USER MANUAL FOR THE
MED-EL TEMPO+
EAR LEVEL SPEECH PROCESSOR

Manufacturer:
MED-EL™ Corporation
2222 East Highway 54 Suite B180
Durham, NC
27713 USA
Tel: (919) 572-2222
Fax: (919) 484-9229

AW2934 Rev. 1.0

1. *Table of Contents*

2. *Introduction*

This User Manual is a brief guide to your new TEMPO+ Speech Processor. It will serve as a reference when learning to use the COMBI 40/40+ System with the TEMPO+ Speech Processor. It contains information for adults and parents of children implanted with the MED-EL COMBI 40/40+ Cochlear Implant System. The COMBI 40/40+ Cochlear Implant System consists of the COMBI 40 Implant or COMBI 40+ Implant, the CIS PRO+ or TEMPO+ Speech Processors, and the external components, such as the coil, cable set, and clips.

Initial fitting of the speech processor will considerably change your or your child's life. Emotions accompanying the first days of Cochlear Implant use may range from great excitement to disappointment. During fitting sessions, the settings of the speech processor will be readjusted or fine-tuned. This is necessary, because the sensitivity of the hearing nerves changes over time as they begin to get accustomed to stimulation from the implant. Your implant center will require that you or your child return at regular intervals to have the program and surgical site checked. The regularity of these fitting sessions will be decided by your implant center. On average, a programming session takes between one and three hours. The sessions will be more frequent during the first year following surgery, and may be required annually thereafter. Most patients need occasional adjustment of the program for as long as they use the implant.

We recommend that you read this manual in its entirety either before the first fitting of the speech processor or shortly after you or your child have gained some experience perceiving voices and sounds with your Implant system.

The information given in this manual is intended to help you derive greater benefit from your Cochlear Implant and the various accessories available for different listening situations.

☞ *Information particularly relevant for parents of implanted children is added, wherever necessary, in this (italic) font.*

If you still have questions after reading the manual, please do not hesitate to contact MED-EL, your

ear doctor, or clinician.

You will benefit from new hearing sensations with increasing hearing experience. The COMBI 40/40+ Cochlear Implant System will soon enrich your daily life.

3. *Indications for Use*

The MED-EL COMBI 40+ Cochlear Implant System, hereinafter referred to as the COMBI 40+, is intended to provide the opportunity to detect and recognize auditory information through electrical stimulation of the auditory nerve for severe to profoundly hearing-impaired individuals who obtain little or no benefit from conventional acoustic amplification in the best-aided condition.

Candidates and families should be well motivated and possess appropriate expectations.

The TEMPO+ Speech Processor is implicitly indicated for use with a COMBI 40+ Implant only.

71

4. Getting Started

How your Cochlear Implant works

A Cochlear Implant system is an electronic device providing deaf people with hearing sensations. Part of the device is surgically implanted behind the ear in the skull, while the external components are worn behind the ear or on the body.

The COMBI 40/40+ System consists of the COMBI 40 or COMBI 40+ Implant, the CIS PRO+ or TEMPO+ Speech Processor, the coil, cable, and clips. Please refer to the CIS PRO+ User Manual for additional details.

The speech processor codes the signals picked up as sound waves by the microphone of the control unit. The circuitry in the speech processor simulates the function of the normal ear as closely as possible with modern electronic signal processing.

The coded signal is transferred through the intact skin to the Implant. The coil is worn under the hair behind the ear and held in place by magnetic attraction to the Implant.

The implanted part consists of a ceramic housing including the reference electrode and the electrode array. The electrode array is inserted into the cochlea during surgery. The electrodes stimulate the auditory nerve with small, safe electrical currents, which correspond to the sound waves picked up by the microphone.

In response to this electrical stimulation, the auditory nerve generates neuronal impulses to transmit the acoustic information to the brain.

The speech processor uses batteries providing sufficient power for both the external and the implanted electronics. The implanted part contains no batteries.

72

Functional diagram

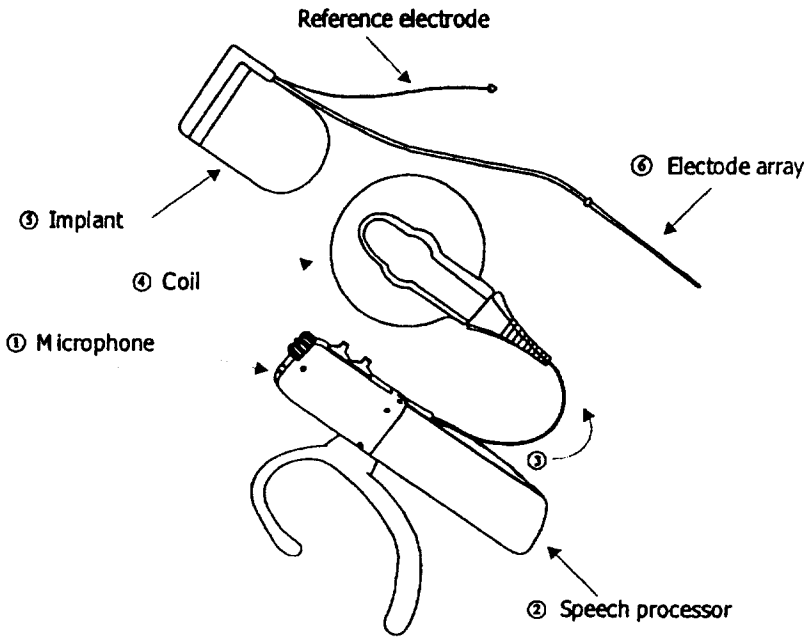


Fig. 4–a shows a functional diagram of the MED-EL COMBI 40/40+ Cochlear Implant System

1) The small microphone at the level of the ear picks up sound waves.
2) The TEMPO+ Speech Processor codes the acoustic signal into current pulses according to the CIS+ speech coding strategy.
3) The coded signal is sent via the cable to the coil.
4) The coil sends the signal and the required energy through the intact skin to the MED-EL COMBI 40H / COMBI 40+ high-performance implant. The electronics of the MED-EL Implant decode the signal and send a low-current impulse pattern to the electrodes in the cochlea.
5) The contact pairs of the electrodes use the decoded impulse pattern to stimulate the auditory nerve at various locations. The auditory nerve, in turn, sends neuronal impulses to the brain, where these impulses are interpreted as sound. The entire process requires a few milliseconds, which corresponds to the time delay in the normal functioning ear.

Characteristics of the COMBI 40/40+ Cochlear Implant

Systems

The COMBI 40/40+ Cochlear Implant System is the result of many years of research and development in Europe and the USA. Several features distinguish the COMBI 40/40+ from conventional Cochlear Implant systems:

- It is capable of implementing CIS+, a very fast and further developed version of the speech processing strategy called "CIS" (Continuous Interleaved Sampling). The CIS strategy was originally developed at the Research Triangle Institute (RTI).
- The COMBI 40/40+ System Implants, support fast stimulation rates allowing better resolution and accurate presentation of the acoustic signal to the auditory nerve. This is a prerequisite for better speech understanding.
- The Implant fulfills the highest safety requirements. The very flexible electrode array allows placement of the electrodes into the cochlea with minimal trauma. The ceramic housing of the COMBI 40/40+ Implants have very high mechanical strength that is similar in hardness to the surrounding bone. Ceramic implant housings are highly reliable but very expensive to manufacture.
- Each stimulation electrode of the Implant is protected by individual coupling capacitors against accidental charge build-up. Protective coupling capacitors are a key safety feature in the design of COMBI 40/40+ System Implants.
- The transmission system and the electronics of the Implant are highly power efficient.
- Your Implant has been designed to support future speech processors and various speech coding strategies so that you may benefit from improvements in speech processing and miniaturization of the external system components.

The COMBI 40/40+ Implants

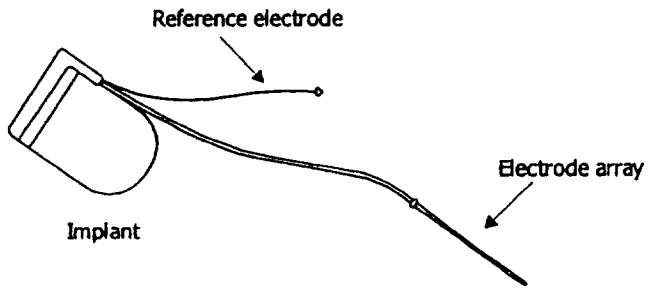


Fig. 4-b The MED-EL COMBI 40 and COMBI 40+ Implant

The Implant consists of a small Implant package, an electrode array, and a reference electrode. All materials used in the construction of the Implant have been extensively tested for biocompatibility and durability.

- All electronic parts of the *Implant package* are contained in a hermetically sealed ceramic housing. The Implant is permanently implanted in the bone behind the ear.
- The Implant contains *no batteries*. The energy required to power the Implant is provided by the external speech processor and transferred to the Implant together with the signal through the intact skin.
- The *electrode array* attached to the ceramic Implant package is inserted into the cochlea during surgery. The stimulating contacts (electrodes) are arranged in pairs.
- The electrode contacts are mounted on the electrode array such that they are optimally positioned for stimulating the auditory nerve.
- The *reference electrode* is required to complete the electrical circuit. It is placed under a muscle behind the ear.

15

Components you should have received

1 TEMPO+ User Manual

1 TEMPO+ Speech Processor Control Unit

1 Straight Battery Pack

1 Angled Battery Pack

1 Children's Battery Pack

2 Coil Cables

1 Coil

2 Magnets

3 Earhooks for Straight Battery Pack

3 Earhooks for Angled Battery Pack

12 batteries 675 zinc-air

1 Speech Processor Test Device, if first patient kit

1 Drying Kit

1 Registration card for external components

If any of these components are missing, or if you do not understand their use or function, please contact your clinic.

Please fill out the registration card included at the end of this manual and return it to the indicated address.

76

5. *TEMPO+ Speech Processor and Coil*

The TEMPO+ Speech Processor

This section explains the functions of the switches and controls of your speech processor.

The microphone receives acoustic signals and sends them to the speech processor. It picks up the sound from all directions. If you were accustomed to hearing with both ears, you may find it initially quite different to receive all sound information on one side of the head. Sounds from the opposite side may appear softer. You or your child will need visual support to determine the direction of the sound.

The speech processor is held behind the ear with an ear hook. Using an ear level speech processor has proven beneficial in everyday listening situations.

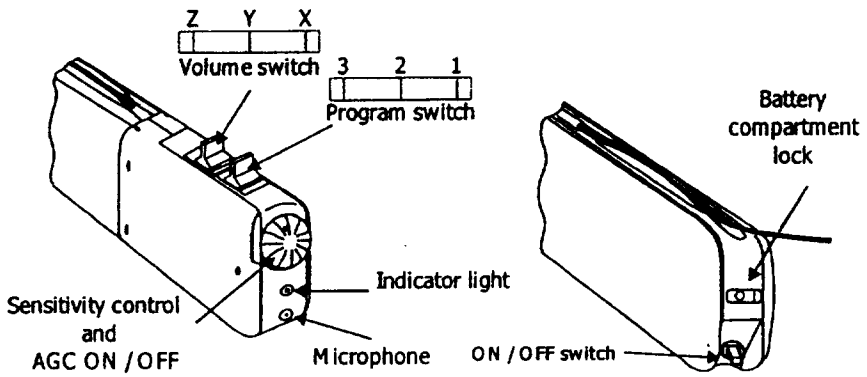


Fig. 5–a TEMPO+ controls

77

TEMPO+ controls

ON/OFF switch

The ON/OFF switch is located at the back of the battery pack.

You may select the following positions:

OFF – lever down

ON – lever up

After switching on the processor, the red control light comes on for about 5 seconds indicating readiness for operation. During this time the speech processor is already working.

In switch position OFF, the processor is turned off. No current is drawn in this position. Make sure to switch your processor to the OFF position when not in use, as this prolongs the lifetime of your batteries (see also chapter Care and Maintenance).

The processor should be switched off:

- whenever the coil is not worn,
- while changing batteries,
- when plugging in or unplugging the coil and programming cable,
- when you are asleep
- when loud noises are annoying after the volume has been reduced. However, it may be more beneficial to reduce the sensitivity.

Switching your processor on or off may cause you to perceive a sound. It is recommended that you remove the coil before operating the on off switch.

Program switch

You can select one of the following positions:

Switch positions

front:	Program 1
center:	Program 2
back:	Program 3

In order to accommodate a variety of listening environments during processor fitting, up to three different programs may be loaded into your TEMPO+ Processor. You can select between these programs with the program switch. *Parents of implanted children should consult their clinic to find out the most beneficial setting for their child.* The same program may be placed into all three ON positions to prevent small children from changing programs inadvertently.

If the red indicator light flashes twice, after selecting a program, no program was loaded into this position. In this case you should contact your clinic.

18

Volume control

With the volume control you can adjust the loudness of your hearing sensations in steps between 1 and 3.

Switch positions

front:	Loudness X
center:	Loudness Y
back:	Loudness Z

In normal situations, e.g. for conversation in a quiet room, the volume control should be set to level Y for comfortable loudness.

Your speech processor is programmed to supply you with a natural and comfortable range of loudness.

Your ability to perceive acoustic sensations may vary from day to day. The volume control serves to accommodate these slight variations.

It will typically be unnecessary to adjust the volume control during the day, unless you find yourself in extreme listening situations.

If your child is too young to tell slight variations in loudness, the speech processor will be programmed to avoid uncomfortable hearing sensations. For young children, the clinic personnel will preprogram a defined loudness level to prevent inadvertent adjustment. Your clinic will inform you about the loudness setting most suitable for your child.

Please contact your clinic for reprogramming your processor:

- if you prefer to regularly use your speech processor with the volume control set to position Z.
- if you would prefer increased loudness, although the volume control is already set to position X.

When selecting a volume setting below position Y, your ability to discriminate various degrees of loudness and, consequently, your speech understanding may be impaired.

☞We recommend verifying comfortable loudness perception when switching on your TEMPO+ in the morning by loudly talking to yourself. If necessary you may select a volume position different from the one you normally use. Further volume adjustments should not be required during the day.

Microphone sensitivity control

The sensitivity control is located in the front of the speech

79

processor.

Speech understanding becomes increasingly difficult with increasing background or other interfering noise. Since the sensitivity control enables you to adjust for difficult listening situations, it is the most frequently used. You should use the sensitivity control to adjust to your daily listening environment.

Background noise is generally lower in amplitude than spoken language in the immediate vicinity. When setting the sensitivity control to maximum, all sounds, including very soft ones, will be processed by the TEMPO+. At lower sensitivity settings, more quiet sounds, like background noise, are no longer processed by the TEMPO+, while you will still be able to perceive language spoken by a person nearby.

To reduce background noise in a loud environment, you should select a low sensitivity setting. A control knob is used to adjust the sound sensitivity. When turning the knob clockwise, more background noise is processed. You should make yourself familiar with the various sensitivity settings b y experimenting with them. Some COMBI 40/40+ users like to frequently change the sensitivity setting to adjust to different listening situations, while others prefer to stay with one setting.

IMPORTANT

When setting the sensitivity control to minimum, you will feel a slight mechanical "click".

In this position the Automatic Gain Control (AGC) is disabled ("AGC Off").

The "AGC Off" position is recommended when there is little background noise, e.g. when using the telephone.

Please note that the "AGC Off" position differs from a low sensitivity setting: it is particularly designed for listening situations without background noise.

For young children, particularly children without hearing experience before implantation, we recommend to select a medium sensitivity setting. Children learning speech via their Cochlear Implant seem to handle this setting very well.

