs to choose from.

The five program settings are freely programmable by the audiologist. One possibility is that the five programs feature five different volume settings. Another possibility is that programs can be used to switch between certain features of the signal processing (e.g. Program 1 – ambient sound, Program 2 – optimized for noisy environment, Program 3 – optimized for music, Program 4 and 5 – inactive). Programs are activated / deactivated by your audiologist during programming.

Your Samba audio processor is equipped with wireless technology and can therefore be controlled by a remote control. Please refer to section **Part Six – The remote control** for further information.

NOTE *After turning the audio processor on, the first program is always active.*

NOTE *In case of a loss of the remote control the audio processor still can be used for best benefit. However, it is not possible to change or modify the selected program without the remote control. It is recommended to set program 1 for the most commonly used hearing situation. Just remove and insert the battery to run the settings of program 1.*

Alternative remote control

Apart from the remote control distributed by MED-EL and explained in the section **Part Six – The remote control**, the Siemens miniTEK is compatible for the use with your Samba audio processor. It can be purchased separately.

Please refer to the appertaining user guide for information about the miniTEK. This user guide is provided by the manufacturer of the respective remote control.

NOTE *Wireless connectivity feature is available with the Siemens miniTEK, sold separately. Sivantos is not responsible for the operation with the Samba or its compliance with safety and regulatory standards in operation with the Samba.*

Batteries

Battery status

The Samba is designed to be very energy-efficient and has a battery life of approximately three days. This is based on an average daily use of 16 hours at an average volume level. The battery life of the audio processor may vary depending on selected program, environment, and duration of use. The battery should be replaced regularly or when the sound level of the Bonebridge System drops off dramatically.

If the battery is low, it must be replaced when you hear a series of beeps. The loudness and pitch of the beeps can be preset by your audiologist. Additionally, if you notice a change in sound quality, it is recommended that you replace the battery as your first troubleshooting step. If the problem persists, contact your audiologist.

Changing the battery

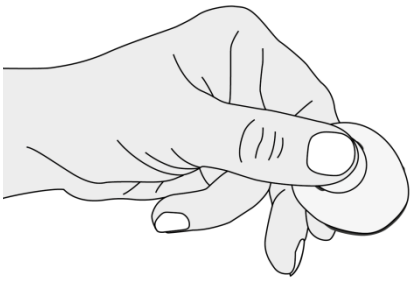
Caution

Use only size 675 zinc–air batteries (also called PR44 batteries). Using batteries of other sizes, voltages, or power levels may cause irreparable damage to the audio processor and will void the warranty.

Never try to recharge 675 zinc–air batteries. Do not throw batteries into fire or try to open them.

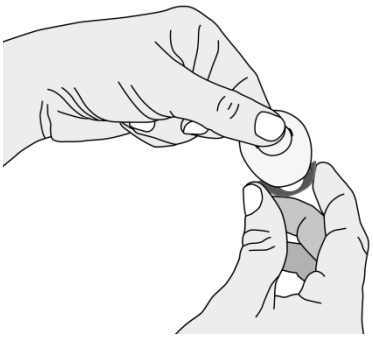
Open battery compartment

- Hold the Samba between your fingers. Place one finger on the top of the audio processor and another on the bottom.

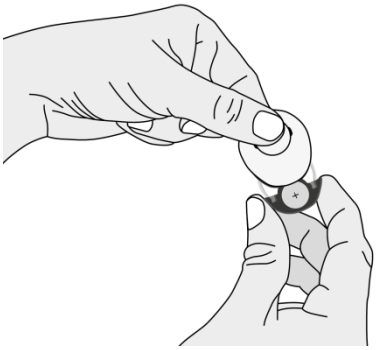


First open one side of the battery compartment, then open the other side.

NOTE *It does not matter which side is opened first.*



Open the battery compartment until the battery is completely visible.



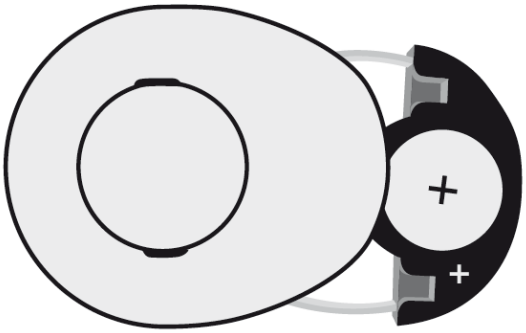
Remove battery

- Turn the Samba upside-down carefully, allowing the battery to drop out.

  Do not apply force if the battery gets stuck in the battery compartment, but push it back down and try again.

Insert new battery

- Take a new 675 zinc-air battery and remove the foil covering the battery to activate the battery.
- Place the battery in the audio processor's battery compartment
- Make sure that the battery's polarity matches the marking on the battery compartment.
- The positive (+) pole (i.e. the flat side of the battery) must be on top.
- If the battery does not slide in smoothly, it may be upside down. Do not force the battery into the battery compartment.



Close battery compartment

- Slide the battery compartment into the audio processor.
- Do not force the battery compartment to close, check for the correct position of the battery and try again.

Spare battery

It is recommended that you keep a spare battery with you, but it must be carried in its original packaging or in another container that will keep it clean and away from metal. Be sure not to remove the foil covering the battery until just prior to inserting it in the audio processor.

Disposal of battery

Always remove used batteries immediately to avoid battery leakage and possible damage to the audio processor. To avoid environmental pollution, do not throw batteries into household trash. Recycle or dispose of used batteries according to local regulations.

Parents are advised to regularly change the battery as necessary and, if in doubt, check the status of the battery.

Warning

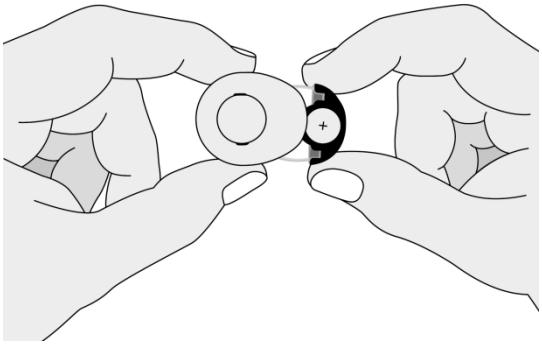
To prevent children and mentally challenged people from swallowing or choking on batteries, always keep new and used batteries out of the reach of children and mentally challenged people.

NOTE *If you are the parent/guardian/carer of a Bonebridge System user and the user refuses to wear the system or indicates uncomfortable hearing sensations, remove the audio processor immediately and have the user's system checked at the clinic.*

Changing the cover

The Samba is provided with different exchangeable covers, which you can change easily. The different covers can be used to change and customize the appearance of your Samba.

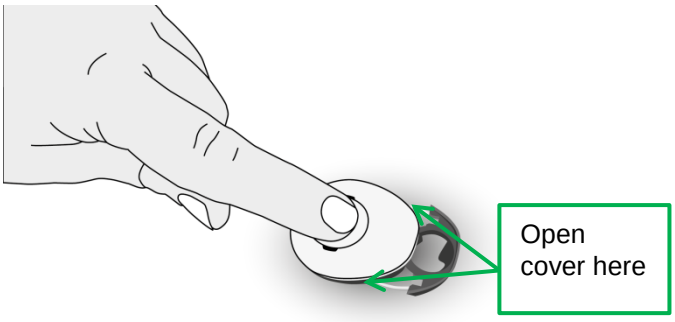
Open the battery compartment and remove the battery (see **Changing the battery**).

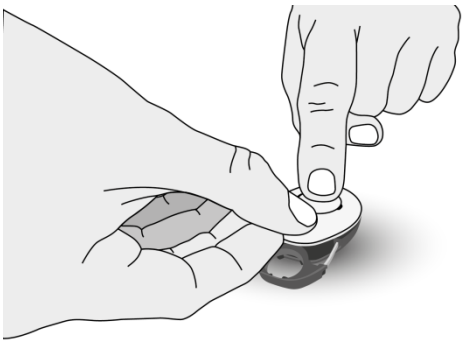


To remove the cover:

- Place the Samba on an even surface (e.g. table) and put one finger on top.
- The cover should be opened from the sides.
- First, lift one side of the cover, then lift the other side.

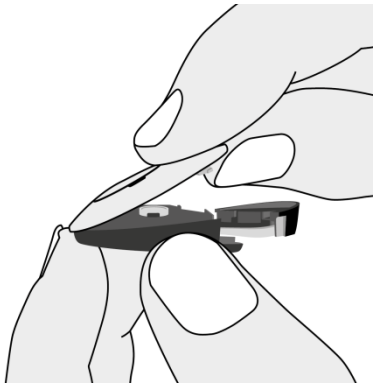
NOTE *It does not matter which side is opened first.*



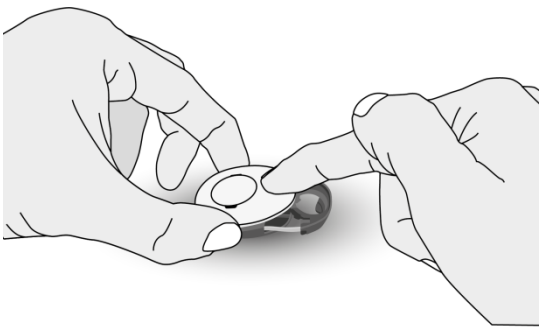


Remove the cover completely from the audio processor.

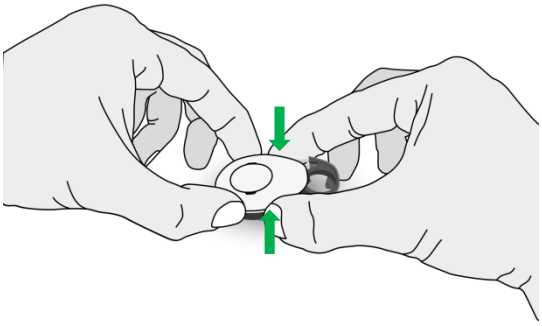
Place the new cover on the Samba. First, place the back side of the cover on the audio processor.



Place the Samba on an even surface (e.g. table) and press the cover down. Make sure that it snaps into place.