You should choose a quiet room to become familiar with the sensitivity settings. Set the volume control to the center position and start with the lowest sensitivity setting (maximal suppression of background noise). Ask someone to talk or read to you at normal loudness levels, while slowly increasing the sensitivity setting, and listening to the loudness and quality of the other person's voice. When the voice is loud enough but not uncomfortably loud, make a note of the sensitivity setting. Now focus your attention on softer sounds, such as your own breathing, the tapping of a pencil, or rustling paper. You should perceive some of these noises. If not, you should select a slightly higher sensitivity setting.

It is important to experiment while continuously increasing sensitivity. If the speaker's voice seems very loud or even uncomfortably loud, you are probably outside your individual sensitivity range. Make a note of the setting, where sound is most comfortable for you, and use this setting in listening situations with relatively low background noise. In listening situations with more background noise, as in a busy street or a larger group, try to reduce background noise by selecting a low sensitivity setting. When the sensitivity is excessively reduced, the overall loudness of the sound perceived would also decrease. Increasing loudness with the volume control can compensate for this. Reset the volume control to its normal setting when bringing the sensitivity control back to the most comfortable setting. You

will probably notice that your preferred sensitivity setting will change over time, as you become more experienced in listening with the COMBI 40/40+ System.

Coil

The coil (previously called transmitter) connects the TEMPO+ Speech Processor with the Implant. It sends both energy and the coded acoustic signal through the intact skin to the Implant. This transmission is referred to as "transcutaneous transmission".

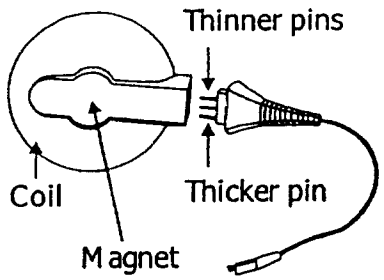


Fig. 5–b Coil

A small magnet is located in the center of the coil to hold it in place on the head over the implanted Implant package. Magnetic attraction force can be adjusted to meet individual needs. Your clinic will adjust these magnets for you.

Please contact your clinic if there are any signs of skin irritation to adjust the magnetic attraction force.

It is easiest to observe children when playing or in everyday situations to determine whether the coil is properly attracted to the Implant. If the coil falls off too easily, your child may develop an aversion to wearing the coil. During the first months post-surgery, you should regularly check the skin under the coil for irritation. As the child grows, skin thickness may increase and the magnetic attraction force will need to be adjusted accordingly.

Coil cable

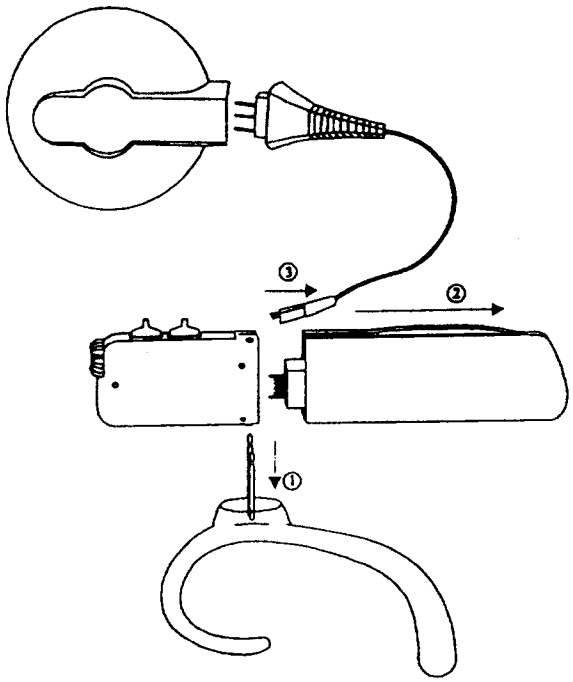


Fig. 5–c Unplugging the TEMPO+ coil cable

The speech processor is connected to the coil by the coil cable. The cable may be unplugged from the speech processor and the coil. The cable needs to be unplugged from the speech processor for maintenance only. It is, however, not necessary to unplug the cable when changing the batteries. The cable is unplugged from the coil in

three steps:

1. Pull the ear hook straight down until you feel a mechanical click. You may also pull out the ear hook completely.
2. Pull the battery pack back until it is completely detached from the control unit.
3. The cable can now be carefully unplugged.

To reconnect the cable, proceed from step 3 to 1. Make sure that the cable plug is correctly positioned: the slanting edge should face up.

To prolong your cable's life, we recommend the following:

- Do not pull on the cable.
- Do not bend the cable.
- When unplugging the cable, pull on the plug and not on the cable itself.
- Do not lift the speech processor by the cable.

There is a guide pin on the coil end of the cable. This guide pin is thicker than the two remaining pins, so there is only one way to plug the cable into the coil.

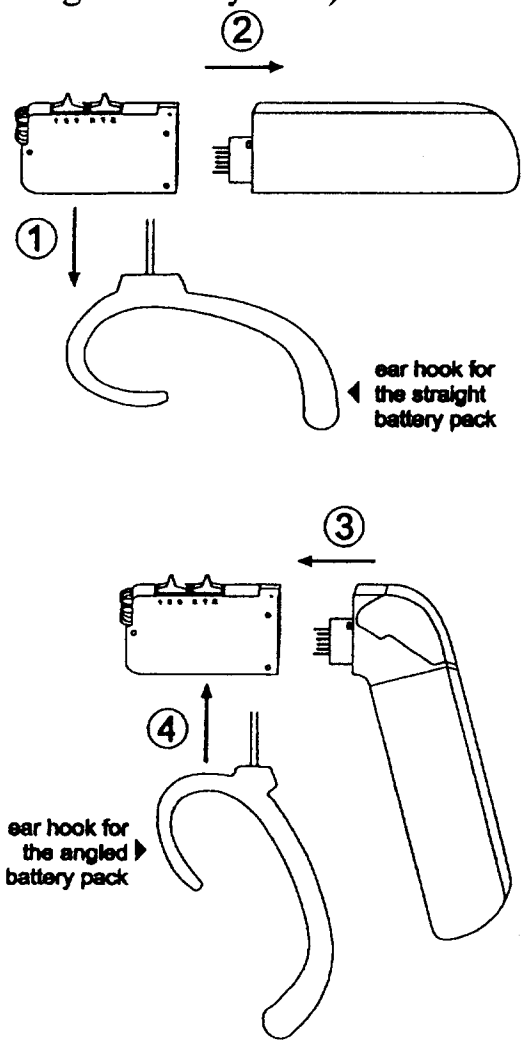
Do not use excessive force when connecting the cable, as this may decrease the lifetime of the cable, the speech processor and the coil. The cable must not be used with devices other than the TEMPO+ Speech Processor.

Although the cable is designed for maximum durability and flexibility, this part of the COMBI 40/40+ System is most likely to wear out.

If a cable fails, please order a new one immediately.

Angled Battery Pack

As an option, the Angled Battery Pack may be used in place of the straight battery pack. (A special ear hook has to be used with the Angled Battery Pack)



In order to attach the Angled Battery Pack proceed as follows:

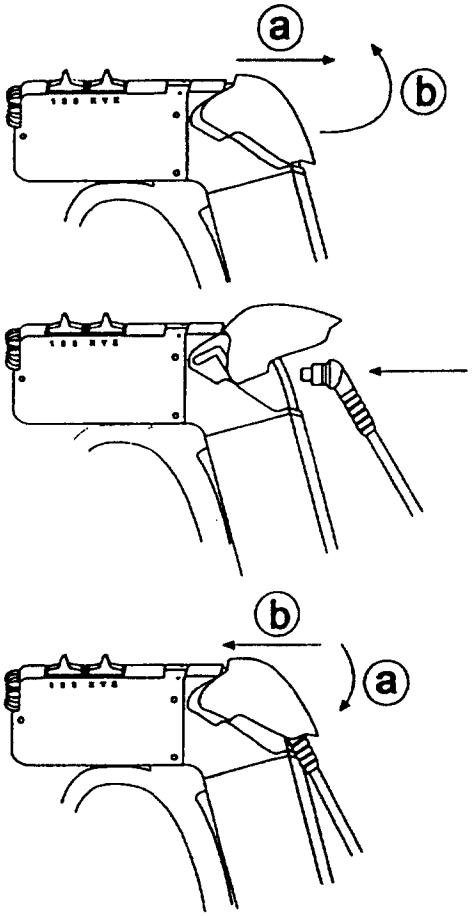
1. Pull the ear hook of the Straight Battery Pack out until it completely detaches from the device.
2. Pull the straight battery pack out of the Control Unit until it completely detaches.
3. Push the Angled Battery Pack into the Control Unit until it attaches firmly.
4. Attach the ear hook (angled version) by inserting the two pins into the two holes on the bottom of the control unit. The pins should be inserted completely.

Use the same procedure whenever battery packs are changed. Always make sure that the appropriate ear hook (angled or straight version) is used.

85

Connector for FM Systems

The Angled Battery Pack includes a connector for assistive listening devices like FM-Systems.



To connect a cable that leads to a FM-system or a similar device proceed as follows:

1. Open up the cover at the angled part of the device by first pulling the cover straight to the back (a) and then lifting the cover by turning it as shown (b).
2. Insert the connector of the cable into the socket underneath the cover. Be careful not to force the connector into the socket in wrong orientation. The red dot on the cable connector must point upwards. If orientated correctly, the connector slides into the socket gently.
3. Gently push the cover back downward (a,b) until it rests on the connector. This ensures maximum protection of the connector.

Important:

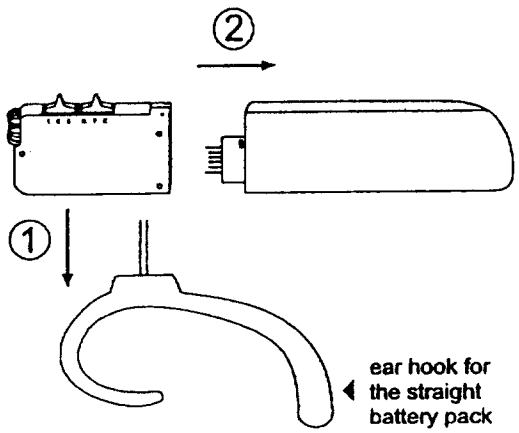
Never connect devices that can be powered by main supply to the Angled Battery Pack of the TEMPO+!

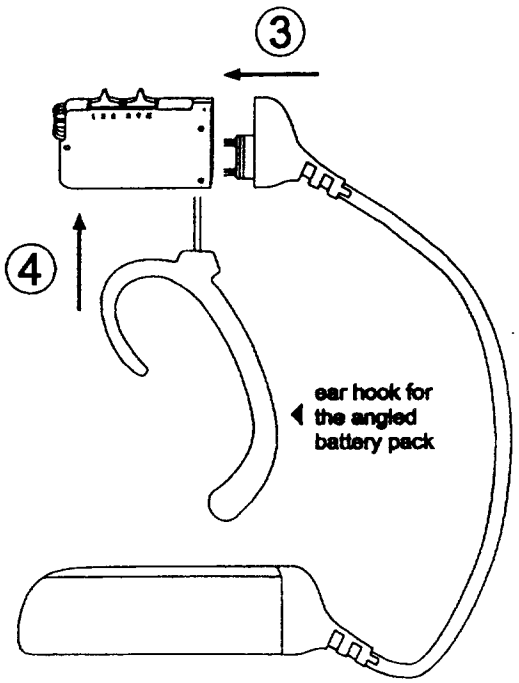
- **Use only cables provided by MED-EL.**

Compatibility with specific devices has been assessed and details can be found in the ***Guide to FM Systems*** (available from your MED-EL representative).

Children's Battery Pack (Option)

As an option, the Children's Battery Pack may be used in place of the straight battery pack.





In order to attach the Children's Battery Pack proceed as follows:

1. Pull the ear hook of the Straight Battery Pack out until it completely detaches from the device.
2. Pull the straight battery pack back until it is completely detached from the control unit.
3. Push the connector of the Children's Battery Pack onto the Control Unit until it is attached closely.
4. Attach the ear hook (angled version) by inserting the two pins into the two holes on the bottom of the control unit. The pins should be inserted completely.

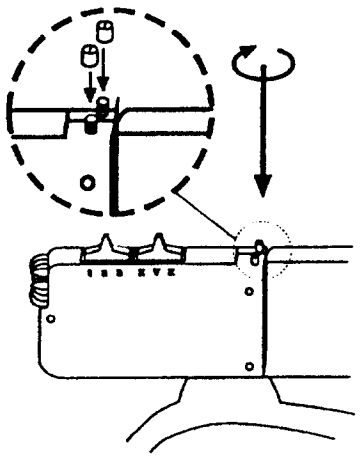
Use the same procedure whenever you want to exchange one battery pack for another.

Always make sure that the appropriate ear hook is used.

87

Locking Screws for Ear Hooks (Option)

If a small child is using the processor, it might be desirable to lock the ear hook, so it cannot be pulled by the child. For this purpose, special versions of the ear hooks are available, that can be locked with two small nuts on the pins.



To lock the ear hook, attach it just like a standard ear hook. Then use the little screwdriver to screw the two nuts onto the threaded pin endings, protruding from the top of the speech processor.

Important: Never leave this version of the ear hook in place without the locking nuts. The protruding ends of the ear hook pins might scratch the skin or lead to other injury.

Locking Battery Lever (Option)

All versions of the battery pack (Straight, Angled, and Children's Battery Pack) can be provided with a locking battery lever. With this lever, only using a ballpoint or other pen can open the battery door. Thus, a little child is not able to open the battery door to take out the batteries and possibly swallow the batteries. See section Batteries for detailed instructions on how to open the battery door.

Locking Sensitivity Control (Option)

In order to avoid unintended turning of the sensitivity control when small children use the processor, a smooth knob that can be turned only by a small screwdriver can replace the standard knob.-

6. *Preparing the TEMPO+ for small children*

If the user of the TEMPO+ is a small child, several options may be implemented in order to avoid unintended risks for a child. These options include:

- Locking battery lever: This lever can be operated only by use of a pen, therefore a small child cannot open the battery door to take out the batteries and possibly swallow them.
- Locking screws for ear hooks: Special versions of the ear hooks are available, that can be locked with two small nuts on the pins. With these nuts it is impossible for a small child to pull off the ear hook and possibly hurt itself by the two pins.
- Locking sensitivity control: In order to avoid unintended turning of the sensitivity control, the standard knob can be replaced by a smooth knob that can be turned only by a small screwdriver.
- Locking the program- and volume switches: These switches cannot be locked, but by loading the same program and volume into each memory position, there is no change in the perception, if the switches are manipulated. Your audiologist in the clinic setting performs this programming.
- Children's Battery Pack: This option allows the patient to wear the battery pack in a different location. The control unit is still placed on the ear, while the battery pack may be clipped to the collar, to a hair band or a similar position. This option is useful in cases where the ear of a small child is too small to carry the complete processor.

7. General Precautions and Warnings

This section contains information on the safe use of your Cochlear Implant system. Please read this information carefully. Your Implant clinic or nearest MED-EL office will assist you with any additional questions.

Before you undergo medical treatments or examinations, always inform your doctor that you have a Cochlear Implant.

General precautions for your Cochlear Implant system

Expected performance with the Cochlear Implant cannot be accurately predicted. Past experience with the COMBI 40+ may provide some general guidelines during patient counseling, depending on individual regulatory rules. Duration of deafness, age at implantation, primary communication mode, communicative ability and the patient's auditory environment all have an impact on the success with the Cochlear Implant, as do other factors, some of which may be unknown.

Do not use your cochlear implant system with any device other than those listed in this manual or released by MED-EL for use with the COMBI 40/40+ system.

Your TEMPO+ Speech Processor and other parts of the system contain sophisticated electronic components. The electronics are designed to be durable and will function for a long time when handled with care.

- Do not open the housing of your speech processor. Unauthorized opening causes loss of warranty. To change the batteries or clean the battery contacts, open only the battery pack lid as described in the appropriate manual section.
- Before switching on your TEMPO+ Speech Processor, check the entire COMBI 40/40+ System for proper mechanical condition, e.g. for loose or broken parts. In case of problems, do not switch on your processor but refer to chapter 9 (Troubleshooting) or ask your clinic, COCHLEAR IMPLANT center, responsible acoustic technician, or MED-EL for assistance.

90

- Your TEMPO+ Speech Processor and coil do not require regular maintenance by clinic personnel or other experts.
- The defined operating temperature range for the processor is between +10°C (50° F) and +45°C (113° F).
- If you ever experience loud or uncomfortable sounds, please remove your coil immediately: this will stop stimulation at once.

Daily Life - General

- As a rule, care should be taken to protect the Implant from any direct sources of impact. This is especially important for young children.
- Accidents such as falling down from a chair or bumping into other furniture etc. might cause damage to the speech processor. Parents are highly advised to take measures to prevent such accidents (e.g. using child seats, blocking drawers, etc.). Parental supervision is also highly recommended outside the house (e.g. in the playground) to avoid any of the above-mentioned adverse incidents, which might cause interference or damage to the Implant.
- Do not leave the speech processor in direct sunlight (particularly inside a car).
- Do not attempt to use the speech processor of another Cochlear Implant user. Your processor has been adjusted to your individual needs. Using another speech processor may cause painful or uncomfortable stimulation.
- Avoid getting your speech processor wet as this may impair its function. Keep your speech processor away from

91

moisture, e.g. heavy rainfall, swimming and activities that may cause your speech processor to become wet. Always remove and switch off the external parts of your Implant system and keep them in a dry place before bathing or showering.

- If the external parts become wet, switch off your processor as quickly as possible, remove the batteries from the battery pack, unplug the battery pack from the control unit, and gently wipe all external parts dry, using a soft, absorbent cloth. Then store the speech processor at least over night in a dry place to allow moisture inside the processor to dry.
- A drying kit, as used for hearing aids, can provide some help. If in doubt, extend the drying period to a day or longer, especially if water has been draining out of the processing unit.
- Activities or sports, particularly contact sports (e.g. boxing, kick boxing, rugby, hockey, gymnastics), that might result in severe blows to the head or continuous pressure on the Implant, should be avoided since they could damage the Implant.

  Non-contact sports (e.g. tennis, golf, badminton, squash, running etc) are generally allowed, however the patient must make sure that the external equipment is worn securely and protected from physical damage.

  Sports for which a helmet is recommended or required (e.g. cycling, riding, motor biking, sailing, football) are also acceptable if they do not exceed the given capabilities of the patient. The use of a helmet is strongly advised, since this will help to protect the Cochlear Implant site from any blows. The helmet should be of high quality and might need to be modified for the patient's needs.

  Swimming, shallow diving, snorkeling, and most water sports should cause no problems as long as the external parts of the Implant system are removed. When scuba diving or snorkeling, placing the strap directly onto the site of the Implant should be avoided. In any case, the patient shall consult an experienced physician about the possibilities and personal restrictions while engaging in water sports, especially diving and scuba diving.

- Patients that have skin

92

sensitivity to the materials in contact with skin (i.e. earhook) may experience minor skin irritation. If this condition persists, contact your Implant clinic or nearest MED-EL office for assistance.

- When styling your hair, please be careful that the skin over the Implant site is not being harmed (there is often a slight bulge in this area). Extensive scratching and causing the skin to bleed (trichotillomania) should be strictly avoided.

Daily Life - Technical

Metal detectors

Your TEMPO+ Speech Processor should be switched off when walking through a metal detector. Such detectors at airports or commercially available anti-theft devices can cause strong magnetic fields. Cochlear Implant users may perceive a soft sound near such devices. The sensation should cease when the speech processor is switched off.

In case the program (map) stored in your TEMPO+ Speech Processor is erased, you should contact your clinic, COCHLEAR IMPLANT center, or responsible acoustic technician, in order to reprogram it. If your processor has stored more than one program you can make use of one of the other programs in the meantime.

The Implant may also trigger metal detectors. You should always have your patient ID card ready to identify yourself as a Cochlear Implant user.

Flights

Airlines request that computers or other electronic devices be switched off during takeoff and landing because electronic devices may interfere with the

93

communication system and instruments of the airplane. Your TEMPO+ Speech Processor is an electronic device and should therefore be switched off during takeoff and landing.

TV, (amateur) radio, mobile phone, short wave transmitter interference

Avoid any equipment that can be physically connected to the wall socket. If required, it is necessary to use audio isolation devices when establishing a connection to electrically powered appliances. Special cables might be necessary for battery operated devices. For further information feel free to contact MED-EL.

Your speech processor may interfere with some TV or radio models that have indoor antennas. Interference may be reduced by increasing the distance to the TV set/radio or realigning the antenna.

Mobile phones may interfere with the external parts of your Cochlear Implant system when used within a radius of less than 3 meters. Based on the experience of other COMBI 40/40+ Cochlear Implant users, the system is compatible with some mobile devices. If you plan to buy and use a mobile phone, test it first for possible disturbing interference with your Implant system.

The electromagnetic radiation of short wave transmitters or amateur radios operate in similar frequency ranges as the MED-EL Cochlear Implant does. Up to now, no cases of disturbing interference have been reported. Yet, it is highly recommended not to get too close to the antennas of such systems.

Electrostatic discharge

Electronic devices are influenced by electrostatic discharge (ESD). Despite internal safety features, there will always be a certain risk of interference or damage. Electrostatic discharge due to friction generally causes the processor to switch off. In rare cases, uncomfortably loud hearing sensations have been experienced. Until now (spring 2000) no MED-EL Implant has been damaged due to electrostatic discharge.

Electrostatic charge build-up occurs most frequently when the air is very dry. If you touch anything that is connected to the ground, discharge of the current occurs through that item. If this discharged current flows through the external parts, it might damage part of the system.

94

Switching off your processor will not prevent damage from occurring. Following the listed guidelines can reduce the probability of electrostatic discharge.

- Whenever you believe you may be statically charged, discharge yourself by touching a radiator, water tap, or any grounded metal.
- Discharge yourself before taking off or putting on your speech processor!

  Two step approach:

(A) When removing a person's processor
Step 1 touch the person's body.
Step 2 Touch the equipment.

(B) When picking up a speech processor from a table
Step 1 Touch the table.
Step 2 Pick up the processor.

- Do not allow another person to touch the external parts of your Implant system unless both you and the other person are "discharged".
- Discharge yourself when leaving a car, e.g. by touching the door. The processor or the cable should never touch the door or other parts of the car body. Young children and elderly persons should be helped out of the car!
- When working on a computer, make sure the computer is grounded.
- Place an antistatic mat under your work place.
- Do not directly touch the screen of your computer or TV.
- Use an antistatic spray for your car's upholstery, TV or computer screens. These sprays are also available for carpets or clothes.
- Remove your speech processor before taking off or putting on garments, which include synthetic fibers. Generally, clothes made of cotton and natural fibers are preferred since they are less likely to cause ESD problems than synthetic materials. Fabric softeners might also help reduce this problem. Your TEMPO+ SPEECH PROCESSOR and cables should always be worn under your clothing so that they do not rub against anything that is charged. When getting dressed, put on the Cochlear Implant equipment last of all, and when taking off your garments remove your speech processor first in order to avoid ESD.
- Remove your speech processor before touching play equipment made of plastic (e.g. plastic slides, crawl tunnels, pool balls).

95

Switching off your speech processor will not prevent damage from occurring! Afterwards, do not touch an implanted child at the site of implantation.

- Before experimenting with static electricity and "high" voltage, e.g. at school, college or university, remove your speech processor. Van de Graaf generators must not be operated by implant users since they produce very high levels of static electricity.
- If your speech processor stops working and you suspect an ESD event as the reason, switch off the processor, wait for 10 to 20 minutes and switch it on again, the programs may be restored.

Swallowing external parts or small components

Parents should instruct their children not to swallow or put any components of their Cochlear Implant system into their mouths. This applies particularly to the batteries.

WARNINGS

MRI

WARNING: Implantees with the COMBI 40+ Cochlear Implant system should not be subjected to MRI, should not enter the MRI suite, or come into close proximity to the source of the magnetic field. MRI involves the use of very strong magnetic fields, the effect of which could possibly dislodge the implant or demagnetize the internal implant magnet.

Precautions for medical procedures

Neurostimulation or Diathermy

Neurostimulation or diathermy must not occur in the area of the Implant since it could lead to current induction at the electrodes. This may damage the Implant and/or the surrounding tissue.

Electrical surgery

Monopolar electrical surgery devices should not be used in close proximity to the Cochlear Implant. Instruments used in electrical surgery can produce high-frequency voltages, which may induce currents in the

96

electrodes of the Cochlear Implant. Such currents may damage the Implant and/or the surrounding tissue.

Electroconvulsive therapy

Electroshock or electro-convulsive therapy should not be used in patients with Cochlear Implants. Such therapy may damage the Implant and/or the surrounding tissue.

Therapy using ionizing radiation

Ionizing radiation may damage the Implant. Tissue surrounding the cochlea and the Implant should therefore be exempt from therapy using ionizing radiation.

Switch off and remove your speech processor in the vicinity of strong ionizing radiation like X-ray diagnosis machines.

8. *Care and Maintenance*

Maintenance

Your TEMPO+ is designed for durability and reliability. When handled with sufficient care, it will continue to function for a long time. The battery pack and its cover may wear out due to frequent opening and closing and therefore have to be replaced more frequently.

Do not clean the external parts in or under water. Use a damp cloth to gently clean the processor. Do not use aggressive cleaning agents. Prevent water from running into the speech processor via the connectors, controls, or the battery pack.

While you should take every precaution to prevent inadvertent exposure of your TEMPO+ Speech Processor to water, uncomfortable stimulation will not occur if the processor does become wet.

If your TEMPO+ is exposed to water, do not switch it on immediately. Test its function only after it is completely dry. Repair by a MED-EL service center may be necessary.

Do not try to repair electronic parts of your TEMPO+ and do not try to open the control unit.

Do not touch the battery contacts. If the contacts need to be cleaned, use a cotton swab and a small amount of cleaning alcohol. Gently wipe dry after cleaning.

If you do not use your speech processor for an extended period of time, you should remove the batteries and store them separately. While batteries are stored, self-discharge can be avoided by covering the air openings on the top. They should be covered with adhesive tape.

98

Batteries

In its current version, the TEMPO+ Speech Processor requires three 675 high power zinc-air batteries.

These batteries supply the external and internal components with energy.

Please use only the following zinc-air batteries:

- Rayovac H675 AE
  High Power Extra
- Activair 675 HPX
  High Power

For more information on batteries, please contact your local MED-EL representative or COCHLEAR IMPLANT center.

Changing the batteries

When the red warning light blinks continuously, the battery set must be replaced.

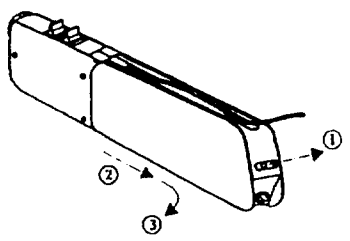


Fig. 8–a Opening the TEMPO+ battery

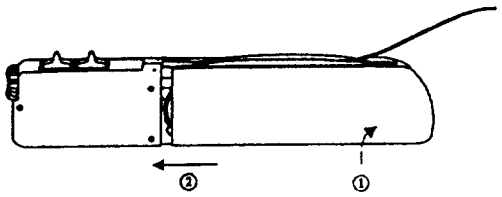


Fig. 8–b Closing the TEMPO+ battery pack

To change the batteries the following steps should be followed:

1) Remove the coil from your head and switch off the TEMPO+ before replacing the batteries.
2) To open the battery pack of the TEMPO+, push the lever at the back of the device (shown in Fig.8–a) and hold it in this position ①. Push the lid on the battery pack backward about 3 mm ②, then remove it by pushing it to the front ③.
3) Replace the used battery set by removing the three batteries with the coil magnet or by gently shaking them into your hand. Try not to touch the battery contacts.

4) Before inserting the new battery set, make sure that the battery contacts are clean and dry. The foil covering the zinc-air batteries must be removed before use. Check for correct polarity when inserting the new batteries. The positive pole (+) must face upwards, i.e. the "+" sign is still visible when the batteries are inserted.

5) To close the battery pack (see Fig. 8–b) put the lid on the housing so that it overhangs the back of the processor by about 3 mm ①. When the lid is positioned correctly, it can be pushed forward ②, where it snaps in place. Do not use excessive force when closing the battery pack.

IMPORTANT

Drained batteries should always be removed immediately to avoid leaking and possibly damaging your speech processor.

Batteries shall be disposed of according to local regulations. As a rule, batteries are collected separately and not disposed of with the household garbage.

Drying kit

Cleaning your TEMPO+ Speech Processor:

For Initial Use of the Tissues

Take the tissues out of the shrink-wrapped packet and thread the first tissue from the inside through the package top. The tissues are perforated.

Weekly Maintenance of your TEMPO+

Thoroughly wipe the external parts of your TEMPO+ Speech Processor with a tissue and let it dry off completely.

Drying your TEMPO+ Speech Processor

Be sure that the drying beaker is absolutely dry! Remove a drying capsule from the blister pack to activate it and place it into the drying container. Place your TEMPO+ Processor into the drying beaker and close the beaker carefully.

100

Some of the earhooks do not fit together with the TEMPO+ into the drying beaker. In this case, remove the earhook from the processor before placing it into the beaker. We recommend that you dry your TEMPO+ Processor on a daily basis (preferably over night). The frequency of drying is dependent on the environmental humidity. For example, high atmospheric humidity or perspiration may require more frequent use of the dry aid kit.

After use, the activated drying capsule should be kept in the carefully closed beaker to prolong its durability. The capsule can be re-used until the blue indicator has completely changed to a reddish-pink color.

Do not swallow the capsules! For further information, please read through the drying kit manual inside the drying kit.

101

9. *Troubleshooting*

Once you are familiar with your Cochlear Implant system, you will not find it difficult to handle minor technical problems, which are similar to those encountered in other electronic devices. Functional problems are most frequently related to batteries or cables.

You have been provided with a small Speech Processor Test Device (previously called CIS PRO+ test box) that may be used to verify proper functioning of the system. Simply place the coil underneath the Speech Processor Test Device (as shown in Fig. 9–a) with the speech processor switched on. The coil will position itself correctly due to magnetic attraction.

When speaking into the microphone, the red light on the Speech Processor Test Device should flicker in the rhythm of your voice. If the Speech Processor Test Device indicates a system malfunction, please check the batteries and cable.

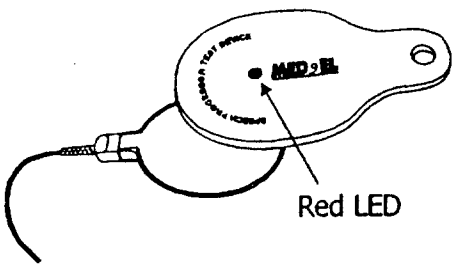


Fig. 9–a Speech Processor Test Device

If you are uncertain about the status of your battery set, you may want to test the system with a new set of batteries.

If the above-described steps do not solve the problem, please contact your clinic. Do not try to open your speech processor's control unit or battery pack other than described in this manual or disassemble the coil, as this immediately voids any warranty.

Using cables or plugs not delivered by MED-EL may damage your Cochlear Implant system or cause uncomfortable or painful stimulation. If you have any questions or problems, please contact your clinic or MED-EL representative.

182

Warning lights

Your TEMPO+ Processor has a red indicator light on the front. Different blinking patterns indicate various malfunctions:

| | light blinking
. | no light blinking

Continuous blinking

Pattern: |.|.|.|.|.|.|

The batteries are dead and must be replaced.

One-sequence

Pattern: |.....|.....|.....|

A defect in the memory access occurred. The device must be repaired.