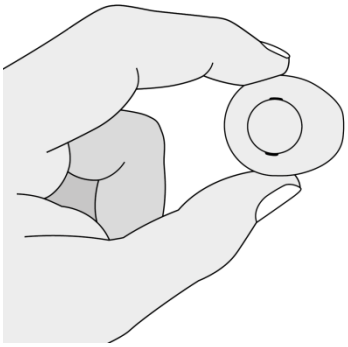


Press the sides just below the cover and behind the opened battery compartment together to ensure that the cover is in the correct position.



Insert a battery and close the battery compartment (see **Changing the battery**).

NOTE *Always attach the cover before you close the battery compartment*



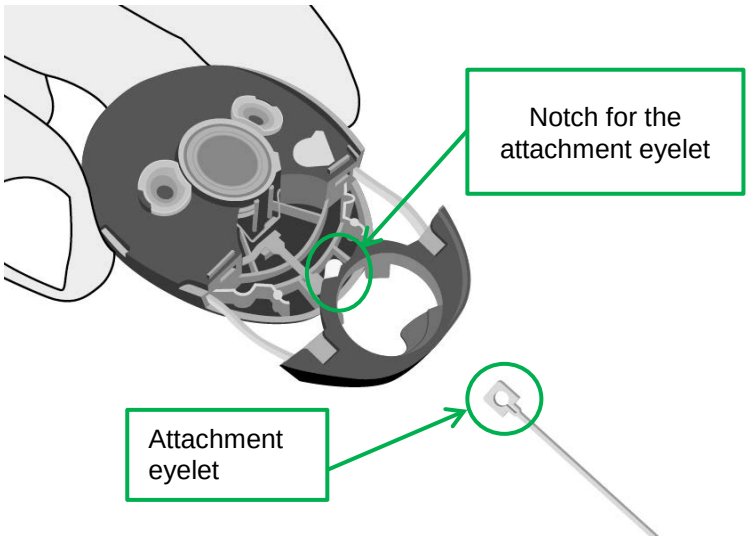
Using the hair clip

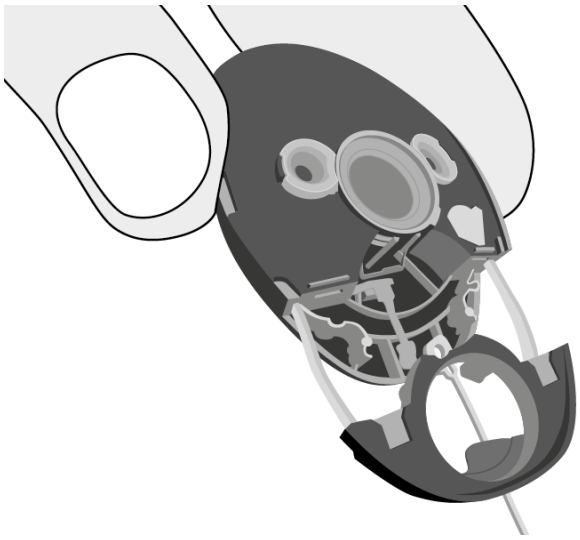
You can use the provided attachment eyelet or replace it with one of the hair clips to prevent an accidental loss of the Samba. Simply attach the hair clip to a strand of hair after fitting the audio processor to the implant.

The attachment eyelet is attached to the Samba on delivery. If necessary, you can replace or reattach it as follows:

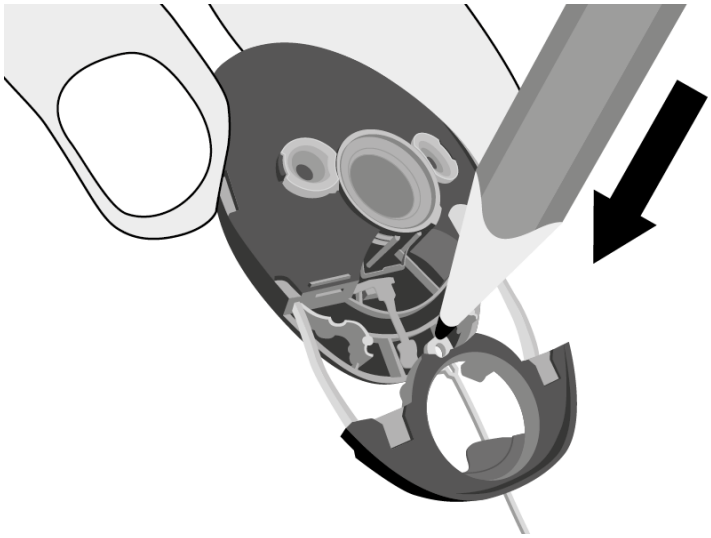
Remove the cover and the battery of your audio processor (see **Changing the cover**).

Pass the attachment eyelet under the battery compartment and insert it in the small notch under the battery compartment.





Press the attachment eyelet down to fixate it in the audio processor. Use a small pointed object like a pencil for doing this.



Insert a battery and reattach the cover (see **Changing the cover**).

Troubleshooting

Problem in your audio processor	Possible cause	Recommended action
No sound	No battery inserted	Insert a new battery (see **Changing the battery** in **Part Two – User information**)
	Battery empty	Replace the battery (see **Changing the battery** in **Part Two – User information**)
	Foil covering the battery still in place	Remove the foil covering the battery (see **Changing the battery** in **Part Two – User information**)
	Battery inserted upside-down	Check polarity, flat side (+) must be on top (see **Changing the battery** in **Part Two – User information**)
	Microphone inlets blocked	Carefully try to remove any dirt /obstructions from the microphone inlets. If you cannot remove the obstruction easily, contact your audiologist and/or MED-EL representative.

Problem in your audio processor	Possible cause	Recommended action
	Loss of electrical connection due to draggled battery contacts	Remove the cover (see **Changing the Cover** in **Part Two – User information**), check visible battery contacts and clean carefully if necessary. Use a cotton swab and a small amount of cleaning alcohol. Gently wipe dry after cleaning.
	No air flow to battery	Check battery compartment for gap, remove dirt/obstruction
	Device damaged (e.g. by moisture/shock)	Contact your audiologist and/or MED-EL representative
	Device turned off unknowingly via the remote control	Turn on the Samba using the remote control (see **Part Six – The remote control**)
Sound weak	Battery low	Replace battery (see **Changing the battery** in **Part Two – User information**)
	Microphone inlets blocked	Carefully try to remove any dirt /obstructions from the microphone inlets. If you cannot remove the obstruction easily, contact your audiologist and/or MED-EL representative.
	Incorrect position of audio processor	Adjust the orientation of the audio processor (see **Fitting the Samba to the implant** in **Part Two – User information**)
	Volume is turned too low	Use the remote control to reset the Samba to the default volume program (see **Part Six – The remote control**)
Sound too loud	Volume is turned too high	Use the remote control to reset the Samba to the default volume program (see **Part Six – The remote control**)
	Internal signal processing defective	If you cannot turn down the volume with the remote control, stop using the audio processor and contact your audiologist and/or MED-EL representative
Audio processor cannot be switched on	Battery compartment blocked	Check for correct battery position, carefully push down the battery when closing the battery compartment (see **Changing the battery** in **Part Two – User information**)
Battery insertion not possible	Wrong battery type	Use 675 zinc–air batteries (PR44 batteries) only
	Battery upside-down	Turn battery, flat side (+) must be on top (see **Changing the battery** in **Part Two – User information**)
Audio processor falls off frequently	Hair over implant too long	Shave hair over implant to about 6 mm (1/4 in.)
	Magnet too weak	Contact your audiologist
Skin irritation over implant	Allergic reaction	Stop wearing your audio processor and contact your audiologist. Please refer to **Part Five – Samba technical data** of this manual for materials of the Bonebridge System in tissue contact.
	Attachment force too high	Contact your audiologist
Program selection not possible	Only one program activated	Contact your audiologist
	Remote control not working	If program selection is not possible, refer to the solutions provided under **Remote control not working** (see **Troubleshooting** in **Part Two – User information**)

Problem in your audio processor	Possible cause	Recommended action
	Electrical problems	If all other options listed in this table fail, contact your audiologist and/or MED-EL representative
Remote control not working	Distance between audio processor and remote control exceeds operating distance	Bring the remote control closer to the audio processor and/or change the orientation of the remote control (see **Part Six – The remote control**)
	Key lock activated	Check if the key lock is activated and deactivate it, if necessary (see **Part Six – The remote control**)
	Batteries empty	Replace the batteries (see **Part Six – The remote control**)
	Another remote control affects your audio processor	Contact your audiologist

Caution

Never try to open or repair the Samba yourself. Always contact your audiologist or your local MED-EL representative.

NOTE *If the housing of the audio processor becomes damaged or a problem persists after trying the recommended actions described in the troubleshooting section, contact your audiologist or MED-EL representative.*

Signal interference with other equipment

Sound is picked up by the microphones of the Samba and is then transmitted to the Bonebridge implant. A short-range wireless technology called “Near Field Magnetic Induction (NFMI)” is used for this transmission. Transmissions of up to approximately 10 mm (0.39 in.) are possible in the Bonebridge System with this technology. The system has been tested to and complies with IEC 60601-1-2. Additionally, it has been tested for interference with commonly used wireless devices.

Please keep the following precautions in mind:

- Some devices such as hand-held computers, mobile telephones and theft and metal detection systems may cause interference with the Bonebridge System.
- Do not stay in areas where theft and metal detection systems are used.
- Remove the audio processor when you are moving through security checkpoints. Alert the security personnel that you have a Bonebridge implanted. It is advised that you carry your Bonebridge User Identification Card at all times.
- Move away from any possible source of interference when you experience any audible interferences.

If you experience any unusual sound and the condition persists, contact your audiologist or your local MED-EL representative.

Part Three – Audiologist information

Caution

This section is intended for audiologists and other professionals like hearing aid programmers.

If your patient refuses to wear the system or indicates uncomfortable hearing sensations, remove the audio processor immediately and check the user's system.

Please do not hesitate to contact your MED-EL representative for any information not provided in this manual.

Also refer to the section **Samba audio processor overview** in **Part One – General information** for more details.

Supplementary equipment to program and handle the Samba

- Programming cable CS64 (provided by MED-EL, catalogue number 51768)
- Battery pill (provided by MED-EL, catalogue number 51769)
- SYMFIT 7.0 (programming software provided by MED-EL, catalogue number 51529)
- Connexx 6.5.5 (programming software provided by Sivantos)
- ConnexxLink (wireless programming system provided by Sivantos)
- Magnet lid driver (provided by MED-EL, catalogue number 51771)
- Magnets of different strengths (provided by MED-EL, check the current catalogue numbers in MED-EL's catalogue)

Information for audiologists and recommended training

Audiologists should be experienced in the fitting of hearing aids and the application of standard audiological tests and measures. It is recommended that audiologists receive specific training regarding the evaluation of candidates and fitting of the Bonebridge System in adults as well as in children.