Two-sequence

Pattern: ||.....||.....||.....||

The selected program or the selected loudness are not programmed or a program failure occurred. Select another program or another loudness then turn your processor off and back on again. You should have your processor reprogrammed as soon as possible.

Three-sequence

Pattern: |||.....|||.....|||

An internal memory failure occurred. Turn your processor off and back on again. If the problem persists, you should have your processor serviced by MED-EL.

10. Technical Data

Speech processor

Dimensions[1]:

· length	67 mm
· width	8,3 mm
· height	13,5 mm
· weight	11 g

Power supply:

- 3 hearing aid batteries TYPE 675 Zinc-Air High Power

Hardware / Software:

- fully digital; fully programmable
- 3 programs selectable
- up to 12 band pass filters of 6th order; filter characteristics programmable
- nonlinear amplification programmable
- frequency range: up to 10,000 Hz
- processor self test: checksum on programs, continuous parity check
- AGC may be disabled

Controls / Control system:

- sensitivity control
- programmable volume control (3 positions)
- ON/OFF switch
- program switch (3 positions)
- indicator LED: 1 red LED for alarm and indicator functions

Symbols:

see manual

Class BF
(IEC 601-1/EN 60601-1)

[1] Typical values

11. Appendices

Warranty, Guarantee and Registration Card

Our warranty is in agreement with statutory warranty claims.

In addition, we grant a three-year guarantee for the TEMPO+ Speech Processor and coil. This warranty exclusively covers product failures; it shall 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.

Statutory warranty claims shall not be granted unless the registration card, included at the end of the user manual, is completed and returned to MED-EL within three weeks of the initial fitting.

The warranty period for the TEMPO+ Speech Processor and coil begins with the date of first processor fitting.

The Implant itself is covered by a 10-year warranty. MED-EL shall provide a new Implant free of charge if the Implant fails due to a mechanical or electrical defect caused by MED-EL.

The warranty period for the Implant begins with the date of Implant surgery and depends on the completion and return of the registration form (COCHLEAR IMPLANT patient card) that is delivered to the clinic together with the Implant. Guarantees exceeding statutory warranty periods shall not be granted unless the registration form is completed and sent to MED-EL.

Please ensure that you and your clinic complete both the registration card and registration form (COCHLEAR IMPLANT patient card), and return them to MED-EL.

Useful Address

Further information about our products may be obtained from one of the following MED-EL addresses:

MED-EL CORPORATION
2222 East NC Hwy 54, Suite B-180,
Durham, N.C. 27713, USA
TEL: +1-919/57 22 222
FAX: +1-919/48 49 229

MED-EL HEADQUARTERS
MED-EL MEDICAL ELECTRONICS.
FÜRSTENWEG 77a
A-6020 INNSBRUCK, AUSTRIA
TEL: +43-512/28 88 89
FAX: +43-512/29 33 81

MED-EL DEUTSCHLAND GMBH.
MÜNCHNER STR. 15b
D-82319 STARNBERG, GERMANY
TEL: +49-8151/77 03 0
FAX: +49-8151/77 03 23

MED-EL VIENNA OFFICE
WÄHRINGER STRASSE 6-8/4/17
A-1090 VIENNA, AUSTRIA
TEL: +43-1/31 72 400
FAX: +43-1/31 72 400-14

MED-EL UK LIMITED
BRIDGE MILLS, HUDDERSFIELD ROAD,
HOLMSFIRTH HD7 2TW, UK
TEL: +44-1484/68 62 23
FAX: +44-1484/68 60 56

MED-EL LATIN AMERICA
SARMIENTO 212 / 4A
1041 BUENOS AIRES, ARGENTINA
TEL: +54-11/4342 3071
FAX: +54-11/4343 9078

MED-EL OFFICE SPAIN
C/RONDA DE PONIENTE 16
ALA DERECHA; PLANTA BAJAL
E-28760 MADRID, SPAIN
TEL: +34-91/80 41 527
FAX: +34-91/80 44 348

MED-EL FRANCE SARL
34, RUE DE PENTHIÈVRE
F-75008 PARIS, FRANCE
TEL: +33-1/53 89 64 45
FAX: +33-1/53 89 64 48

MED-EL ASIA PACIFIC
SUITE 1501 RICHVILLE CORPORATE TOWER
INDUSTRY ROAD, MADRIGAL BUSINESS PARK, AYALA ALABANG
1702 MUNTINLUPA CITY, METRO MANILA
PHILIPPINES
TEL: +63-2/807 8780
FAX: +63-2/807 4163

MED-EL MIDDLE EAST
P.O.BOX 54320
DAFZ DUBAI, UNITED ARAB EMIRATES
TEL: +971-4/299 4700
FAX: +971-4/299 4255

MED-EL JAPAN LIAISON OFFICE
11TH FLOOR AKASAKA DAIICHI BUILDING
9-17 AKASAKA 4-CHOME
MINATO-KU, TOKYO 107-0052
TEL.: +81-3/5414 5353
FAX: +81-3/5414 5388

MED-EL HONGKONG OFFICE
INTERNATIONAL TRADE CENTER, RM. 1106/7,
11-19 SHA TSUI ROAD, TSUEN WAN, N.T.
HONGKONG
TEL: +85-291/701734
FAX: +85-224/379883

107

Declaration of Conformity

MED-EL Elektromedizinische Geräte Ges.m.b.H.
Fürstenweg 77A
A-6020 Innsbruck, Austria,

is the manufacturer of the products listed below:

TEMPO+ Speech Processor

consisting of: Control unit
Battery pack
Coil
Cables

As manufacturer of the products listed herein, MED-EL declares that these products correspond to the EC Directive on Active Implantable Medical Devices 90/385 EEC (AIMD) and the Essential Requirements in Annex I of the Directive.

Conformity assessment was certified by the notified body. For use within the EU, in children and adults, the device is marked with the CE-mark.

0123

CE

1999

The device was developed per the requirements of the Standards listed below:

EN ISO 9001 (1994): Quality Systems - Model for quality assurance in design, development, production, installation and servicing

EN 46001 (1996): Quality systems- Medical devices - Particular requirements for the application of EN ISO 9001

CAN/CSA ISO 13485-98: Quality Systems – Medical devices – Particular requirements for the application of ISO 9001.

Innsbruck, August 2001

106

The Human Ear and Deafness

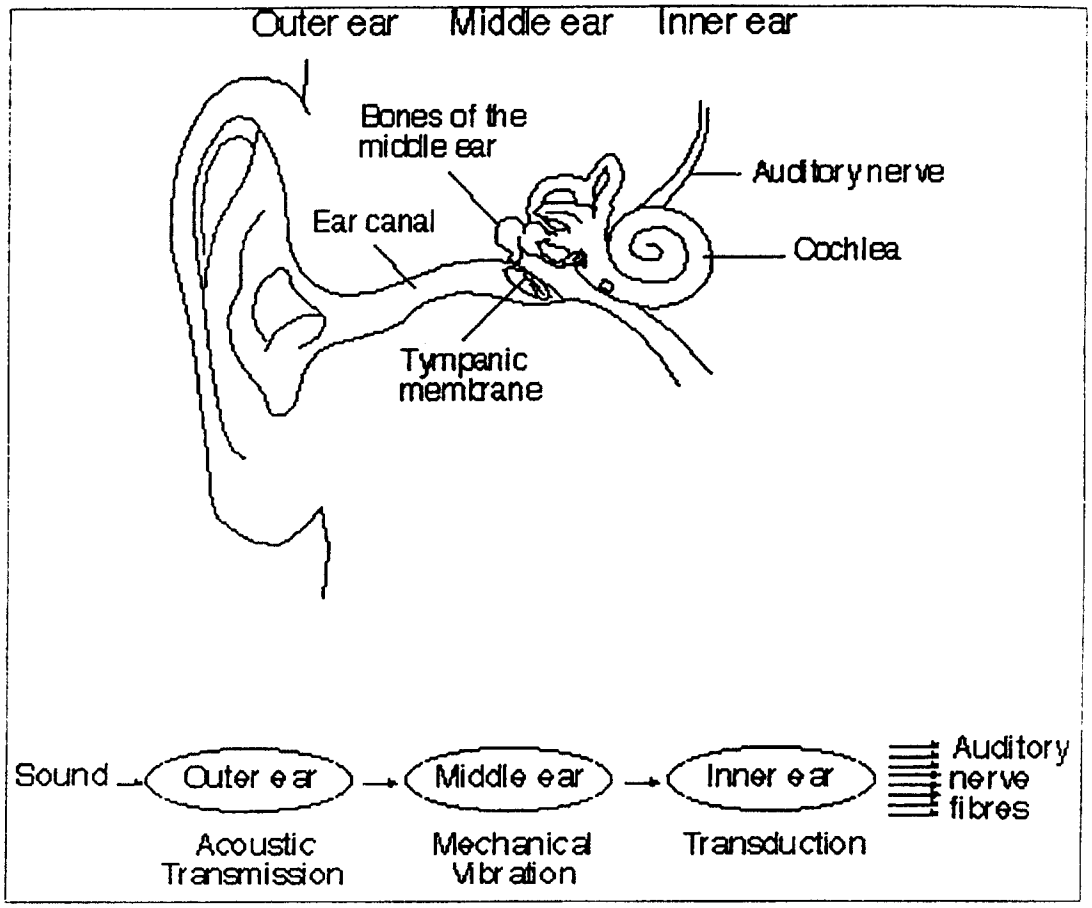


Fig. 11–a The human ear

The outer and middle ear

The outer and middle ear conduct sound. Sound waves cause changes in air pressure in the ear canal, which make the eardrum vibrate. The eardrum vibrates in time with the acoustic stimulus and moves a chain of small bones known as ossicles (hammer, anvil and stirrup). The footplate of the stirrup, the end of the ossicle chain, is attached to the oval window, a flexible membrane forming the entrance to the inner ear or cochlea.

The inner ear

The inner ear or cochlea is a snail shell-like bony chamber filled with liquid and connected to the middle ear via the oval and round windows. The vibrations conducted from the middle ear to the oval window are passed on to

the liquid in the cochlea.

The mechanical vibrations are transformed into neuronal impulses by sensory cells of the inner ear, the so-called hair cells. When vibrations in the cochlear liquid are sensed by these hair cells, they generate neuronal action potentials sent to the brain via the auditory nerve. In the brain these potentials are interpreted as acoustic events (e.g. noise, sound, speech).

The highly sensitive hair cells are easily damaged by various influences, such as certain diseases or excessive loudness. Damaged hair cells are unable to transform vibrations into action potentials. When all hair cells are damaged, absolute or profound deafness results.

Deafness

Hearing impairment

Patients with hearing impairment or residual hearing have limited perception of speech or other sounds. They can usually be helped with optimally adjusted hearing aids that amplify sound.

Congenital and prelingual deafness

Children born deaf are called congenitally deaf. Children deafened postnatally but before having acquired speech are called prelingually deaf. Congenitally or prelingually deaf children usually have only limited speech understanding and speech production. Unless other factors contraindicate implantation, a child should be implanted as early as possible, since acquiring speech becomes increasingly difficult with increasing age. Early diagnosis of deafness is extremely important.

Postlingual deafness

Patients who lost their hearing after having acquired fluency in speech understanding and speech production are called postlingually deaf. Deafness can happen suddenly or start with moderate hearing loss getting progressively worse, until the patient received no speech understanding benefit from hearing aids. Many postlingually deaf people can benefit from a Cochlear Implant. The benefit to be expected from an Implant depends on the duration of complete deafness, i.e. the shorter the period of complete deafness the better the results to be expected from an Implant.

Causes of Deafness

In most cases of deafness the hair

cells in the cochlea have been damaged by disease so that the sound (mechanical vibrations) can no longer be transformed into action potentials in the cochlea. Some causes for deafness include the following:

- Otitis media
- Meningitis
- Encephalitis
- Measles
- Cytomegalovirus
- Mumps
- Ototoxic drugs
- Severing of the auditory nerve (e.g. due to an accident)
- Sudden hearing loss (causes often unknown)
- Hypoxia
- Genetic causes
- Pendred's syndrome
- Usher's syndrome
- Mondini anomaly
- Waardenburg's syndrome
- Hereditary causes

Cochlear Implants

A Cochlear Implant can, at least partially, replace function of the inner ear by directly electrically stimulating the auditory nerve. The outer and middle ears are completely bypassed and have no function in acoustic perception with the Cochlear Implant.

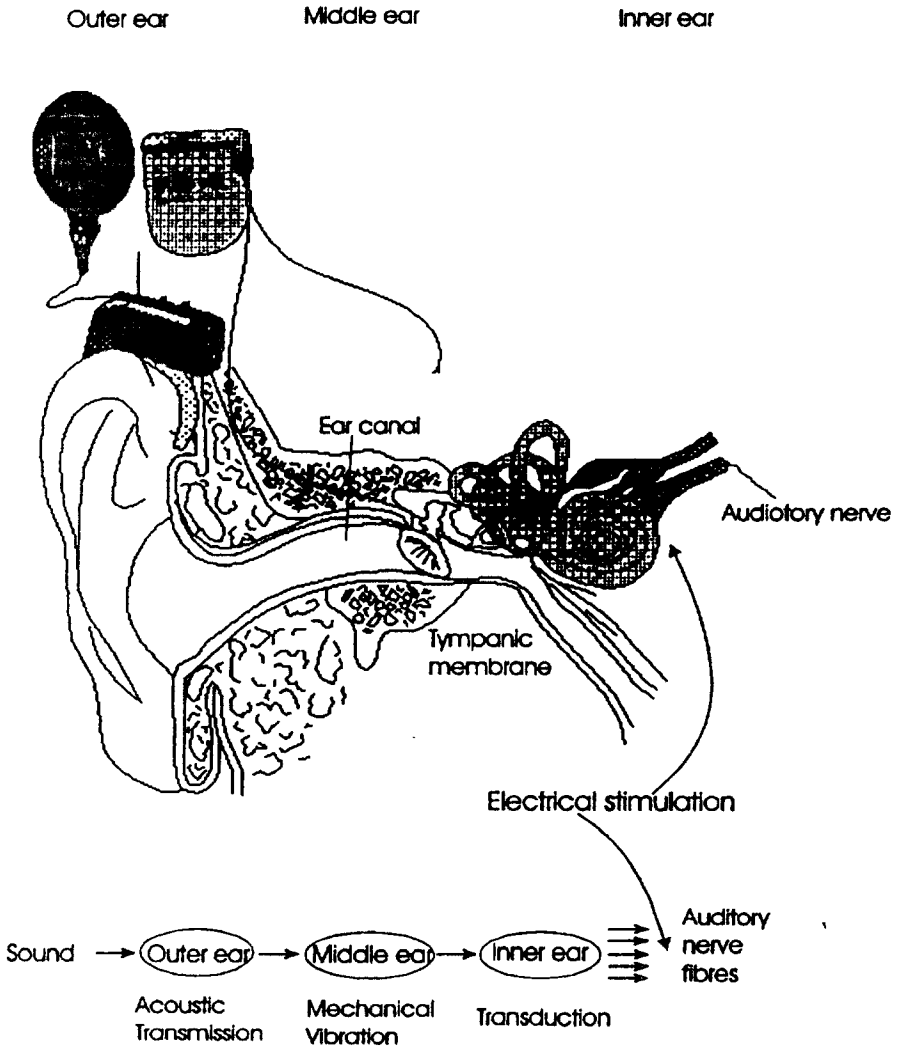


Fig. 11–b Electrical stimulation of the ear

112

Contents of CIS PRO+ User Manual

113

1. Introduction

This manual provides information about the MED-EL COMBI 40+ high rate cochlear implant system.

The *COMBI 40+ Cochlear Implant system* consists the C40+ implant and the CIS PRO+ speech processor.

The first activation of the speech processor, which usually takes place about one month after implant surgery, represents a major change in your life. Emotions accompanying the first days of cochlear implant use may range from great excitement to disappointment. Initial fitting of the speech processor will considerably change your or your child's life. Emotions accompanying the first days of Cochlear Implant use may range from great excitement to disappointment. During fitting sessions, the settings of the speech processor will be readjusted or fine-tuned. This is necessary, because the sensitivity of the hearing nerves changes over time as they begin to get accustomed to stimulation from the implant. Your implant center will require that you or your child return at regular intervals to have the program and surgical site checked. The regularity of these fitting sessions will be decided by your implant center. On average, a programming session takes between one and three hours. The sessions will be more frequent during the first year following surgery, and may be required annually thereafter. Most patients need occasional adjustment of the program for as long as they use the implant.

115

We recommend that you read this manual in its entirety either before the first speech processor activation or shortly after you have gained some experience in the way you perceive voices and sounds with your implant. Some of the information contained in this manual may help you to derive greater benefit from the cochlear implant and the various accessories available for different listening environments.

If any of your questions remain unanswered, please do not hesitate to contact MED-EL, or ask your ENT specialist or audiologist.

2. *Indication for Use*

The MED-EL COMBI 40+ Cochlear Implant System, hereinafter referred to as the COMBI 40+, is intended to provide the opportunity to detect and recognize auditory information through electrical stimulation of the auditory nerve for severe to profoundly hearing-impaired individuals who obtain little or no benefit from conventional acoustic amplification in the best-aided condition.

Candidates and families should be well motivated and possess appropriate expectations.

The CIS PRO+ Speech Processor is implicitly indicated for use with a COMBI 40+ Implant only.

3. Getting Started

How your cochlear implant works

What is a cochlear implant?

A cochlear implant system is an electronic device that can provide totally deaf people with auditory sensations. Part of the device is implanted into the ear during an operation, and another part is worn externally on the body. The COMBI 40+ cochlear implant system consists of a) the C40+ implant, b) the CIS PRO+ speech processor, and c) the CIS PRO+ BTE-headset made up of the microphone and the transmitter coil.

The speech processor selects and processes the signals it receives from the microphone that is worn behind the ear. The circuitry in the speech processor replaces the function of the normal ear to the extent possible with modern electronic signal processing. The processed signals are transferred by the transmitter coil to the receiver that is contained in the implant. The transmitter coil is worn under the hair behind the ear. It is held lightly on the head by magnetic attraction to the receiver. The transmitter coil sends the electronic signal through the intact skin to the receiver.

The implanted part contains small stimulating electrodes that are placed into the cochlea (inner ear). They stimulate the auditory nerve with tiny current pulses that correspond to the sound picked up by the microphone and processed by the speech processor. In response, the auditory nerve produces neural impulses and carries out its intended function of transmitting auditory information to the brain. The speech processor contains rechargeable batteries that provide energy for both the external and the implanted electronics. There are no batteries contained in the implanted part.

Functional diagram

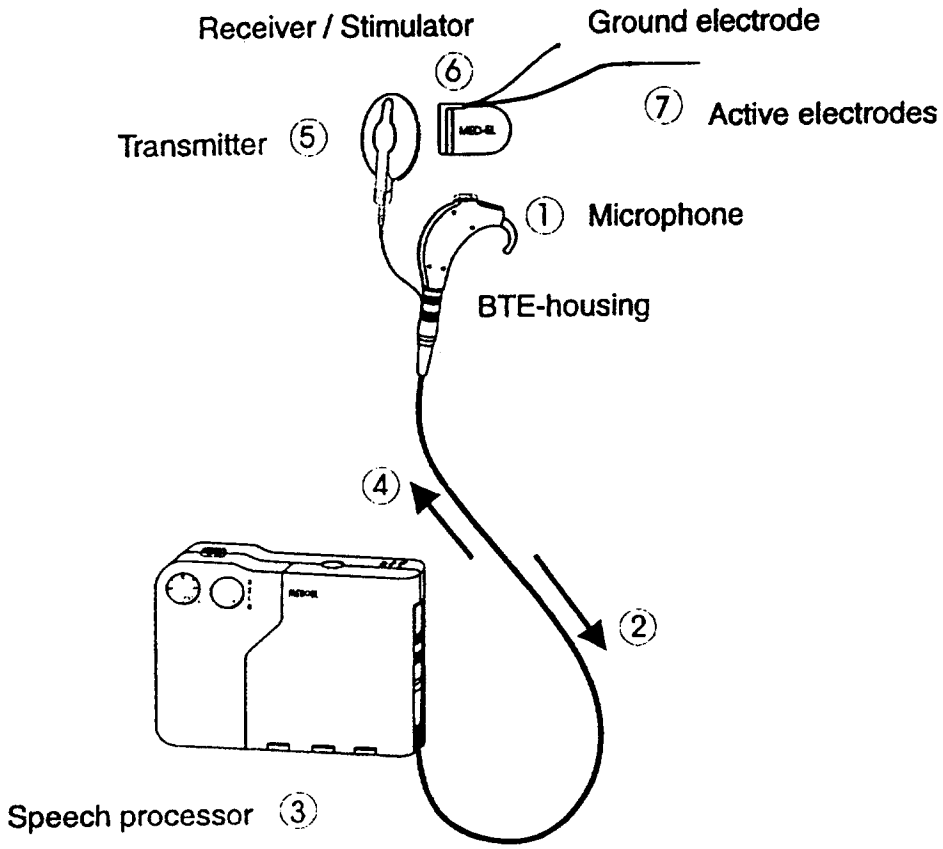


***Figure 2a** shows a functional diagram of the MED-EL COMBI 40+ cochlear implant system:*

1) Sound waves are received by the microphone.
2) The signal from the microphone is amplified and then sent down along the cable to the CIS PRO+ speech processor.
3) The CIS PRO+ acts on the signal according to coding strategies developed to enable optimal hearing with the cochlear implant. The output of the CIS PRO+ is a coded signal of electrical pulses.

119

4) The coded signal is sent up through the cable to the transmitter.

5) The transmitter coil transfers the signal, together with the energy required by the implanted electronics, through the intact skin to the implant.

6) The MED-EL implant and stimulator circuits decode the signal and send a pattern of small pulses to the electrodes in the cochlea.

7) The individual electrode pairs conduct the electrical pulses according to the pattern decoded by the receiver/stimulator. The pulses stimulate the auditory nerve at various sites. In response, the stimulated fibers of the auditory nerve generate neural impulses which are conducted to the brain. The brain receives the neural impulses and interprets them as auditory events. The implant user hears.

The whole process takes place within a few milliseconds, corresponding to the time delay in the normally functioning ear.

Characteristics of the COMBI 40+ cochlear implant system

The COMBI 40+ cochlear implant system is the result of many years of research and development in Europe and the USA. The following characteristics distinguish it from other cochlear implant systems:

- It is capable of accurately implementing in a portable system a very fast version of the speech processing strategy called "CIS" (Continuous Interleaved Sampling) according to the specifications of the inventors. The CIS strategy was developed at the Research Triangle Institute (RTI) in the United States, under a grant of the National Institute of Health. The CIS strategy has been shown to enable very high levels of speech understanding in many patients. Alternatively, a high rate "N-of-M" strategy is also available.
- The COMBI 40+ implant is capable of fast stimulation rates that allow better resolution and a more accurate representation of the temporal components of the acoustic signal to the auditory nerve. It therefore offers the potential for improved speech understanding. Both the CIS and the "N-of-M" strategies can be programmed to run at slower stimulation rates for patients who cannot benefit from fast stimulation.
- The implant is constructed according to highest standards of quality assurance. The electrode carrier is very soft to enable deep placement in the inner ear with minimal trauma. The housing of the implant is made of modern ceramics that has favorable mechanical properties. The ceramic housing used in the COMBI 40+ is more expensive to produce than materials used in conventional cochlear implants.

121

- Each stimulating electrode is protected by individual coupling capacitors against accidental charge build-up. Protective coupling capacitors are a key safety aspect in the design of modern, high-rate cochlear implants.
- The transmission system and the electronics of the implant are designed to work with very little energy loss. This makes the COMBI 40+ system particularly suitable for future miniaturization of the speech processor.

Your implant was designed to be upgradable with improved external hardware and is capable of implementing different speech processing methods. You may thus benefit from improvements in speech processing and miniaturization of the external hardware in the future. The C40+ implants are suitable for use with CIS+ speech processor that fits completely behind the ear (BTE).

- If new speech processing methods can be carried out by your current CIS PRO+ processor, they will be made available to you by simply reprogramming your processor at the clinic.
- If new external hardware is required to implement improved processing methods, it may be offered at additional cost, although it is not certain that all health care providers will cover this cost.

Your clinic will keep you informed of innovations as they become available.

122

The implant

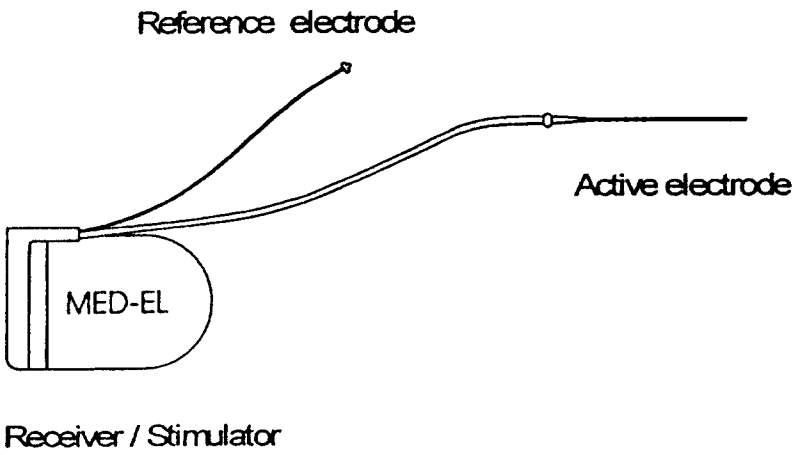


Figure 2b *The MED-EL C40+ implant*

The implant consists of a receiver / stimulator package, an active electrode carrier, and a reference electrode. All materials used in the construction of the implant are fully tested for biological compatibility and durability.

- All electronic components of the *receiver / stimulator* are held in the sealed ceramic housing. The implant is embedded under the skin behind the ear, usually into a small recess in the thick part of the bone, during surgery.
- The implant contains *no batteries* of its own. Energy required to produce the tiny electrical pulses is derived from the batteries in the external speech processor and is transferred to the implant with the signal through the skin.
- The electrode carrier with the *active electrodes* connects to the receiver / stimulator and is inserted into the cochlea. It contains electrodes arranged in pairs for electrical stimulation. Each pair, or channel, can thus act on different parts and stimulate different fibers of the auditory nerve.
- The *reference electrode* is needed to complete the

123

electrical circuit. It is placed behind the ear under a muscle. Its exact position is not critical.

A list of components that you should have received

1 User manual
1 Patient ID card
1 Speech processor
1 BTE-microphone housing
2 Cable assemblies (1 for backup)
1 Transmitter coil
1 Battery charger with instructions
6 Rechargeable batteries (3 sets)
1 Test box
1 CIS PRO+ belt clip
1 Carrying pouch
1 Registration form for the external parts (contained in the back of the manual)

If any of these components are missing, or if you do not understand the use or function of any of the components, please contact your implant clinic for further assistance.

We kindly ask you to fill out the registration card inserted at the back of this manual, within one month of initial fitting of the processor and return it to the indicated address.

125

4. *Speech Processor, BTE-microphone, and Transmitter*

BTE-microphone

The standard CIS PRO+ microphone is contained in a behind-the-ear (BTE) housing, which together with the transmitter coil comprises the "BTE-headset". The microphone receives acoustic signals from the environment. The BTE-housing also contains an amplifier. The amplified sounds are then sent via the cable to the speech processor.

Sounds are picked up by the CIS PRO+ microphone from all directions. If you have previously heard with both ears it may take some time to get used to receiving all sound information only on one side of the head. Sounds coming from the opposite side may be perceived a little bit softer. Because the cochlear implant enables hearing with only one ear, it will always be difficult for you to know which direction a sound comes from without visual assistance.

The BTE-housing sits behind the ear and is held in place with an ear hook. Its shape and

size have been designed for maximum comfort. If you are not used to wearing hearing aids, the BTE might feel slightly uncomfortable in the beginning. If a feeling of discomfort persists, or if the skin gets irritated, please contact your clinic.

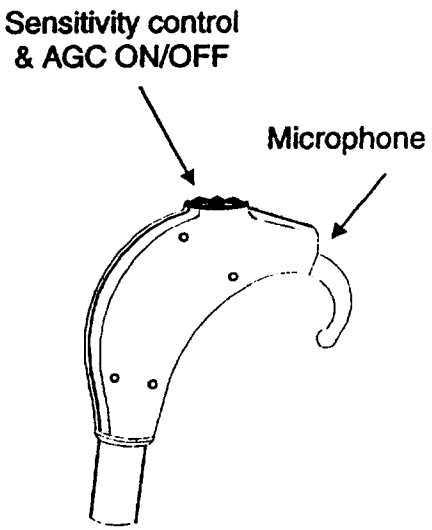


***Figure 3a** CIS PRO+ BTE-housing*

The BTE-housing incorporates a microphone sensitivity adjustment control. Its function is described together with that of the other adjustments that are available to you on the CIS PRO+ speech processor in the next section.

For listening situations within a

126

group of people, or when there is a large amount of background noise, it can be of help to use a separate microphone that connects to the external input of the CIS PRO+ (see the section entitled "External Audio Connection"). An example where an external microphone can be useful is a conference or group meeting where several people sit around a table, or a cocktail party situation. The external microphone can be placed in front of the speaker to enhance his/her voice and thereby suppress background noises and other sounds. When connecting an external microphone to your CIS PRO+ you can deactivate he BTE microphone via a switch inside the battery compartment of the processor. The volume control on the CIS PRO+ (as explained in the following paragraphs) works the same way with the external microphone as it does with the standard BTE microphone.

Please contact your nearest MED-EL office for information about whether a particular model of an external microphone is compatible with the CIS PRO+.

127

CIS PRO+ adjustment controls

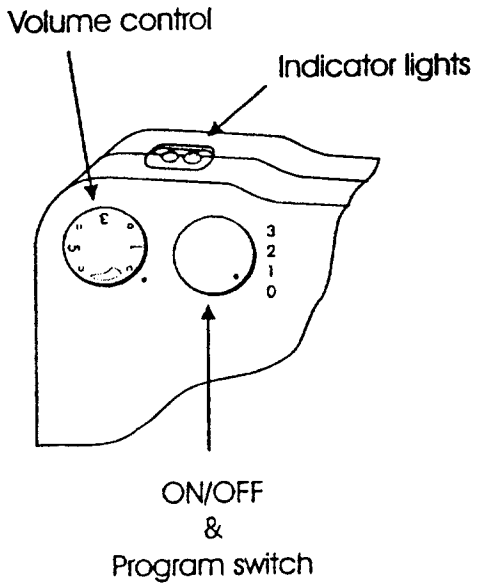


Figure 3b *Controls on the speech processor.*

Program selection and ON/OFF switch

The following positions are available:

O	OFF
1	ON - program 1
2	ON - program 2
3	ON - program 3

When switched to the OFF position the processor performs no function and there is no drain on the batteries. To save battery life, you should always leave your processor in this position when you are not using it.

Up to three different parameter settings or speech processing strategies can be loaded into the CIS PRO+ when your speech processor is programmed at the clinic. Different fitting programs of the CIS strategy, or a different speech processing strategy selection, may be advantageous for you in various listening situations.

In the following situations it is recommended that you turn your processor OFF:

- during sleeping hours
- whenever the transmitter coil is not placed on the head
- while changing the batteries
- when plugging or unplugging the CIS PRO+ cable assembly
- when severe noise or sound in the environment bother you
- when connecting or disconnecting any accessories at the External Audio Connection.