Supplementary equipment to be connected to the Samba audio processor for fitting by the audiologist, the programming cable and the battery pill (both available separately) must be compliant with *Type BF* of the electrical safety standard IEC 60601-1 / EN 60601-1, indicated by the symbol . Anyone who connects additional equipment to the audio processor's programming interface configures a medical system, and is, therefore, responsible that the system complies with the requirements of IEC 60601-1 electrical safety standard. If there are any questions, please consult with MED-EL or the regional representative.

Also refer to the hearing aid programmer's manual (e.g. HI-PRO, NOAHLink).

Programming the Samba audio processor

The Samba can be programmed either wired or wireless.

NOTE *The remote control is not activated by default and has to be activated with the programming software (SYMFIT 7.0 or higher).*

Wired programming

Follow these steps for the wired programming of the Samba:

Caution

Battery pills and programming cables not intended to be used with the Samba can cause irreparable damage to the device. Only use the battery pill and the programming cable provided.

- Open the battery compartment and remove the battery. Refer to section **Changing the battery** in **Part Two – User Information** for information regarding opening the battery compartment.
- Insert the battery pill straight into the battery compartment (see Figure 5).

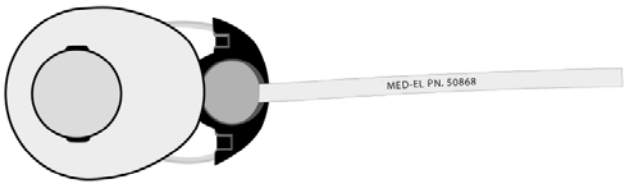


Figure 5: Samba with battery pill inserted

- Close the battery compartment. Do not force the battery compartment to close, check for the correct position of the battery pill and try again.
- Connect the programming cable CS64 to the battery pill.
- Connect the programming cable CS64 to the hearing aid programmer.
- Place the audio processor over the implant.
- Program the audio processor. Follow the instructions in the SYMFIT 7.0 or higher software manual.
- After programming, remove the programming cable CS64 and the battery pill from the audio processor. Insert a new type 675 zinc-air button cell battery into the audio processor.
- Close the battery compartment.

Wireless programming

The use of ConnexxLink is necessary for the wireless programming of the Samba. ConnexxLink is not provided with the audio processor and has to be purchased separately. Please follow the instructions provided with the user manual of ConnexxLink.

Changing the magnet assembly

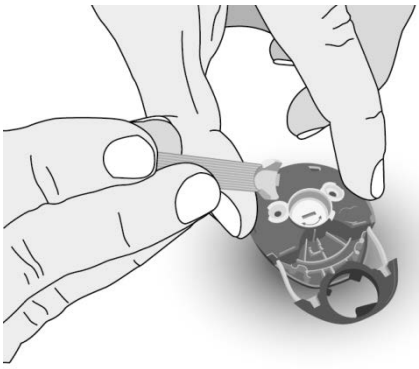
The Samba is held in place only by magnetic attraction. The magnet assembly is exchangeable. In some cases it may be necessary to use a stronger or weaker magnet.

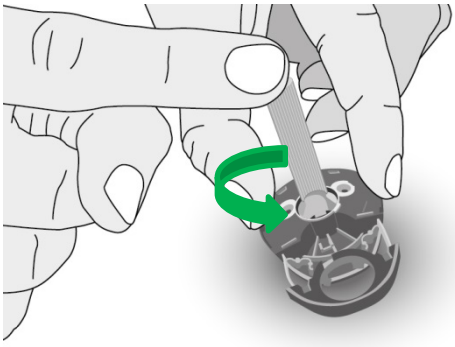
To change the magnet assembly, follow these steps:

Remove the cover (see section **Changing the cover** in **Part Two – User information**)

Use the provided magnet lid driver to remove the magnet lid together with the magnet.

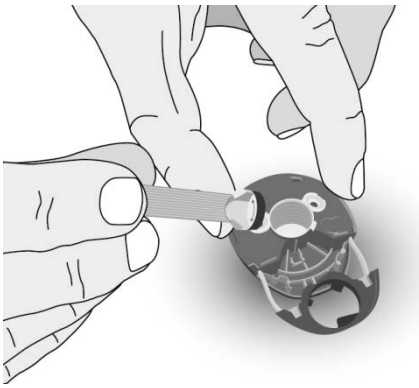
- Place the tip of the magnet lid driver into the groove of the magnet lid and turn the magnet lid driver anti-clockwise. Magnet lid driver and magnet attract each other magnetically and thus hold the magnet lid too.

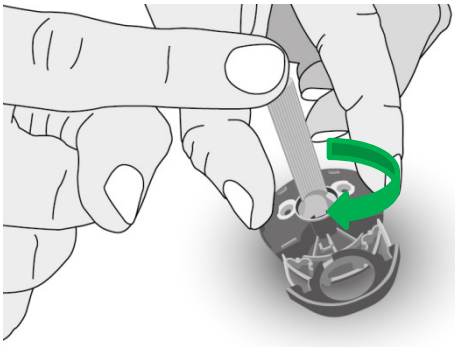




Use the provided magnet lid driver to insert the chosen magnet together with the magnet lid:

- Place the magnet lid between the magnet and the magnet lid driver. The tip of the magnet lid driver must be placed into the groove of the magnet lid. Magnet lid driver and magnet attract each other magnetically and thus hold the magnet lid too.
- Turn the magnet lid driver clockwise to tighten the magnet and the magnet lid in the correct position.





Attach the cover again (see section **Changing the cover** in **Part Two – User information)**.

Advanced troubleshooting

This section only deals with problems not covered in the section **Troubleshooting** in **Part Two – User information**.

Problem	Possible cause	Recommended action
No sound or sound too weak	Microphone inlets blocked	Remove obstruction/dirt, or contact your MED-EL representative
Sound too loud	Internal signal processing defective	Stop patient from using the audio processor and adapt the characteristics of the affected program. See **Part Three – Audiologist information, Programming the Samba audio processor** for further details. Otherwise contact your MED-EL representative
Audio processor falls off frequently	Magnet too weak	Exchange the magnet assembly with a stronger version (see **Part Three – Audiologist information, Changing the magnet assembly** for more details)
	Magnet positioning incorrect	Check for correct magnet position in housing (see **Part Three – Audiologist information, Changing the magnet assembly** for more details)
Skin irritation over implant	Attachment force too high	Exchange the magnet assembly with a weaker version (see **Part Three – Audiologist information, Changing the magnet assembly** for more details)
Program selection not possible	Electrical problems	Exchange the remote control. If problem persists, contact your MED-EL representative
Insertion of battery pill not possible	Battery pill not inserted correctly	Insert the battery pill straight into the battery compartment (see **Part Three – Audiologist information, Programming the Samba audio processor** for more details)
	Programming contacts blocked/dirty/corroded	Remove obstruction/dirt, or contact your MED-EL representative
Connection of programming cable CS64 to battery pill not possible	Programming contacts blocked/dirty/corroded	Remove obstruction/dirt using a cotton swab and a small amount of cleaning alcohol, or contact your MED-EL representative
Device failure during/after programming	Intermittence during programming	If problem persists after reset of audio processor, contact your MED-EL representative
Remote control not working	Another remote control affects the audio processor	Change the wireless address to avoid interference.

NOTE *If the audio processor becomes damaged or a problem persists after trying the recommended actions described in the troubleshooting sections, contact your MED-EL representative.*

Part Four – Warnings and precautions

The following section describes warnings and general precautions that apply to your Bonebridge System. Read the following section carefully. If you have any questions, consult the surgeon who performed your implant surgery.

Always inform any physician that you are visiting for medical treatment that you have a Bonebridge implanted. He or she may not be aware that you have an implant, and this knowledge may affect your treatment.

⚠ *Warnings*

The device must not be altered and may only be used as intended!

Electromagnetic compatibility

The Bonebridge System needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this manual.

Portable and mobile Radio Frequency (RF) communications equipment may affect the performance of your Samba audio processor.

Precautions

The Samba audio processor contains complex electronic parts. These parts are durable but must be treated with care. The audio processor must never be disassembled by anyone other than authorized service personnel or the warranty will be void. The magnet compartment must be opened only by a trained audiologist or professional. All sound adjustments shall be made only by a qualified audiologist.

The audio processor is specifically adjusted for each individual user. Never exchange your audio processor with another Bonebridge or Vibrant Soundbridge System user.

If you are the parent/guardian/carer of a Bonebridge System user and the user refuses to wear the system or indicates uncomfortable hearing sensations, remove the audio processor immediately and have the user's system checked at the clinic.

Before switching on the Samba audio processor, check it for proper mechanical condition, e.g. for loose or broken parts and for the presence of the attachment eyelet. In case of problems, the audio processor should not be switched on. Read the section **Troubleshooting** in **Part Two – User information** or contact your audiologist and/or MED-EL representative.

Head trauma

A blow to the head may damage the implant and result in its failure. Implant recipients are strongly encouraged to use head protection whenever possible during sports and activities in which head trauma is a risk (i.e., bicycling, motorcycling, skiing) and should never participate in sports in which head trauma is part of the activity (i.e., boxing).

Ingestion of small parts

The audio processor contains small parts that may be hazardous if swallowed. Children should be instructed not to swallow or put any components of the Bonebridge System into their mouths and not to play with any components.

Use your own audio processor

Patients should use only the audio processor that has been specifically programmed for them by their clinician. Use of a different audio processor may cause distorted or uncomfortably loud sounds.

Water damage

Protect the audio processor from water or perspiration. Never bathe or shower while wearing the audio processor. The warranty is void when damage is caused by moisture. When playing sports or engaging in other activities in which you may perspire a lot, it is recommended that you wear a sweatband to absorb moisture near the audio processor. The use of a drying container (not provided with your device) in high humidity or moist conditions is also recommended.

If the Samba gets wet, switch it off as quickly as possible, remove the battery from the battery compartment and gently wipe the outside dry, using a soft absorbent cloth. Then allow the audio processor to dry out (preferably overnight). If in doubt, repeat the drying process.