Switching the CIS PRO+ on and off may cause a switching sound. It is recommended that you, take the transmitter off your head before switching the processor on or off.

Volume control

The volume control allows you to adjust the overall loudness of the system. Its scale ranges from 1 to 6. Under normal conditions (e.g., talking to people in a quiet room) the volume control should be set between 4 and 5 for comfortable loudness.

Your speech processor is programmed by the clinic to provide a useful and comfortable range of loudness perception. The volume control on the speech processor serves only to accommodate for slight daily fluctuations in your ability to perceive loudness. Such minor daily fluctuations may occur based on your general physical condition. Unless you find yourself in extreme hearing situations, it should not be necessary to manipulate the volume control during the day.

You should see your clinic for reprogramming of the processor if any of the following situations persist:

- You find it preferable to regularly wear your speech processor with the volume control set below 3
- You frequently wish for increased loudness when the volume control is already set to maximum

When adjusting the volume control to below 3, the number of different loudness levels that can be perceived by you may be reduced. This could cause a worsening in your ability to understand speech.

☞ We recommend that you verify comfortable loudness perception when turning on your CIS PRO+ in the morning by loudly talking to yourself (we do not recommend this procedure in the presence of strangers.) If necessary, the volume control may be set to a different position than usual. No further volume adjustments should be necessary in the course of a regular day.

129

Microphone sensitivity control

The understanding of speech becomes more difficult with increasing amounts of background noise or other interfering noises. The sensitivity control allows you to adjust to listening environments with varying amounts of competing noises. It is the most frequently used adjustment of the CIS PRO+ and is therefore located on the BTE-housing. We recommend that you make use of the sensitivity control to adjust to changes in listening situations in the course of a regular day.

Background noise is generally softer in amplitude than the speech of a person in close physical proximity. When the sensitivity control is set to maximum, all sounds, including very soft ones and all background noise, are processed by the CIS PRO+. When the sensitivity control is turned down, softer sounds, such as background noise, are no longer processed, while the speech of a person standing close by is still processed and thus heard by you more clearly.

In a noisy listening environment we recommend that you turn the sensitivity control down to reduce background noise. The scale of the sensitivity control ranges from maximum background suppression to no background suppression. We recommend that you experiment with the sensitivity control setting in different listening situations to get used to it. Some COMBI 40+ users find it useful to frequently adjust the sensitivity setting to accommodate for acoustic changes in the environment, while others prefer to leave it in one position most of the time.

Important

When the sensitivity control is turned all the way to minimum, you can feel a slight mechanical click. In this position, the control is completely disabled and the speech processor functions in a standardized sensitivity mode. In this standardized mode, the Automatic Gain Control (AGC) of the processor is disabled. This standardized mode is recommended for use in situations where there is no competing noise, for example

130

when using the telephone. The speech signal will be softer with the AGC disabled, and you may want to compensate by increasing the volume of the telephone (where possible) or by increasing the volume setting on your speech processor.

Please note that the "AGC off" position is different from just a low sensitivity setting and is only meant for special listening situations without any background noise.

In order to become familiar with the action of the sensitivity control on the BTE-housing, begin by practicing in a quiet sound environment. Set the volume control on the CIS PRO+ to its normal level, which will probably be between 4 and 5. Start with the sensitivity control turned all the way down (maximum background suppression). Have someone else talk (or read) to you in a level voice from a distance of approximately 1 yard. Slowly increase the sensitivity dial while paying attention to the loudness and quality of the voice you hear. When the voice seems to be adequately loud but not uncomfortable, make note of the dial's position. Now try listening for softer sounds, such as the sound of your own breathing, a pencil tapping the table top, or papers rustling against one another. Some of these sounds should be audible also. If not, try to slightly increase the sensitivity setting.

Continue experimenting with small increases in the sensitivity control. If at some point the speaker's voice or your own voice seem to be excessively or uncomfortably loud, you may have exceeded your individual range on the control. Make note of the dial's position at which you are *most comfortable* with the sound levels, and use this as your normal setting for the control when listening in relatively quiet circumstances. As more background noise is present in different situations (such as being on a busy street or in a large crowd), experiment with *lowering* the sensitivity setting to reduce the interference caused by the background noise. If you make a very large downward change in the sensitivity, the overall loudness of the sound may decrease substantially. You can compensate for this by slightly increasing the volume control on your speech processor. You will probably want to return the volume control to its normal

setting when you reset the sensitivity to the "most comfortable" position. You may find that your preferred setting for the sensitivity control changes as you gain more experience in listening with the COMBI 40+ system.

Transmitter

The transmitter establishes the link between the CIS PRO+ speech processor and the implant. It transmits energy, as well as a coded version of the acoustic signal through the intact skin to the implant. Such a transmission mode is called "transcutaneous transmission".

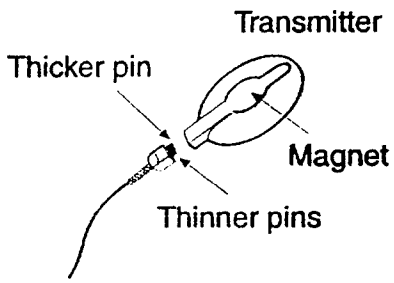


***Figure 3c** CIS PRO+ transmitter*

☞ *A small magnet is contained in the center of the transmitter coil. It serves to hold the transmitter in place on the head via attraction to the implanted receiver magnet. The force of magnetic attraction can be adjusted individually to provide the correct attraction force of your transmitter coil. To change attraction force, please talk to your clinic or nearest MED-EL service center for instructions.*

If signs of minor skin irritation are observed, you should see your clinic as soon as possible. Your clinic will gladly assist you in adjusting the attraction force of the transmitter coil to an appropriate level.

Cables

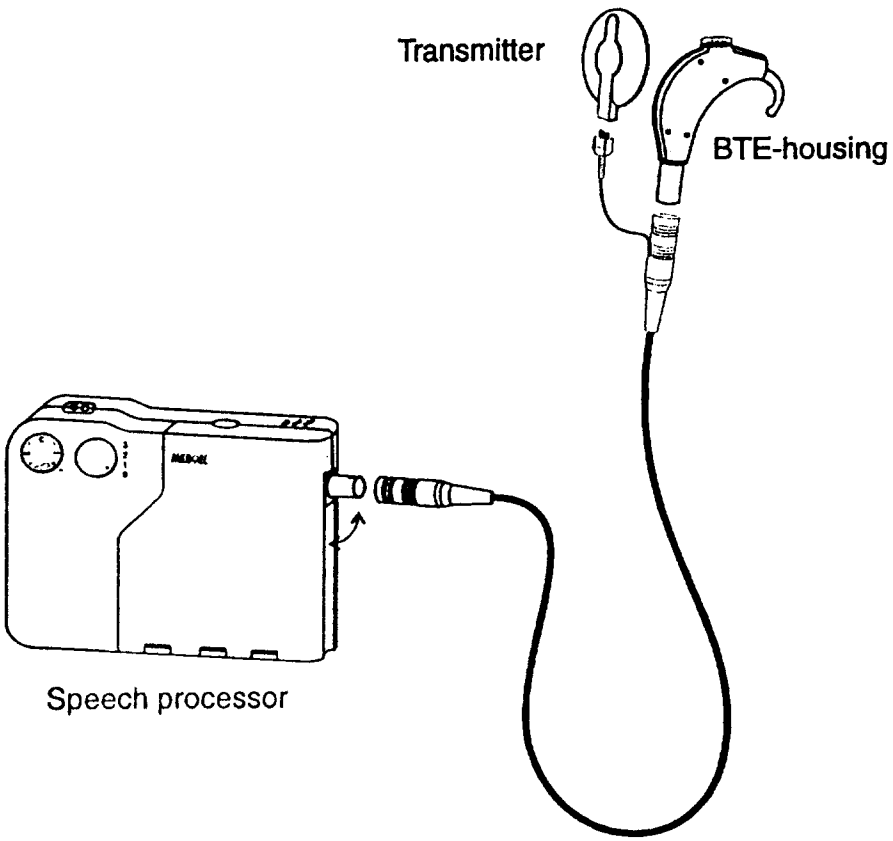


Figure 3d *CIS PRO+ cable assembly*

The connection between the BTE-housing, the speech processor, and the transmitter is accomplished via a cable with multiple conductor wires. The cable can be unplugged from the speech processor, the transmitter coil, and the BTE-housing. You may find it helpful to disconnect the cable from the processor when changing clothes or when repositioning your CIS PRO+ on the body.

Disconnection is also required for some maintenance purposes. It is not necessary to disconnect the cable for changing the batteries.

The following guidelines help to preserve your cable:

- Do not pull or tug on the cable
- Do not bend the cable
- When unplugging the cable, please hold it at the plug. Do not pull directly on the cable
- Do not lift up the processor by pulling it on the cable

There is a guide pin on the transmitter end of the cable. This guide pin is thicker than the remaining two pins and there is thus only one correct way to plug the cable into the transmitter. There is also only one correct way to plug the cable into the speech processor and the BTE housing, as dictated by the guidance and the matching red dots on the connector and the cable plug. Never exert unnecessary force when connecting the cable, as this may shorten the lifetime of the cable, the processor and the headset. Do not try to connect the cable to any other plugs or devices than the CIS PRO+ components.

☞ If you disconnect the cable, we recommend you keep the transmitter coil off the head and the CIS PRO+ turned to the OFF position. You may otherwise hear soft switching noises.

Although the cable has been designed for maximum durability and flexibility, it is the component of your COMBI 40+ system that is most likely to wear out with time. Your CIS PRO+ has an indicator light (warning LED), which will go on together with a buzzing sound when the connection to the transmitter is open. This may indicate an unplugged cable; if all plugs are connected correctly and the warning LED is still on, the cable is defective and needs to be exchanged. MED-EL delivers your CIS PRO+ with two cables. If one cable stops functioning, please order a new one immediately. Do not wait until both of your cables are broken.

Batteries

The CIS PRO+ speech processor requires two AA-sized batteries.

The batteries supply the external as well as the implanted electronic components with energy. For environmental as well as financial reasons, the use of rechargeable batteries is strongly recommended. The types of rechargeable batteries currently available in AA size include:

- Nickel Metal Hydride (NiMH)
- Nickel Cadmium (NiCd)

The CIS PRO+ is delivered with three sets (3 x 2 = 6 cells) of rechargeable AA-type NiMH batteries. Rechargeable batteries can be recharged with modern battery chargers in a few hours and should provide between 10 and 14 hours of use with your cochlear implant system. Duration of use derived from a set of batteries depends on various factors and will slightly vary from day to day.

In order to achieve optimal battery longevity, it is important to fully discharge your batteries before proceeding to recharge them. Please follow the instructions specific for your charger, which are included with your charger.

A space is provided in the CIS PRO+ carrying pouch to allow you to carry a spare set of charged batteries with you.

The time rechargeable batteries can supply your implant system with energy before they require recharging will also decrease with increasing use and age of the batteries. When the duration of use provided by a set of batteries has decreased substantially, we recommend that you replace the used batteries with a new set. When they are used on a daily basis, rechargeable batteries are specified for 1 to 2 years of operation. MED-EL has supplied you with the best batteries available at present for use with the CIS PRO+.

You should not mix batteries from different sets, especially if the batteries are from different manufacturers or of different rating. You may find it convenient to mark the batteries belonging to one set with a colored felt pen. When the time

of use achieved with a given set has significantly declined, replace both batteries in the set.

Disposable Batteries

Some alkaline disposable batteries provide more hours of operation than one cycle of rechargeable batteries, however, this may vary among battery manufacturers. Their use is expensive in both financial and environmental cost. Some CI users find it advantageous to use disposable batteries while traveling, or in other situations where the recharging of empty batteries is difficult. We recommend that you always keep at least one set of disposable batteries with you when traveling.

Please do not try to charge disposable batteries in the battery charger supplied by MED-EL. Disposable batteries can not be recharged with your charger once they are empty, and attempting to do so could lead to potentially adverse effects and will likely damage the charger. Recently, new types of battery chargers have been marketed for specially designed disposable batteries. At the present time those units do not represent a reasonable alternative to NiMH batteries. Whenever you decide to use different rechargeable batteries, make sure you use an appropriate charger.

If you require more detailed information about batteries or battery chargers please do not hesitate to contact your nearest MED-EL office or your implant center.

Changing the Batteries

If the red LED on the CIS PRO+ is flashing, the batteries are low and the processor will go off in a short time.

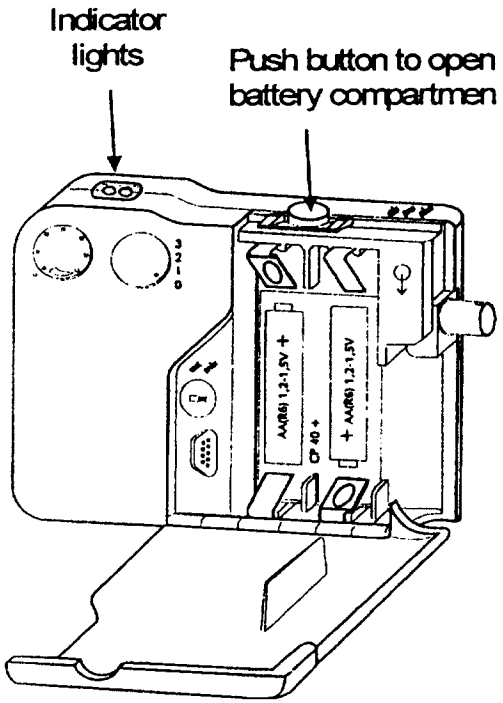


***Figure 3e** CIS PRO+ battery compartment*

To change batteries please follow the listed steps:

1) Before replacing the batteries, remove the transmission coil from your head and turn the CIS PRO+ to OFF.

137

2) To open the battery cover on the CIS PRO+, push down on the button on top of the processor housing. The cover will unlatch and can be opened. Do not open the battery cover too far by force, as this will damage the cover.

3) Remove the used set of batteries. Try not to touch the battery contacts.

4) When inserting the new set of batteries, make sure you insert them with the correct polarity. For each battery, the + polarity is indicated in the battery compartment of the CIS PRO+. Push the + polarity (tip) of each battery against the contact latch in the compartment and then position the battery in the compartment.

5) To close the battery cover, gently push it toward the processor until the push-button locks with a click.

Suggestions for carrying your CIS PRO+

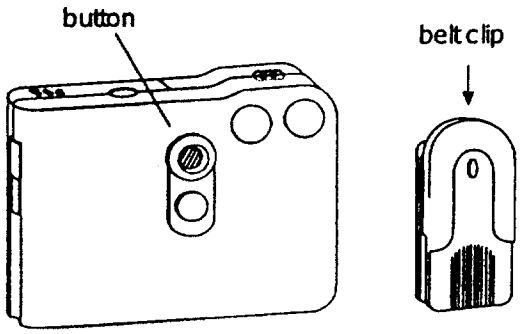


***Figure 3f** belt clip and button*

A belt clip and button are available and can be attached to the back of your CIS PRO+ processor.

When you clip the processor onto your belt, please make sure that it is properly fixed and cannot slide off when you sit down or bend over.

You can also use the carrying pouch for protected wear of the CIS PRO+.

Maintenance

The CIS PRO+ was designed to be robust and reliable. If handled with care and precaution, it will perform its intended function for a long time.

None of the external components should ever be placed in or under water for cleaning. Use a moist piece of cloth to gently clean the processor. Do not use aggressive cleaning agents. Take care that water does not get into the speech processor via the connectors or the battery compartment.

While you should take every precaution to prevent accidental exposure of your CIS PRO+ to water for reliability reasons, you will not be in danger of harm or over-stimulation if the processor or headset do become wet.