If the problem persists, return the audio processor to your audiologist or MED-EL representative for repair or replacement.

Dirt damage

Avoid getting sand or dirt into any part of the audio processor. If the audio processor is not working, try the actions recommended in the section **Troubleshooting** in **Part Two – User information**. If the problem persists, return the audio processor to your audiologist or MED-EL representative for repair or replacement.

Range of benefits

The Bonebridge System does not restore normal hearing and benefits may vary from one patient to another. The correlation between the degree of benefit obtained from an implant and the cause or degree of hearing impairment has not yet been evaluated. There are no definitive tests that can be administered prior to implantation to estimate the degree of benefit a patient may receive.

Possible adverse events

The following are known to be possible adverse events associated with middle ear surgery: Implant patients are exposed to the usual risks of surgery and general and/or local anesthesia, which include, but are not limited to, bleeding, local skin numbness or pain, infection, transient tinnitus, vertigo or headache. If these occur, they are usually transient and resolve within a few weeks after the surgery. Please consult or contact your clinic for further information.

Other complications that may occur include: post-surgery displacement of the implant; post-surgical translocation of the BC-FMT due to trauma or inferior surgical positioning and extrusion of the implant.

Interference with other equipment

Samba audio processor

- **Mobile phones, Cordless telephones (DECT):** The Bonebridge System has been tested for wireless device compatibility. The Bonebridge System is in near field category “M4”. This is the best possible category and ensures usable performance with any portable phone. For further details please refer to **Part Five – Samba technical data.**
- **Wireless LAN (WLAN):** To avoid interferences, a distance of 70 cm (27.56 in.) shall be observed to transmitters.
- **Other radio frequency transmitters:** Portable and mobile RF communications equipment should be used no closer to any part of the Samba than the recommended separation distance given in Table 6 in the section **Guidance and manufacturer’s declaration** in **Part Five – Samba technical data.**. Please contact the operator of a specific radio frequency transmitter to obtain transmission frequency and rated power.
- **Other electronic equipment:** The Samba uses radio frequency only for its internal function. Therefore, its radio frequency emissions are very low and are not likely to cause any interference in nearby electronic equipment. The Samba is suitable for use in all establishments.
- **Theft and metal detection systems:** Commercial theft detection systems and metal detectors produce strong electromagnetic fields. Patients with an implant should be advised that passing through security metal detectors may activate the detector alarm. For this reason, it is advised that patients carry their Bonebridge User Identification Card at all times.
- **Ionizing Radiation Therapy:** It is recommended not to wear an audio processor during irradiation.
- **Magnetic Resonance Imaging (MRI):** 

The audio processor is MR unsafe and shall not be worn during an MRI examination.

Bone Conduction Implant (BCI 601):

- **Surgical diathermy:** Electrosurgery instruments can produce radio frequency voltages that might result in direct coupling between the instrument and the implant. Monopolar electrosurgical instruments must not be used within the vicinity of the implant. The induced currents could cause damage to the implant or the patient’s hearing.
- **Ionizing radiation therapy:** Radiation therapy does not harm the implant. It is recommended not to wear an audio processor during irradiation.
- **X-ray, CT, cobalt treatment, PET scan, diagnostic ultrasound:** No restriction within clinically useful exposures.

- **Monopolar electrocautery, therapeutic ultrasound, transcranial magnetic stimulation, electroconvulsive therapy:** May never be applied directly over the implant because these procedures may damage it.

Magnetic Resonance Imaging (MRI):

- MR Conditional

  Non-clinical testing has demonstrated the “Bonebridge hearing implant, single (68 x 28 x 10 mm)” is MR conditional.
- The audio processor shall not be worn during an MRI examination, however, it is still possible that audible interference can occur.
- It can be scanned safely under the following conditions:
  - static magnetic field of 1.5 Tesla or less, with
  - spatial gradient field of 118 T/m or less
  - spatial gradient field product of 141 T^2/m or less
  - theoretically estimated maximum whole body averaged (WBA) specific absorption rate (SAR) of < 1.6 W/kg at 1.5 Tesla, (local SAR < 5.6 W/kg), for 15 minutes of continuous MR scanning.
- In non-clinical testing the “Bonebridge hearing implant" produced a temperature rise of less than 2.0 °C (with a background temperature increase of ≈ 1.6 °C) at a maximum whole body averaged specific absorption rate (SAR) of ≈ 2.3 W/kg assessed by calorimetry for 15 min. of continuous MR scanning with body coil in a 1.5 Tesla Intera, Philips Medical System (PMS) (Software: Release 12.6.1.3, 2010-12-02) MR Scanner.
- General notice: the whole body or head averaged SAR is inappropriate to scale exact local temperature increases. Local SAR can deviate and result in much higher values than the WBA-SAR software displayed.
- Gradient magnetic fields: stimulation level parameter PNS = 47 % (1.5 T Intera, Philips Medical Systems (PMS)) was used during RF heating tests. No tests have been performed regarding possible nerve or other tissue stimulation.
- The “Bonebridge hearing implant” has not been tested in simultaneous combination with other devices.
- MR image quality is compromised. Worst-case image artifacts are expected to affect the image in a surrounding area with a radius of 15 cm measured from the geometrical center of the implant. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this implant.

Initial activation

The patient should return for medical clearance and initial activation of the audio processor after the swelling of the skin flap has reduced.

Warranty statement

MED-EL’s warranty is in agreement with mandatory local statutory warranty provisions.

Any extension of the statutory warranty is subject to agreement between MED-EL and the purchaser. Therefore these extensions may be different in various countries. Please contact your clinic or local MED-EL representative for information on your individual warranty rights.

Extension of statutory warranties shall not be granted unless the audio processor is properly registered. You can register your audio processor either by completing the provided registration card and sending it to MED-EL or by using MED-EL’s online registration website (upon availability). Ask your clinic or local MED-EL representative for help if you need assistance in the registration process.

Extensions of statutory warranties exclusively cover product failures. This does not apply to any MED-EL product subjected to physical or electrical abuse or misuse, or operated in any manner inconsistent with the applicable MED-EL instructions.

NOTE *Please make sure to receive your Bonebridge User Identification Card from your surgeon.*

Part Five – Clinical trial description

The purpose of this multi-center, non-randomized, non-blinded, repeated-measures clinical study was to demonstrate the safety and effectiveness of the MED-EL Bonebridge system consisting of the Bone Conduction Implant (BCI) and the externally worn audio processor (AP). The MED-EL Bonebridge is a medical device designed to provide benefit in speech perception and sound quality to individuals who demonstrate a Mixed Hearing Loss (MHL) or Conductive Hearing Loss (CHL), with stable inner ear function.

Six tests were evaluated in order to determine safety and effectiveness of the MED-EL Bonebridge System pre-operatively and 1, 3, and 12 month post-operatively:

Word Recognition Score	(WRS; Freiburger Monosyllables)
Speech Reception Threshold	(SRT; OLSA)
Warble Tones	(WT)
Bone Conduction	(BC)
Air Conduction	(AC)
Hearing Device Satisfaction Scale	(HDSS)

In total, 57 subjects were enrolled in the study. The data presented here covers all 53 subjects who had reached 12-month post-operative evaluation at the time of data analysis. Subjects were fitted approx. 1 month postoperatively with the audio processor.

Primary Study Endpoint

The primary effectiveness endpoint was the improvement in speech perception in the post-activation aided condition compared to the pre-operative unaided condition. A change of at least 15 % in the Freiburger Monosyllable Test was considered clinically significant and was the primary endpoint for this study. To underline this test, the Oldenburger Satztest (OLSA) was analyzed post hoc. For this analysis an improvement of 15 dB SPL in OLSA was considered clinically significant.

Secondary Study Endpoints

The secondary effectiveness endpoint was the improvement in sound perception (Warble Tones: WT) in the post-activation aided condition compared to the pre-operative unaided condition for audiometric test frequencies 500-8000 Hz. A more than 10 dB improvement (Functional Gain: FG) at one or more test frequencies was considered significant.

The secondary safety endpoints were stable hearing thresholds for Bone Conduction characterized by no difference between pre- and post-operative Bone Conduction thresholds for audiometric test frequencies 500-4000 Hz. A decrease of 5 dB or less at a particular frequency is within test-retest reliability and was not considered clinically significant.
A decrease of more than 10 dB in subject individual PTA4 (0.5, 1, 2, 4 kHz) at the 12 month interval was reported as an adverse event.

Safety was further evaluated by tabulations of all *adverse events (AEs) / serious adverse events (SAEs).* Safety data was collected on all implanted subjects.

Subject device satisfaction and benefit, determined by the HDSS (Hearing Device Satisfaction Scale) was either preserved or improved from 3 to 12 months post operatively.
The HDSS (German language version) is comprised of 21 categories and is scored using the Likert[1] scale. Items are presented in a phrase related to an aspect of hearing implant use. The rate of satisfaction for each question category is calculated and summarized using descriptive statistics.

Inclusion criteria

Subjects were eligible for enrollment in the study if they fulfilled the following criteria:

General Inclusion Criteria:

a. geographical and physical ability to return to the investigational center for scheduled evaluations and follow-up appointments

[1] Likert (1932-1933). "A technique for the measurement of attitudes." *Archives of Psychology Vol 22 (No. 140): 5-55.*

b. reasonable travel distance to the study center
(arrival, study appointment and departure should be accomplishable within 1 day)
c. fluentness in the language used in the investigational center and used for evaluation
d. age of 5 years or older
e. psychological and emotional stability with realistic expectations of the benefits and limitations of the BB
f. emotional and psychological ability to understand and perform on required study procedures
g. the patient should have tried any means of hearing amplification before (medical and/or audiological feasibility preconditioned)

Audiological /Medical Inclusion Criteria:

h. feasibility of the reliable testing of target parameters (e.g. proper masking of the contralateral side) as listed in the protocol (WRS, SRT etc.)
i. presence of a conductive or mixed hearing loss as indicated by audiometric testing. That is, presence of an air-bone gap of at least 10 dB at three or more of the frequencies 500, 1000, 2000, and 3000 Hz.
j. all audiometric evaluations should be indicative of a conductive or mixed hearing loss.
k. pure-tone bone-conduction threshold levels at or within the levels stated in the Table 3.

Frequency (kHz)	0.5	1.0	2.0	3.0
BC Upper Limit (dB HL)	45	45	45	45

1. *Table 3: Indication range*
2. *Upper limits (dB HL) of bone conduction thresholds as a function of frequency for persons with conductive or mixed hearing loss*

Exclusion criteria

Subjects were excluded from the study for any of the following reasons:

l. chronic or non-revisable vestibular or balance disorders
m. abnormally progressive hearing loss
n. evidence that hearing loss is of retrocochlear or central origin
o. evidence of conditions that would prevent good speech recognition potential as determined by good clinical judgment
p. chronic headache or pain in the head region
q. non-responsive ear infection that could impair success with a bone conduction device
r. skin or scalp conditions that may preclude attachment of the audio processor or that may interfere with the use of the audio processor
s. abnormal skull size or any other abnormality that would preclude appropriate placement of the BCI as determined by CT scan.
t. impossibility to undergo general or local anesthesia.
u. single-sided sensorineural deafness, that is severe to profound sensorineural deafness in one ear while the other ear has normal hearing
v. Pathological conditions causative for inner ear hearing instability (threshold fluctuation) or progressive inner ear hearing loss.
w. Allergy or intolerance to one or more of the materials of the device, that are in contact with the body
x. In patients bilaterally implanted with the BB, only one ear needs to be chosen to be tested in the study.

Description of tests

Speech Perception testing
The following tests were conducted in a sound field with the speaker at 0° azimuth and 1 meter from and at level with the subject's head in a sound-attenuated room.

1. Word Recognition Score
Open-set, monosyllabic words were tested using the Freiburger Monosyllables Word Recognition test. Testing was completed in quiet at 65 dB SPL in the sound field and results were reported as a percent correct for words. This test was performed in quiet.

2. Speech Reception Threshold
Open-set sentences were tested using the OLSA (Oldenburger Satztest). The OLSA was administered and the speech level in dB SPL for 50% correct recognition was determined. This test was performed in quiet.

Audiometric Tests (sound field)

The following test was conducted in a sound field with the speaker at 0° azimuth and 1 meter from and at level with the subject's head in a sound-attenuated room.

Warble Tones

Were applied in the sound field and thresholds were measured using a standard bracketing procedure at 500, 1000, 2000, 3000, 4000, 6000 and 8000 Hz.

Audiometric Tests (basic test battery)

The following tests were conducted, using insert earphones or traditional headphones, on each ear individually.

Bone Conduction

Were tested by pure tones applied in the sound field and thresholds were measured using a standard bracketing procedure at 500, 1000, 2000, 3000, 4000, 6000 and 8000 Hz.

Air Conduction

Was tested by pure tones applied in the sound field and thresholds was measured using a standard bracketing procedure at 500, 1000, 2000, 3000, 4000, 6000 and 8000 Hz.

Device Satisfaction & Benefit

Hearing Device Satisfaction Scale

Subjective Device Satisfaction was tested by means of the Hearing Device Satisfaction Scale (HDSS)/ Hearing Device Satisfaction Scale - Parent (HDSS-P, for parents of implantees) a self-assessment questionnaire. HDSS measures parameters such as comfort, handling, and changes in quality of life. The HDSS consists of 21 questions/categories regarding the subjective device satisfaction with response options transformed into a percentage ranging from very satisfied (100 %), satisfied (75 %), sometimes satisfied/dissatisfied (50 %), dissatisfied (25 %), to very dissatisfied (0 %) based on the answers given.

Clinical trial results

Of the 57 total subjects implanted, 53 had reached the 12 month post-operative time point on the date of analysis. One subject withdrew from the study after implantation; therefore, safety results for 53 subjects and audiometric results for 52 subjects were analyzed. The table below provides details on the number of subjects for each interval completed.

# of Subjects	Total
Pre-operative	53
1 Month post-operative (Initial Activation)	52
3 Month post-operative	52
12 Month post-operative	50

Demographics

The table below provides information on subject demographics, including gender, age at implantation, average of previous ear surgeries and number of subjects with previous ear surgeries.

Parameter/Category or Statistic	Total (N=53)	Adult (N = 45)	Pediatric (N=8)
Gender			
Male %	58.5 % (N=22)	37.7 % (N=17)	62.5 % (N=5)
Female %	41.5 % (N=31)	62.3 % (N=28)	37.5 % (N=3)
Age (years) mean (min-max)	41 (5-76) (N=53)	47 (18-76) (N=45)	11 (5-17) (N=8)
Implant Side			
Left %	41.5 % (N=22)	42.2 % (N=19)	37.5 % (N=3)
Right %	58.5 % (N=31)	57.8 %(N=26)	62.5 % (N=5)
Previous Ear Surgeries			

Average surgeries per subject	3.66	3.61	Only one pediatric subject was previously operated with five previous ear surgeries.
Previously operated subjects	60.38 % (N=32)	68.89% (N=31)	

Parameter/Category or Statistic	Total (N=53)		Adult (N = 45)		Pediatric (N=8)	
Disease Etiology	%	N	%	N	%	N
Chronic Otitis Media	30.19	16	28.30	15	1.89	1
Atresia	22.64	12	16.98	9	5.66	3
Cholesteatoma	20.75	11	20.75	11	-	-
Ear Dysplasia	7.55	4	5.66	3	1.89	1
Malformation	1.89	1	-	-	1.89	1
Ear Dysplasia / Franceschetti Syndrome	1.89	1	1.89	1	-	-
Chronic Mastoiditis	1.89	1	1.89	1	-	-
Stenosis	1.89	1	1.89	1	-	-
Anomalius Bar	1.89	1	1.89	1	-	-
Congenital Syndromic Malformation	1.89	1	-	-	1.89	1
Otosclerosis	1.89	1	1.89	1	-	-
Glomus Tumor	1.89	1	1.89	1	-	-
Osteogenesis Imperfecta Otosclerosis	1.89	1	1.89	1	-	-
Microtia	1.89	1	-	-	1.89	1

Speech Perception Results (primary endpoints)

For the primary endpoint of improvement on Freiburger monosyllabic words in quiet the average unaided preoperative score was 19.57 % (±21.7 %) correct. At 12 months post-operative, in the BB aided condition, subjects scored 82.9 % (±18.1 %) correct. This represents an improvement with BB of 63.3 percentage points. Statistical analysis revealed a significant improvement in WRS in the BB aided condition, as compared to the preoperative unaided condition.

Freiburger	Total (N=52)			Adult (N = 44)			Pediatric (N=8)		
Word Recognition Score	Score [%]	Std.	N	Score [%]	Std.	N	Score [%]	Std.	N
pre-operative	19.57	21.70	46	20.00	21.64	39	17.14	23.60	7
1 month post-operative	74.51	21.01	51	75.00	21.73	44	71.43	16.76	7
3 month post-operative	83.75	15.84	52	84.66	15.72	44	78.75	16.64	8
12 month post-operative	82.90	18.10	50	82.91	18.68	43	82.86	15.24	7

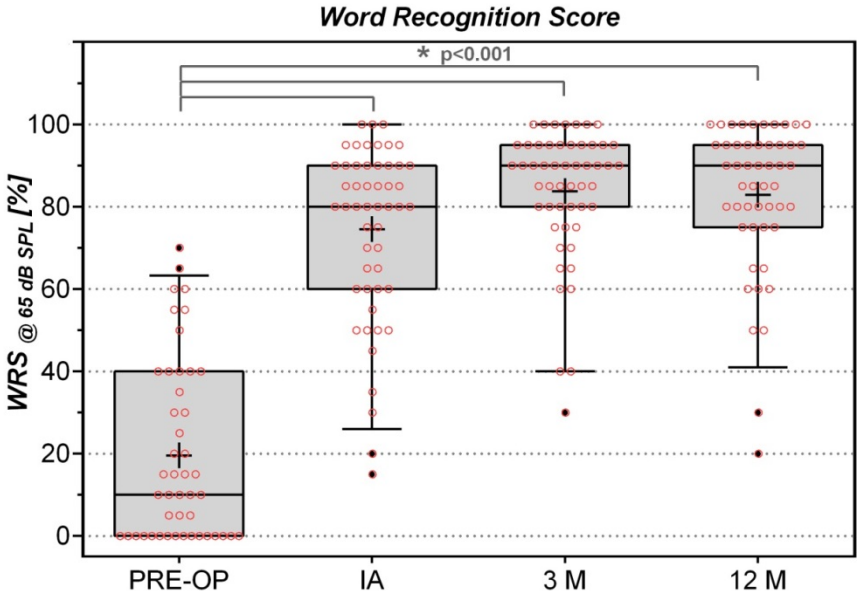


*Figure 6: Word recognition scores for all subjects. Box Plots: median = horizontal lines; + = mean; ANOVA p < 0.05; * = significance; red circles depict distribution of individual values*

Additionally, improvement in speech understanding in quiet was assessed with OLSA sentences in quiet. Subjects improved from 63.69 dB SPL (±11.81 dB SPL) pre-operative unaided to 39.71 dB SPL (±8.84 dB SPL) at 12 months post-operatively aided with the BB. Statistical analysis showed a significant improvement in speech perception of 24 dB SPL.

OLSA	Total (N=52)			Adult (N = 44)			Pediatric (N=8)		
Speech Reception Threshold	dB SPL	Std.	N	dB SPL	Std.	N	dB SPL	Std.	N
pre-operative	63.69	11.81	42	62.21	11.69	36	72.60	8.70	6
1 month post-operative	47.01	10.41	48	45.99	10.51	41	53.01	7.97	7
3 month post-operative	41.42	9.51	50	40.63	9.81	42	45.53	6.83	8
12 month post-operative	39.71	8.84	48	39.19	9.09	41	42.80	7.01	7

Audiometric Results (secondary endpoints)

For the secondary endpoint of improvement on warble tones, the average unaided preoperative threshold improved from 56.94 dB SPL (±12.57 dB SPL) to 29.33 dB SPL (±8.83 dB SPL) at 12 months post-operatively in the aided condition. The functional gain of 28.89 dB SPL is significant in the BB aided condition, as compared to the preoperative unaided condition.