There are no home remedies to repair damaged electronic parts of the CIS PRO+ or

headset. Please never attempt to open the electronic compartment of the processor yourself.

Battery contacts should not be touched. If they do get dirty, they can be carefully cleaned with a cotton swab and a small amount of cleaning alcohol.

If the speech processor is not used for a longer period of time, the batteries should be removed and stored separately.

If batteries are not being used for a longer period of time they should be stored in fully charged condition.

Troubleshooting

Once you have become familiar with your cochlear implant system, you will find that the use and handling are not complicated. Problems that can occur are similar to those with other electronic equipment (such as a Walkman™). Functional problems are most frequently related to batteries or cables.

You have received a small test box to verify proper functioning of the system. Simply place the transmitter coil underneath the test box (as shown in Fig. 3g) with the speech processor turned on. The transmitter will position itself correctly by magnetic attraction force to the test box.

As you speak into the microphone you should see the red light on the box flicker in correspondence with your speech. If the test box indicates a non-functional system, check the battery and the cable indicator light on the processor.

Note: The green light on the CIS PRO+ can also be programmed by your clinic to flicker in correspondence with sound entering the microphone. However, the test box provides a more complete functional check that also includes the cable, the transmitter, and a verification of the coded signal that is sent to the implant.

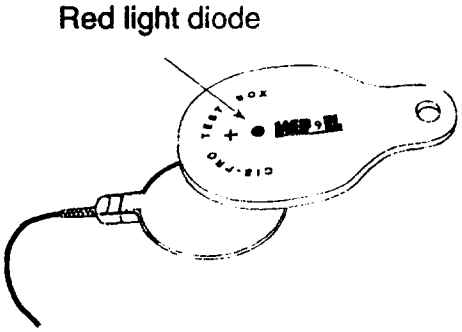


Figure 3g *Test box and transmitter*

If you are not sure about the status of your battery sets, you may want to purchase a set of disposable alkaline batteries and try them in your CIS PRO+.

The battery contacts inside the speech processor may become dirty with time and require gentle cleaning with a cotton swab and small amounts of cleaning alcohol.

If the above described procedures do not solve problems with your cochlear implant system, please contact your clinic for further assistance. Do not try to open the speech processor yourself or disassemble the transmitter or BTE-housing, as this immediately voids any warranty.

The unauthorized use of cables or plugs other than those delivered or recommended by MED-EL may damage your system or cause uncomfortable or painful stimulation. Your clinic or your nearest MED-EL service center will be glad to assist you with any technical problems or questions.

5. *Accessories*

Battery charger

The speech processor is delivered with a battery charger and 3 sets (6 cells) of rechargeable Ni-MH batteries (see batteries). The battery charger contains separate instructions. Its basic operation is very simple.

A different battery charger may be recommended by MED-EL in the future as available technology changes.

Please always refer to the instructions delivered with the charger.

Test box

The test box serves to verify function of the external components. It is described in the section entitled "Troubleshooting" in the previous chapter.

6. *External Audio Connection*

Your CIS PRO+ is equipped with a socket for external audio input such as an assistive listening device.

Compatibility with specific devices has been assessed and details can be found in the ***Guide to FM Systems*** (available from your MED-EL representative).

For safety reasons, you should never connect any device to the external audio input that is plugged into a wall socket (mains supply)!

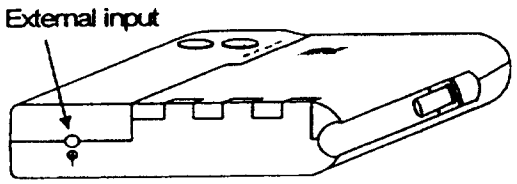


***Figure** 5a external audio input*

7. *General Precautions and Warnings*

This section contains information for safe use of your cochlear implant system. Please read it carefully. Your implant clinic or nearest MED-EL office will be glad to assist with any additional questions.

If you are scheduled for medical procedures or examinations, always inform your physician that you are wearing a cochlear implant.

General precautions for your cochlear implant system

Your cochlear implant system must be used solely with equipment listed in this manual or released by MED-EL for use with the COMBI 40+.

The CIS PRO+ speech processor and other parts of the system contain complex electronic components. These components are robust and designed to last a long time if handled with care.

- Do not open the housing of your speech processor except for changing batteries or cleaning the battery contacts. All warranty claims become immediately invalid if the electronic compartment of the processor housing has been opened by unauthorized persons.
- A regular safety check of the external parts of the COMBI 40+ is not required. For troubleshooting guidelines refer to section 3 of this manual.
- The specified operating temperature range for the speech processor is from +41°F to +122°F.
- In case you should ever experience loud and painful noises (overstimulation) immediately remove your transmitter and the overstimulation will stop.
- You may experience a decrease in sound quality if your speech processor is operating within a distance

144

of 1.25 miles to a radio or TV transmitter. The effect is temporary and does not harm your equipment.

- Do never attempt to use a processor from a different cochlear implant user. Your processor has been programmed especially for your individual loudness requirements. The use of a speech processor not programmed for you may cause severe or painful over-stimulation.

Electrostatic discharge

Electrostatic charge has the potential to damage components of your cochlear implant system. Electrostatic charge build-up occurs most frequently on days when the air is very dry and is not specifically influenced by your cochlear implant. Electrostatic discharge may erase the program in your speech processor. The probability of the occurrence of electrostatic discharge can be reduced by following the listed guidelines:

- Switch off the speech processor before taking off or putting on a sweater or pullover.
- Whenever you think you have been charged with static energy, discharge yourself by touching a radiator, a water tap, or any grounded metal.
- When you are working with a computer, make sure that the computer is grounded.
- Place an anti-static mat under your workplace.
- Do not directly touch TV or computer screens.
- If you encounter yourself in an environment with excessive amounts of static energy, switch off your speech processor.
- Use anti-static spray for upholstery in your car. Such sprays can also be used for carpets and clothes.

Metal detectors

Devices such as metal detectors at airports, as well as commercial anti-theft devices, can cause strong magnetic fields. Cochlear implant users may perceive a soft sound when close to such devices. If the processor is switched off, the perceived sound should vanish.

The implant may also trigger detection equipment. It is recommended that you always keep your patient ID card at hand to identify yourself as a cochlear implant user.

Flying on an airplane

Airlines request that computers and other electronic equipment be turned off during takeoff and landing. Electronic devices can interfere with aircraft communication systems and board instruments. Your CIS PRO+ speech processor is both a computer and an electronic device and should therefore be switched off before takeoff and landing.

Please let the airline attendant know that you are a cochlear implant user, and that you may require special instructions in case an emergency occurs while your speech processor is turned off.

TV interference

Your speech processor may cause interference with some models of television with in-door antennas. Moving farther away from the TV set may reduce the amount of interference.

Head trauma

A blow to the head in the area of the implant can lead to damage of the implant.

WARNINGS

MRI

WARNING: Implantees with the COMBI 40+ Cochlear Implant system should not be subjected to MRI, should not enter the MRI suite, or come into close proximity to the source of the magnetic field. MRI involves the use of very strong magnetic fields, the effect of which could possibly dislodge the implant or demagnetize the internal implant magnet.

MEDICAL CONTRA-INDICATIONS

Neurostimulation or diathermy

Neurostimulation or diathermy must not be carried out in the area of the implant, as it could lead to the induction of currents at the electrode array. This could damage the cochlea and/or surrounding tissue in the inner ear.

Electrical surgery

Monopolar electrical surgery devices must not be activated close to the cochlear implant. Instruments used in electrical surgery can produce voltages at very high frequencies, which might cause induction of currents in the cochlear implant electrodes. Such currents could damage the implant and/or tissue in the inner ear.

Electroconvulsive therapy

Electroshock or electro-convulsion therapy should not be used on patients with a cochlear implant. Use of such therapy could lead to damage of the implant and/or tissue in the inner ear.

Therapy involving ionic radiation

Ionic radiation could damage the implant. Tissue surrounding the cochlea and the implant should therefore be exempt from ionic radiation treatment.

147

8. *Warranty and Registration Card*

Warranties

All goods sold by MED-EL are warranted to be free from defects in material and workmanship. **The foregoing warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including but not limited to any implied warranties of merchantability or fitness.** MED-EL shall not be liable for incidental or consequential losses, damages or expenses, directly or indirectly arising from the sale, handling or use of the goods, or from any other cause relating thereto, and MED-EL's liability hereunder in any case is expressly limited to repair or replacement (in the form originally shipped) of goods in breach of this warranty or at MED-EL's election to the repayment of, or crediting the purchaser with, an amount equal to the purchase price of such goods. This warranty shall not apply to any MED-EL product which shall have been (a) repaired or altered other than by MED-EL or its authorized or approved service personnel; (b) subjected to physical or electrical abuse or misuse; or (c) operated in any manner inconsistent with the applicable MED-EL instructions for use.

Claims - notice of defects

MED-EL will give consideration to settlement of a purchaser's claims, but in no event shall MED-EL be liable on any claims unless (i) the implant registration form, delivered with the sterile implant is completed and returned to MED-EL within one month of surgery and the CIS PRO+ speech processor, the transmitter and the BTE- housing registration form,

included at the end of this manual, is completed and returned to MED-EL within one month of initial fitting, and (ii) written notice of the claim is received by MED-EL within the following limitations: for the implant, 10-years after the date of the implant surgery: and for the CIS PRO+ speech processor, the transmitter and the BTE-housing, 3-years after the date of first processor fitting. Buyer shall afford MED-EL prompt and reasonable opportunity to inspect all materials as to which claim is made. If MED-EL, and a purchaser are unable to reach settlement of any claim relating to material covered hereby, the purchaser must institute legal action against MED-EL within one year after such claim arises and thereafter all such claims shall be barred notwithstanding any statutory period of limitations.

9. *Additional Information*

Declaration of Conformity

MED-EL Elektromedizinische Geräte Ges.m.b.H.
Fürstenweg 77A
A-6020 Innsbruck, Austria

is the manufacturer of the products listed below:

CIS PRO+ Speech Processor and Accessories

consisting of:

CIS PRO+ Speech Processor

CIS PRO+ Headsets with Cables

Coil

Speech Processor Test Device

As manufacturer of the products listed herein, MED-EL declares that these products correspond to the EC Directive on Active Implantable Medical Devices 90/385 EEC (AIMD) and the Essential Requirements in Annex I of the Directive.

Conformity assessment was certified by the notified body. For use within the EU, in children and adults, the device is marked with the CE-mark.

...0123

CE

1996

The device was developed per the requirements of the Standards listed below:

EN ISO 9001 (1994): Quality Systems - Model for quality assurance in design, development, production, installation and servicing

EN 46001 (1996): Quality systems- Medical devices - Particular requirements for the application of EN ISO 9001

CAN/CSA ISO 13485 (1998): Quality systems – Medical devices – Particular requirements for the application of ISO 9001

Innsbruck, August 2001

150

The MED-EL COMBI 40+ Cochlear Implant System is protected by several European and American patents.

10. Useful Addresses

Further information about our products can be obtained from the following MED-EL address:

MED-EL Corporation
2222 East NC Hwy 54, Suite B-180
Durham, N.C. 27713

Tel.: +919 572-2222
Fax: +919 484-9229

The following listing contains US addresses that may be useful to you.

National Institutes of Health
National Institute on Deafness and other Communication Disorders (NIDCD)
Bethesda, MD 20892

National Information Center on Deafness (NICD)
Gallaudet University
800 Florida Ave. NE
Washington, DC 20002-3625

Self Help for Hard of Hearing People (SHHH)
7800 Wisconsin Ave.
Betheseda, MD 20814

Hear Now
9745 E. Hampden Ave.
Suite 300
Denver, CO 80231-4923

Cochlear Implant Club International (CICI)
P.O. Box 464
Buffalo, NY 14223-0464

Alexander Graham Bell Association for the Deaf
3417 Volta Place NW
Washington, DC 20007-2778

11. Appendix

The human ear and deafness

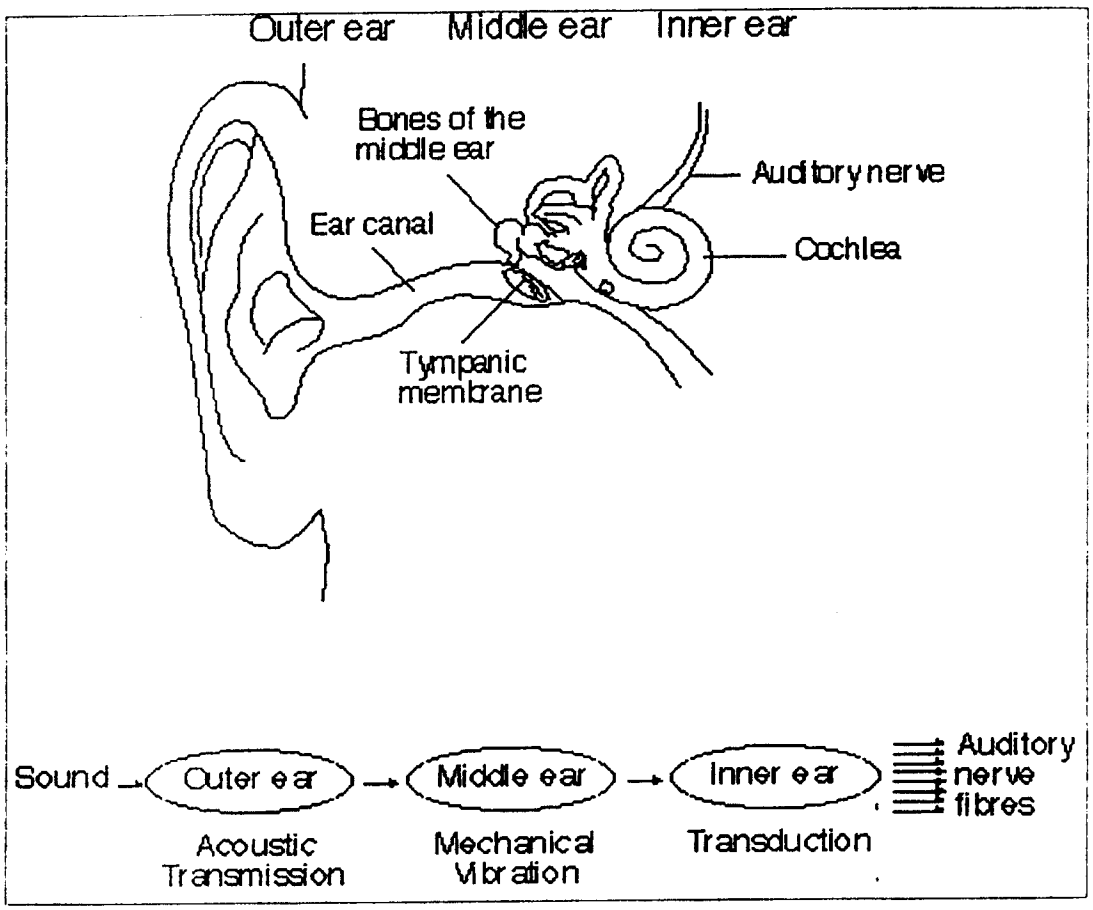


***Figure A.1** The human ear*

The outer and middle ear

The outer and the middle ear serve to conduct sound. Sound waves produce changes in air pressure. These pressure changes occur in the ear canal and act on the ear drum (tympanic membrane). The ear drum vibrates in time with the acoustic stimulus and moves the chain of small bones known as the ossicles (hammer, anvil and stirrup). The footplate of the stirrup (the end of this chain of levers) is attached to the oval window, an elastic membrane forming the entrance to the inner ear or "cochlea".

The inner ear

The inner ear, also called the cochlea, is a snail-like bony chamber that is filled with liquid and is linked with the middle ear by the oval- and the round windows. Vibrations transmitted from the middle ear to the oval window in response to sound are passed on to the fluid in the cochlea.