WT	Total (N=52)			Adult (N = 44)			Pediatric (N=8)		
Warble tones	dB HL	Std.	N	dB HL	Std.	N	dB HL	Std.	N
pre-operative	56.94	12.57	50	57.64	12.89	42	53.28	10.75	8
1 month post-operative	34.16	8.18	52	34.26	8.00	44	33.59	9.69	8
3 month post-operative	29.88	7.99	52	30.06	8.29	44	28.91	6.49	8
12 month post-operative	29.33	8.89	50	29.71	9.11	43	26.96	7.56	7

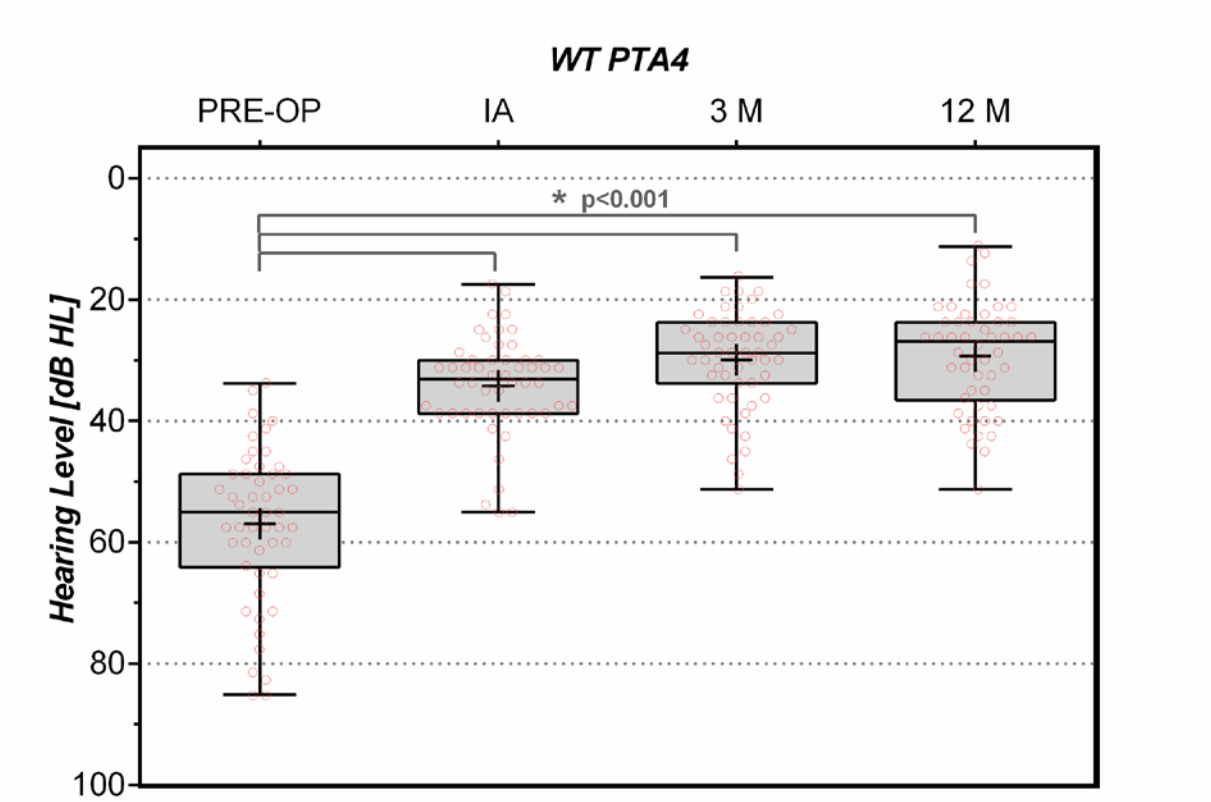


Figure 7: Warble tone thresholds using the pure-tone average: pre-operative (unaided) compared to the aided condition at 1 month (Initial Activation), 3 and 12 months post-operatively for all subjects

The secondary endpoint of unchanged residual hearing was measured by unaided audiologic PTA4 thresholds from preoperative unaided to the 12 month post-operative endpoint. The results of descriptive analyses of BC and AC thresholds presented below show that BB treatment had no significant effect on residual hearing.

BC	Total (N=52)			Adult (N = 44)			Pediatric (N=8)		
Bone Conduction thresholds	dB HL	Std.	N	dB HL	Std.	N	dB HL	Std.	N
pre-operative	16.03	9.70	52	17.41	9.57	44	8.44	6.71	8
1 month post-operative	17.17	10.39	52	18.59	10.27	44	9.38	7.53	8
3 month post-operative	15.66	8.63	52	16.88	8.63	44	8.91	4.88	8
12 month post-operative	17.03	10.24	50	18.11	10.25	43	10.36	7.83	7

AC	Total (N=52)			Adult (N = 44)			Pediatric (N=8)		
Air Conduction thresholds	dB HL	Std.	N	dB HL	Std.	N	dB HL	Std.	N

pre-operative	59.12	14.76	51	59.68	15.08	43	56.09	13.34	8
1 month post-operative	58.52	15.08	50	58.89	15.36	43	56.25	14.03	7
3 month post-operative	58.48	15.26	52	58.43	15.59	44	58.75	14.25	8
12 month post-operative	58.21	16.45	49	58.32	16.84	42	57.50	15.02	7

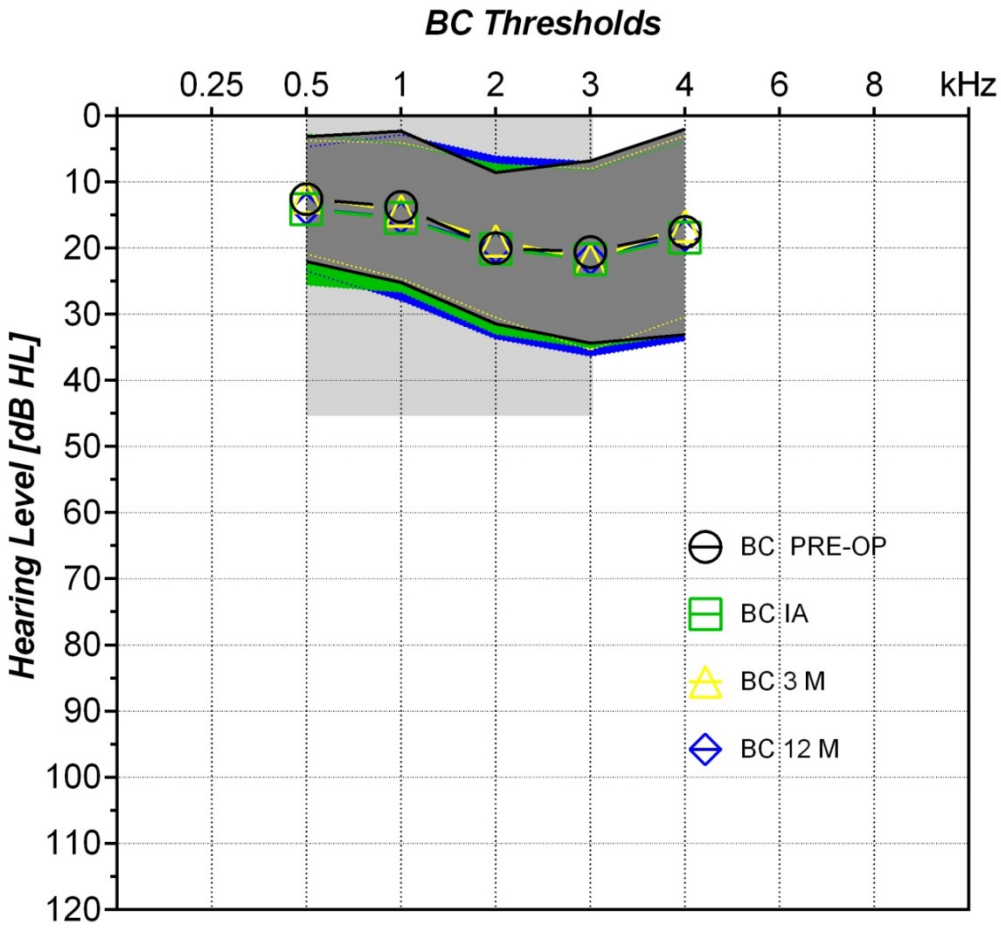


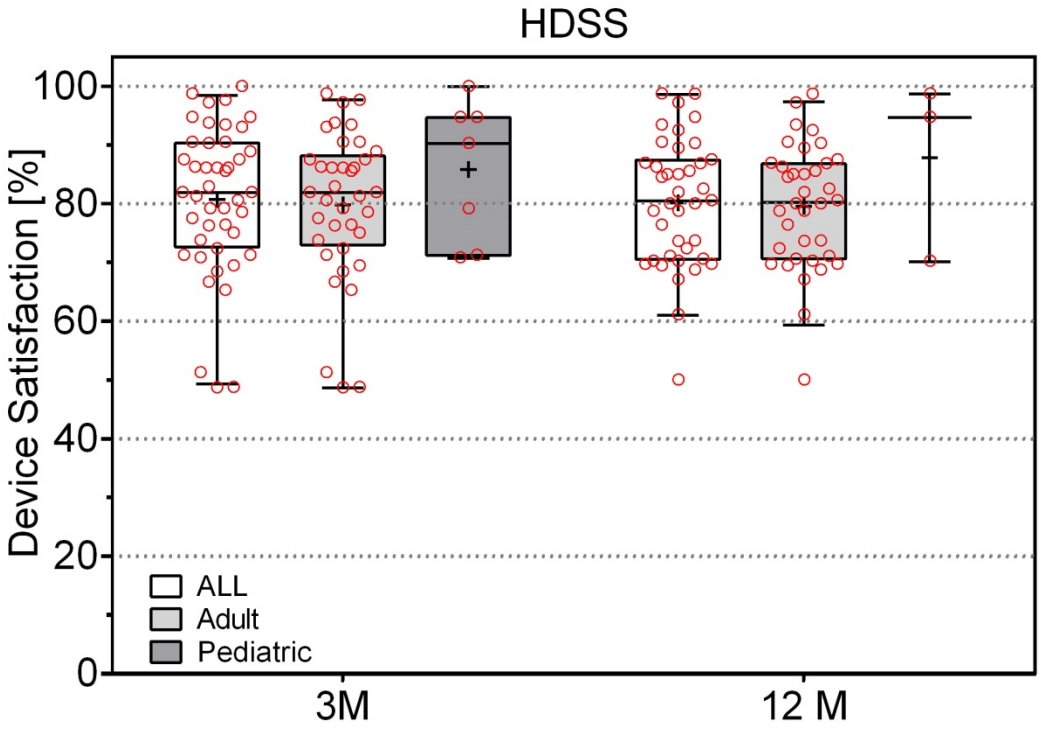
Figure 8: Mean residual Bone Conduction thresholds and area of standard deviation: pre-operative (dark grey), at 1 (green), 3 (yellow) and 12 (blue) months post-operatively for all subjects. The rectangular area (light grey) depicts the indication range at 45 dB HL pre-operatively.

Subjective Device Satisfaction (secondary endpoints)

On average subjects were satisfied or very satisfied 3 months after the BB treatment (80.8 %) and this result remained stable at the 12 month (80.2 %) post-operative appointment.

Only two adult subjects were just under 50 % satisfied at the 3 month evaluation time point (48.68 %, 48.75 %) with both being more satisfied at the 12 month appointment (50 % ,67.11 %).

HDSS	Total (N=52)			Adult (N = 44)			Pediatric (N=8)		
Device Satisfaction	%	Std.	N	%	Std.	N	%	Std.	N
3 month post-operative	80.80	12.61	44	79.40	12.30	37	88.50	12.29	7
12 month post-operative	80.20	10.93	39	79.60	10.52	36	87.90	15.43	3



Safety

Adverse events were collected for all implanted subjects throughout the duration of the study. Adverse events were classified as non-serious/serious, device/procedure related or unrelated. A total of 31 Adverse Events, one temporary loss of residual hearing and one serious adverse event unrelated to the procedure or the device were reported up to 12 months after implantation.

The temporary loss of residual hearing was just 2.5 dB above the limit and was solved without treatment as the residual hearing threshold recovered at a later time point. One serious adverse event unrelated to the device reports on ear canal inflammation with subsequent cholesteatoma removal surgery and antibiotic treatment.

Eighteen adverse events occurring in 15 subjects were reported as related to either the device or the procedure, with two reported as SADE (Device related Serious Adverse Events), 4 reported as device related Adverse Events and 12 reported as procedure related Adverse Events. One subject who experienced a SADE on skin infection and subsequent explantation was excluded from the study analysis as the inclusion criteria were not met (the patient's skin was too thin already preoperatively).

Details on the type and number of device and procedure related adverse events can be found below:

Events Reported as Device- or Procedure-Related for 53 subjects	No. of Events	No. of Subjects	% of Subjects	% Re solved
Itching at the implant side	1	1	1.89 %	100 %
Skin irritation at the implant side	3	3	5.66 %	100 %
Skin infection at the implant side	2	2	3.77 %	100 %
Headaches	1	1	1.89 %	100 %
Headaches and Skin irritation	1	1	1.89 %	100 %
Pain at the implant side	2	2	3.77 %	100 %
Pain at the implant side and skin infection	1	1	1.89 %	100 %
Pain due to post-operative scar formation	1	1	1.89 %	100 %
Occasional pain due to skin nerve cut	1	1	1.89 %	0 %
Postoperative subcutaneous seroma	1	1	1.89 %	100 %
Revision surgery to thin out the subcutaneous fascia.	1	1	1.89 %	100 %
Vertigo	1	1	1.89 %	100 %
Tinnitus	1	1	1.89 %	100 %

* Some subjects experienced more than one adverse event.

Part Six – Samba technical data

Dimensions

- Primarily circular shape
- Diameter ≤ 1.38 in. (battery compartment closed)
- Height ≤ 0.43 in. (tallest point)
- Weight ≤ 0.38 ounces (oz)

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 (IEC identifier: PR44)

Audio frequency range

- 250 Hz to 8 kHz

Signal processing

- 16-band Digital Equalizer
- 16 independent Compression Channels
- Noise Reduction Control
- Feedback Reduction

Controls

- Remote control
- Turn off the system by opening the battery compartment

Degrees of protection provided by enclosures

- IP32

Operating Temperature

- +5°C to +40°C
- Relative humidity: 93 % max.
- Atmospheric pressure: 70 to 106 kPa

Storage and shipping conditions

- -25°C to +60°C
- Relative humidity: 93 % max.

- Atmospheric pressure: 70 to 106 kPa

Removable parts

- Cover
- Magnet assembly
    - Magnet lid
    - Magnet
- Battery (not inserted on delivery)
- Attachment eyelet (has to be in place or can be replaced with the provided hair clips)

Wireless technology

Type:	NFMI (near field magnetic induction)
Frequency:	120 kHz
Modulation type:	Voice AM
Wireless range:	10 mm

Type:	NFMI (near field magnetic induction)
Frequency:	3.28 MHz
Modulation type:	FM
Wireless range:	1 m

Quality of Service:

Once switched on, the Samba will automatically begin to transmit sound. When the Samba is magnetically attached to the implant, the link is established.

The Bonebridge System has been tested for wireless device compatibility. According to ANSI C63.19:2011, the Bonebridge System is in near field category M4.

To determine the system performance when a wireless device is present, obtain the near field category from the wireless device, e.g. from the network operator or the wireless device manufacturer. Add the numerical part of the near field category of the Bonebridge System and the wireless device. The result is interpreted as follows:

Hearing aid category (near field category of the Bonebridge System M4 = 4) + telephone category (M1 = 1) = 5: Normal use

Hearing aid category (near field category of the Bonebridge System M4 = 4) + telephone category (M2 = 2) = ≥ 6: Excellent performance

Security:

The Bonebridge System wireless technology is secure because:

- No patient specific information is stored inside the Bonebridge implant.
- The wireless link of the Bonebridge System is merely 10 mm (0.39 in.) so any intruder to the Bonebridge system is required to be in very close range

FCC ID: VNP-WL700

NOTICE: This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

NOTICE:

Changes or modifications made to this equipment not expressly approved by (manufacturer name) may void the FCC authorization to operate this equipment.

Symbols


Caution


Refer to instructions for use.


Information relevant for parents of implanted children


Type BF (IEC 60601-1 / EN 60601-1): The bottom surface of the Samba, which is in contact with the patient, is a Type BF Applied Part.


Manufacturer

Serial number

Catalogue number


Temperature limit


Humidity limitation

MR conditional

MR unsafe

IP32
Protected against solid objects over 2.5 mm in diameter e.g. tools. Protection against water drops falling vertically over a 15° range.

CE
0123
CE Mark, applied in 2015 (0123 is the TÜV SÜD notified body code)


Non-ionizing radiation (refer to Guidance and manufacturer's declaration Table 4)

Indicator for right side application

Indicator for left side application

Guidance and manufacturer's declaration

Tables according to IEC 60601-1-2

Table 1

Guidance and manufacturer's declaration – electromagnetic emissions		
The Samba is intended for use in the electromagnetic environment specified below. The customer or the user of the Samba should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Samba uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Samba is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity The Samba is intended for use in the electromagnetic environment specified below. The customer or the user of the Samba should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Samba requires continued operation during power mains interruptions, it is recommended that the Samba be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Table 4

Guidance and manufacturer's declaration – electromagnetic immunity

The Samba is intended for use in the electromagnetic environment specified below. The customer or the user of the Samba should assure that it is used in such an environment.

IMMUNITY test	**IEC 60601 TEST LEVEL**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the Samba, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = \left(\frac{3.5}{V1}\right) * \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = \left(\frac{3.5}{E1}\right) * \sqrt{P}$ 80 MHz to 800 MHz
			$d = \left(\frac{7}{E1}\right) * \sqrt{P}$ 800 MHz to 2.5 GHz
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Samba is used exceeds the applicable RF compliance level above, the Samba should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Samba

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 6

Recommended separation distances between

portable and mobile RF communications equipment and the Samba

The Samba is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Samba can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Samba as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = \left(\frac{3.5}{V1}\right) * \sqrt{P}$	**80 MHz to 800 MHz** $d = \left(\frac{3.5}{E1}\right) * \sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left(\frac{7}{E1}\right) * \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Part Seven – The remote control

Table of contents

Your remote control

Your hearing instrument (your Samba audio processor) is equipped with wireless technology and can therefore be controlled by a remote control.

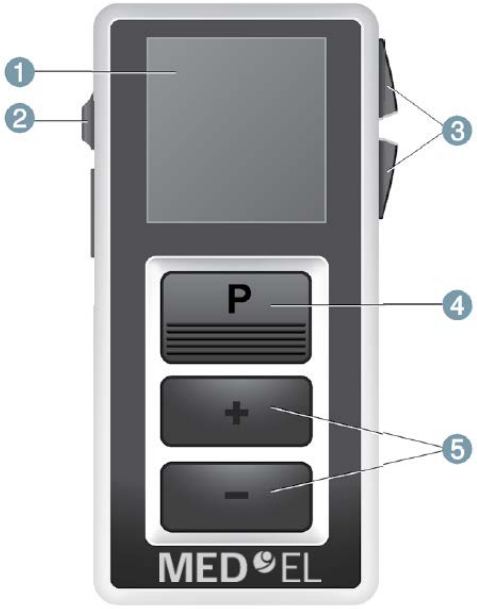
The operating distance of the remote control is approximately 1 meter (40 in.).

➢ Make sure the distance between your remote control and your audio processor does not exceed the operating distance.

CAUTION

Read this user guide thoroughly and completely and follow the safety information in this document to avoid damage or injury.

Overview



① Display

② Key lock switch

③ Control buttons

④ Program change button

⑤ Volume up/down buttons

More functions are available in the menu. To enter or exit the menu, press the volume up button and the volume down button simultaneously.

Display

All actions initiated with the remote control are immediately reflected on the display.

The remote control does not receive information from your hearing instruments. All actions that you initiate with the controls of your hearing instruments are **not** reflected on the remote control's display.

① Indicates change of volume

② Indicates change of hearing program

③ Alarm clock is activated

④ Batteries of the remote control are low

⑤ Function of control buttons

Power save mode

If the remote control is not used for some time, the display automatically turns black. The remote control is then in its power save mode.

➢ Press the program change button to activate the display again.

Control buttons

You can quickly access two functions with the control buttons on the right hand side of the remote control.

Basic functions:

Turn hearing instruments on or off.

Reset to default volume and hearing program.

Key lock switch

To prevent any accidental operation while the remote control is in pockets or bags, move the key lock switch to lock position (red color visible).

When the key lock is active, all buttons on the remote control are disabled. The following icon is displayed.

Wireless compatibility between your Samba audio processor and the remote control

A good functionality of the wireless connection between your Samba audio processor and the remote control depends to a great extent on the orientation of both devices. If you experience problems when using the remote control, try the following recommendations:

- Hold the remote control as close as possible to your body and on the body side where you wear your Samba.
- Turn the remote control a little in such a way that the display and the buttons are not facing straight upwards but that they are facing slightly to the left or to the right until the wireless connection is established.
- In some cases, it could help to decrease the distance between the remote control and your Samba.
- Do not cover the upper part of the remote control with your fingers or hand.

When the wireless connection is established, you can operate your Samba.

Batteries

The remote control uses two AAA batteries.

Inserting batteries

Slide the battery compartment cover in the direction of the arrow.

Insert the batteries.

Make sure the "+" symbols on the battery and the compartment are aligned.

Attach the cover by sliding it onto the remote control.

The current time setting is displayed. If you want to change it, refer to section "Setting the time".

Checking the battery status

When the batteries of the remote control are low, this is indicated in the status bar.

Additionally, you can check the battery status at any time in the menu.

- To enter the menu, press the volume up button and the volume down button simultaneously.
- Navigate to the menu entry Info by pressing the volume up button or the volume down button.
- Confirm your selection by pressing the program change button.

  The battery status is displayed:

battery full

battery empty

- To return to the standard display, press the program change button.

Remove empty batteries immediately and dispose of them according to local regulations.

Daily use

Adjusting the volume

If you are wearing two hearing instruments (in this case two Samba audio processors), the volume will be adjusted on both instruments at the same time.

➢ Press the volume up button or the volume down button to adjust the volume by one step.

Changing the hearing program

If you are wearing two hearing instruments, the hearing program will be changed on both instruments.

➢ Press the program change button to switch to the next hearing program.

Turning on and off (mute)

You have several options to turn your hearing instruments on and off with your remote control. Both hearing instruments are simultaneously turned on or off.

When you turn your hearing instrument off via remote control, the following icon is displayed. It is displayed until you turn your hearing instrument back on.

After turning on, the previously used volume and hearing program are set.

Turning off via control button

Press the control button next to the following icon to turn your hearing instrument on or off.

Turning on:

➢ To turn your hearing instruments back on, press any key or move the key lock switch to unlock position (green color visible).

Alarm clock

You can set an alarm clock reminding you at the same time every day by a repeating signal tone and by an alarm clock icon.

The alarm is initiated by the remote control but the acoustic signal is emitted by your hearing instrument.

➢ Turn on your hearing instrument.

➢ Keep your hearing instrument within the remote control's operating distance.

Otherwise you will not be able to hear the alarm.

Setting the alarm clock

➢ To enter the menu, press the volume up button and the volume down button simultaneously.

➢ Navigate to the menu entry Alarm by pressing the volume up button or the volume down button.

➢ Confirm your selection by pressing the program change button. The entry field for hours is highlighted.

➢ Set the hours by pressing the volume up button or the volume down button.

➢ Confirm your setting by pressing the program change button. The entry field for minutes is highlighted.

➢ Set the minutes by pressing the volume up button or the volume down button.

➢ Confirm your setting by pressing the program change button. The alarm on/off selection field is highlighted.

➢ Press the volume up button or the volume down button to position the cursor next to alarm clock on: 

➢ Confirm your selection by pressing the program change button.

When the alarm clock is turned on, this is indicated in the status bar.

Ending the alarm

When the alarm clock rings, a corresponding icon is displayed on the remote control.

If you do not end the alarm, it is repeated within the next minutes.

➢ To end the alarm, press the program change button.

The alarm clock will ring at the same time on the next day.

Turning the alarm clock off

➢ To enter the menu, press the volume up button and the volume down button simultaneously.

➢ Navigate to the menu entry Alarm by pressing the volume up button or the volume down button.

➢ Confirm your selection by pressing the program change button. The entry field for hours is highlighted.

➢ Press the program change button twice to skip the entry fields for hours and minutes. The alarm on/off selection field is highlighted.

➢ Press the volume up button or the volume down button to position the cursor next to alarm clock off: 

➢ Confirm your selection by pressing the program change button.

Setup and service functions

Setting the time

➢ To enter the menu, press the volume up button and the volume down button simultaneously.

➢ Navigate to the menu entry Clock by pressing the volume up button or the volume down button.

➢ Confirm your selection by pressing the program change button. The entry field for hours is highlighted.

➢ Set the hours by pressing the volume up button or the volume down button.

➢ Confirm your setting by pressing the program change button. The entry field for minutes is highlighted.

➢ Set the minutes by pressing the volume up button or the volume down button

➢ Save the settings by pressing the program change button.

The time is displayed.

The time is always displayed in the header of the menu. To enter or exit the menu, press the volume up button and the volume down button simultaneously.

Resetting volume and hearing program

If you have made changes to volume or program and do not know why the hearing instruments are acting the way they are, you can manually set the **default** volume and hearing program for your hearing instruments.

You can reset the hearing instruments by pressing the control button next to the following icon.

Maintenance and care

NOTICE

➢ Do not put your remote control in water!

➢ Do not clean your remote control with alcohol or benzine.

➢ Clean the remote control as necessary with a soft cloth and use a nonabrasive household soap.

➢ Avoid abrasive cleaning liquids with additives such as citric acid, ammonia, etc.

Troubleshooting

Problem and possible solutions
The remote control does not work.

- Check, if the key lock is activated. Deactivate it, if necessary.
- Change the batteries.

Another remote control affects your hearing instruments.

- Return remote control and hearing instruments to your Hearing Care Professional. Your Hearing Care Professional can change the wireless address to avoid interference.

Consult your Hearing Care Professional if you encounter further problems.

Important information

Intended use

The remote control is intended to operate hearing instruments (i.e. Samba audio processor).

Use the remote control only as described in this user guide.

Explanation of symbols

Points out a situation that could lead to serious, moderate, or minor injuries.

Indicates possible property damage.

Advice and tips on how to handle your device better.

Disposal information

NOTICE

➢ Recycle hearing instruments, accessories and packaging according to national regulations.

NOTICE

➢ To avoid environmental pollution, do not throw batteries into household trash.

➢ Recycle or dispose of batteries according to national regulations or return them to your Hearing Care Professional.

Technical information

MED-EL remote control
Operating frequencies: Fc=3.28 MHz
Maximum field strength @ 10m: -7 dBµA/m
Maximum field strength @ 30m: 28.5 dBµV/m

Important safety information

Personal safety

WARNING

Choking hazard!

Your device contains small parts which can be swallowed.

➢ Keep hearing instruments, batteries and accessories out of reach of children and mentally disabled persons.

➢ If parts have been swallowed consult a physician or hospital immediately

WARNING

Risk of injury!

➢ Do not use obviously damaged devices and return them to point of sale.

WARNING

Note that any unauthorized changes to the product may cause damage to the product or cause injury.

➢ Use only approved parts and accessories. Ask your Hearing Care Professional for support.

WARNING

Risk of affecting electronic equipment!

➢ In areas where the use of electronics or wireless devices are restricted, verify if your device has to be turned off.

WARNING

Wireless systems may interfere with measuring devices and electronic equipment.

➢ Do not use your device in hospitals or airplanes.

WARNING

Risk of interference with active implants or life support systems!

If you wear a pacemaker:

➢ Carry the remote control at a safe distance of about 30 cm (12 in.) away from the pacemaker.

➢ Do not carry the remote control:

- in your breast pocket,
- with a lanyard around your neck,
- or directly on the skin over the active implant.

For all other active implants or life support systems:

➢ Prior to use, have the electromagnetic compatibility verified.

WARNING

Risk of explosion!

➢ Do not use your remote control in explosive atmospheres (e. g. in mining areas).

Radiofrequency radiation exposure information

The radiated output power of the device is far below the FCC radio frequency exposure limits. Nevertheless, the device shall be used in such a manner that the potential for human contact during normal operation is minimized.

Product safety

NOTICE

➢ Protect your devices from extreme heat. Do not expose them to direct sunlight.

NOTICE

➢ Protect your devices from high humidity.

NOTICE

➢ Do not dry your devices in the microwave oven.

NOTICE

Different types of strong radiation, e. g. during X-ray or MRI head examinations, may damage devices.

➢ Do not use the devices during these or similar procedures.

Weaker radiation, e. g. from radio equipment or airport security, does not damage the devices.

In some countries restrictions for the usage of wireless equipment exist.

➢ Refer to local authorities for further information.

NOTICE

Your hearing instruments are designed to comply with international standards on electromagnetic compatibility but interference with nearby electronic devices could occur. In this case, move away from the source of interference.

NOTICE

➢ Your remote control is programmed to exclusively communicate with your hearing instruments. If you experience problems with another person's remote control, consult your Hearing Care Professional.

Please help us to improve the quality of this manual by making any suggestions or for further information regarding the use of this MED-EL product, or to report any problems, please contact:

MED-EL Elektromedizinische Geräte GmbH

Fürstenweg 77a

6020 Innsbruck

Austria

www.medel.com

or call +43 5 77 88

MED-EL Corporation, USA

2511 Old Cornwallis Road, Suite 100

Durham, NC 22713, USA

implants.us@medel.com

1-888-633-3524

Conformance Information

With the CE marking MED-EL confirms compliance with the European Directive 90/385/EEC concerning active implantable medical devices and the European Directive 99/5/EC (R&TTE) concerning radio and telecommunications terminal equipment.

CE
0123

MED-EL Elektromedizinische Geräte GmbH

Fürstenweg 77a

6020 Innsbruck

Austria

Distributed by:

MED-EL Corporation, USA

2511 Old Cornwallis Road, Suite 100

Durham, NC 22713, USA

implants.us@medel.com

1-888-633-3524

CAUTION: Federal law restricts this device to sale by or on the order of a physician or audiologist.

The Bonebridge System is manufactured in Austria. Bonebridge, BCI, Samba and SYMFIT are trademarks of MED-EL Elektromedizinische Geräte GmbH.

NOAHlink and NOAH are trademarks of Hearing Instrument Manufacturers Software Association (HIMSA A/S).

Hi-Pro is a trademark of GN Otometrics A/S.

CONNEXX and miniTEK are manufactured by Sivantos GmbH under Trademark License of Siemens AG.