The transformation of the mechanical vibrations into neural impulses is carried out by sensory cells in the inner ear called hair cells. When the hair cells detect vibrations in the fluid of the cochlea, they produce neural action potentials that are conducted by the auditory nerve to the brain. There they are interpreted as sound (e.g., noises, tones, speech, etc.).

The highly sensitive hair cells are easily damaged by disease or overexposure to excessive noise. They then can no longer transform vibrations into neural action potentials. When all hair cells are dysfunctional, total deafness results.

Deafness

Partial deafness

People who are partially deaf or hard of hearing usually have limited awareness of speech and other sounds around them. They can be helped by conventional hearing aids, which amplify sound.

Congenital deafness

People who have not been able to hear at all since birth are called congenitally deaf. They usually have very limited command of spoken language, and are therefore considered suitable candidates for a cochlear implant only during early childhood up to about eight years of age. Acquisition of spoken language skills at a later age is known to be very difficult. Since the learning of spoken language gets more difficult with increasing age, early diagnosis of deafness is of immeasurable importance.

Postlingual deafness

People who loose their hearing after having acquired fluency in spoken language are considered postlingually deafened. Deafness may occur suddenly, or a slight hearing impairment may get progressively worse and eventually reach a point when no sound at all can be perceived, even with high-power hearing aids. Most postlingually deafened people can benefit from a cochlear implant. The expected level of success with the implant increases when the duration of complete deafness has been short

(a few years or less).

Causes of deafness

In most cases of deafness the hair cells have been damaged by disease, such that sound (mechanical vibration) can no longer be transformed into neural action potentials by the cochlea. Some causes of deafness include the following:

- Meningitis
- Encephalitis
- German measles
- Cytomegalovirus
- Mumps
- Ototoxic drugs
- Rupture of the auditory nerve (e.g. from an accident)
- Sudden onset of deafness (cause unknown in many cases)
- Hypoxia
- Genetic causes
- Pendred's syndrome
- Usher's syndrome
- Mondini anomaly
- Waardenburg's syndrome
- Hereditary causes

Several hundred thousand people in the US are considered totally deaf. A cochlear implant may enable many of them to perceive environmental sounds and speech.

The cochlear implant

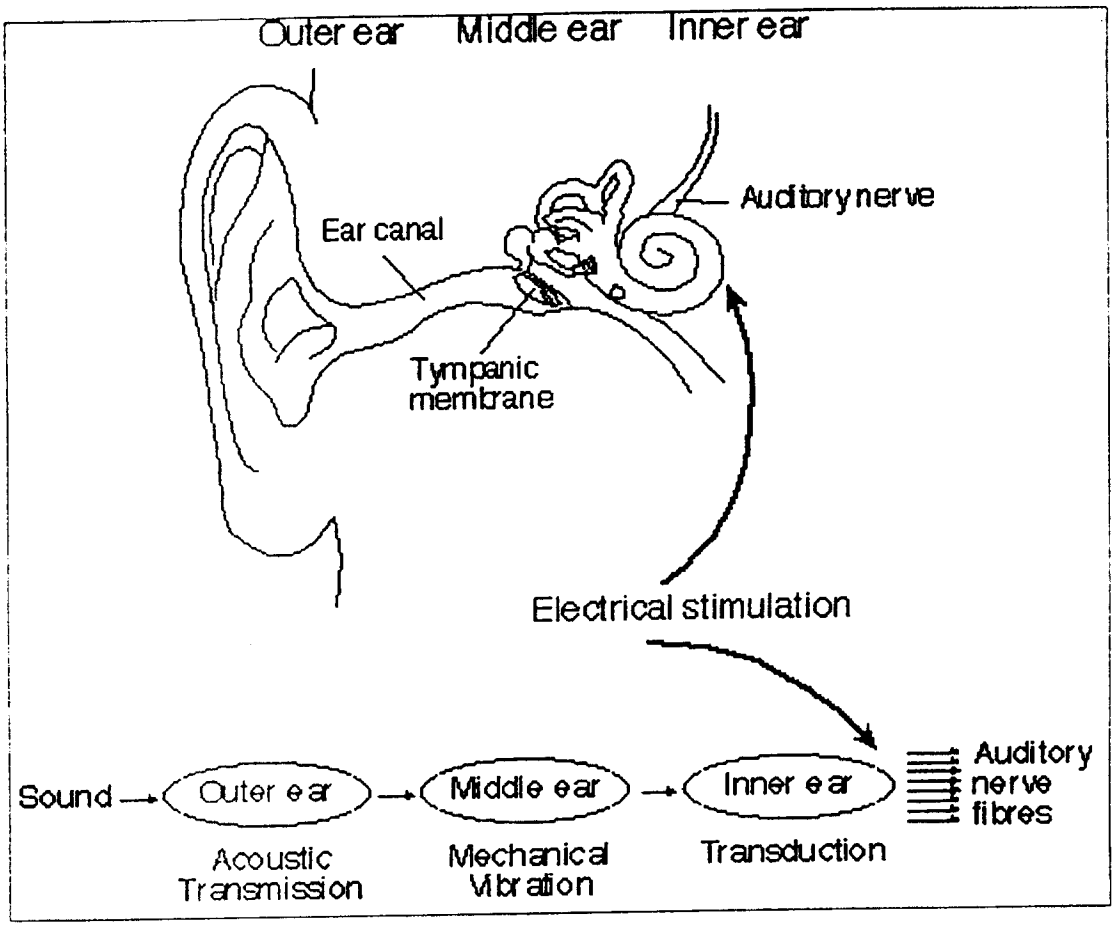


Figure A.2 *Electrical stimulation of the ear*

In the deaf ear, a cochlear implant may replace the function of the ear through direct electrical stimulation of the auditory nerve. The outer and middle ear are completely bypassed and have no function in hearing with the cochlear implant.

INFORMATION FOR CANDIDATES

COMBI 40+

THE MED-EL HIGH-RATE
COCHLEAR IMPLANT SYSTEM

1. INTRODUCTION

This booklet is intended for potential cochlear implant candidates. It explains the COMBI 40+ Cochlear Implant System and addresses associated risks and expected benefits.

A cochlear implant enables deaf people, who have little benefit from conventional hearing aids, to receive the sensation of sound and speech. Unlike hearing aids, which make sounds louder, the cochlear implant bypasses the non-functional parts of the ear and delivers signals directly to the auditory nerve. It thereby produces the perception of sound in a different way. A detailed description of how the COMBI 40+ System works can be found in sections 1 and 2.

A cochlear implant can bring a range of benefits from acting as a very effective aid to lip-reading to enabling an individual to understand speech over the telephone.

These benefits are available whether the hearing loss has been present from birth or has developed late in life as a result of illness, injury or for a genetic reason. Generally speaking, however, the shorter the length of deafness, the greater the benefits of the cochlear implant. [1]

The MED-EL COMBI 40+ Cochlear Implant System is the result of many years of intensive research. It is a modern high-tech device that combines innovative sound processing with the most advanced digital programming available. Further details can be obtained from your Cochlear Implant Center or MED-EL Corporation.

1.1. How People Hear

Sounds such as speech, music and environmental noises travel through the air and into the ear canal in the form of sound waves.

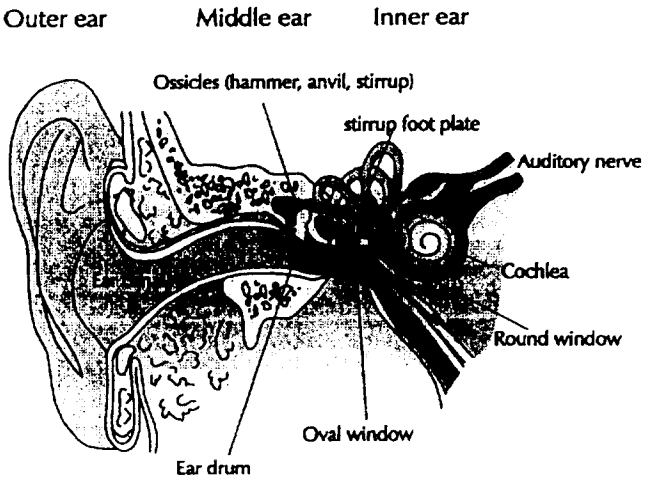


Figure 1: The Ear

[1] Richard S. Tyler (ed.): Cochlear Implants. San Diego, California: Singular Publishing Group, 1993.

161

The sound waves produce changes in air pressure in the ear canal of the outer ear that cause the eardrum to move. In turn the eardrum vibrates a chain of tiny bones in the middle ear that are known as ossicles (hammer, anvil and stirrup). The last bone of the chain transmits the vibrations to the inner ear through an elastic membrane called the oval window, which forms the entrance to the inner ear (Figure 1).

The ***inner ear***, also known as the ***cochlea***, is filled with fluid. The cochlea is rather like a snail shell in shape, and if you imagine it rolled out it is like a piano keyboard, low notes at one end and high notes at the other (Figure 2).

Along the healthy cochlea there are thousands of very sensitive cells called hair cells. When a sound is made the fluid in the cochlea moves and stimulates these hair cells to send a small electrical current to the hearing nerve (the auditory nerve). If the sound is high pitched, the hair cells at the lower end of the cochlea will be stimulated, if it is low pitched, the hair cells at the top end of the cochlea will be activated.

The electrical currents pass along the auditory nerve to the brain where it is understood as sound.

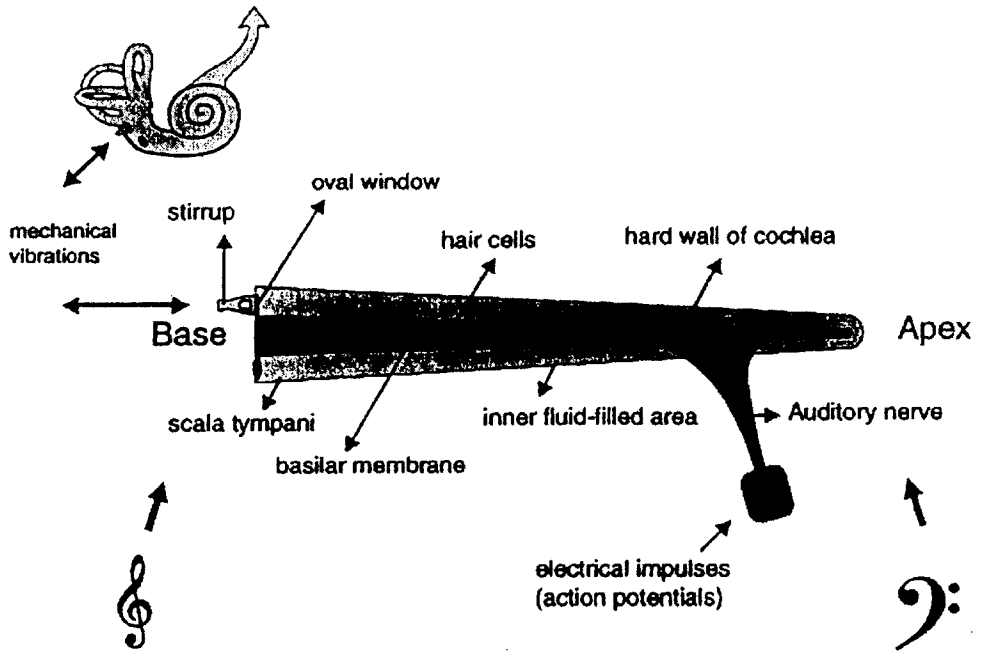


Figure 2: Unrolled Cochlea

1.2. Range of Hearing

Humans can hear a wide range of both pitch (frequency) and loudness of sound. The healthy ear is most sensitive for the pitches used in speech.

Figure 3 shows that the frequency range we use to hear and understand speech is from about 250 Hz (low notes) to about 5,000 Hz (high notes) with a volume range from about 40 dB (quiet speech) to about 70 dB (loud speech).

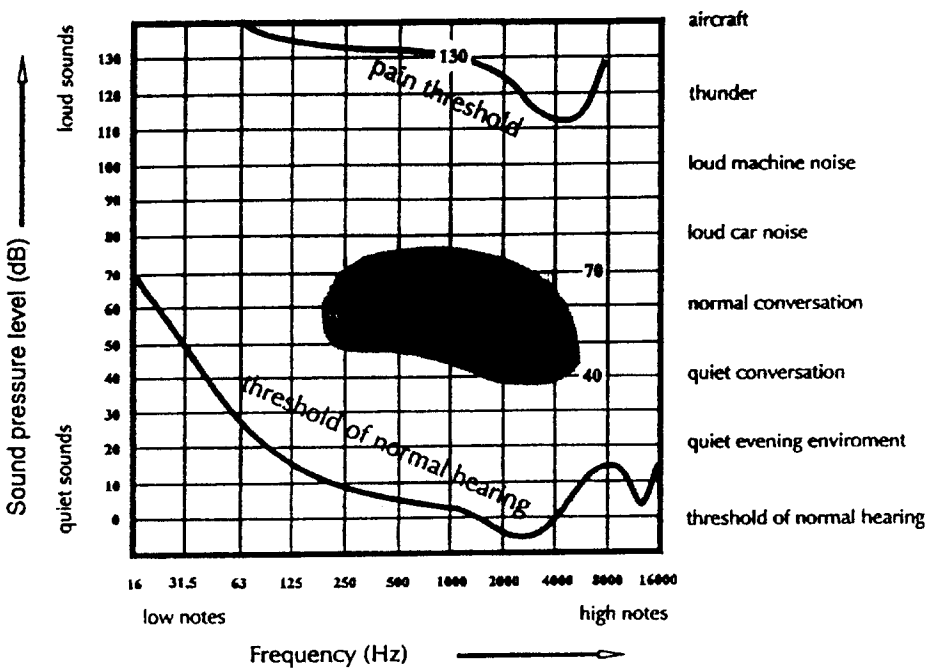


Figure 3: Frequency Range Used To Understand Speech

1.3. Hearing Loss

Many people are severely hearing impaired, or partially deaf, and have limited awareness of speech and other sounds. In most cases, they can be helped with hearing aids, which make sounds louder. However, if an individual has substantially damaged or missing sensory cells (hair cells), hearing aids can-not help. The inner ear is no longer capable of transforming sound vibrations into electrical currents.

1.4. Causes of Hearing Loss

There are many reasons of permanent hearing loss and in many cases it is not possible for the cause to be reliably identified. Some reasons for severe to profound hearing loss include the following:

- Meningitis
- Meningitis – Encephalitis
- Encephalitis
- Head injury
- Complications at birth
- Noise damage
- Congenital failure of the inner ear
- German measles (rubella)
- Cytomegalovirus
- Mumps
- Ototoxic drugs
- Sudden onset of deafness (cause unknown in many cases)
- Hypoxia
- Genetic causes
- Pendred's syndrome
- Usher's syndrome
- Ménière's disease
- Mondini anomaly
- Waardenburg's syndrome
- Hereditary causes

The onset of deafness can be sudden, or the hearing loss can be gradual over a longer period of time.

1.5. Forms of Deafness

Hearing loss is often categorized according to when it started:

- Congenital hearing loss:
  Congenital deafness refers to a profound hearing impairment from birth. These individuals are able to learn spoken language only with great difficulty, and often use sign language for communication.
- Acquired hearing loss:
  - Pre-lingual deafness refers to the loss of hearing during early childhood, before the acquisition of language is complete.
  - Post-lingual deafness signifies a hearing loss after early childhood; communication through spoken language has been learned before the post-lingual onset of hearing loss.

2. HOW THE COCHLEAR IMPLANT WORKS AND WHO CAN BENEFIT

A cochlear implant is an electronic device that substitutes the damaged hair cells of the inner ear by delivering sound and speech information via small electrical charges directly to the auditory nerve. It consists of an implanted part, and externally worn components. The implant contains no batteries or other parts that need replacement, the energy required by the implant is sent from the external components through the intact skin to the implant.

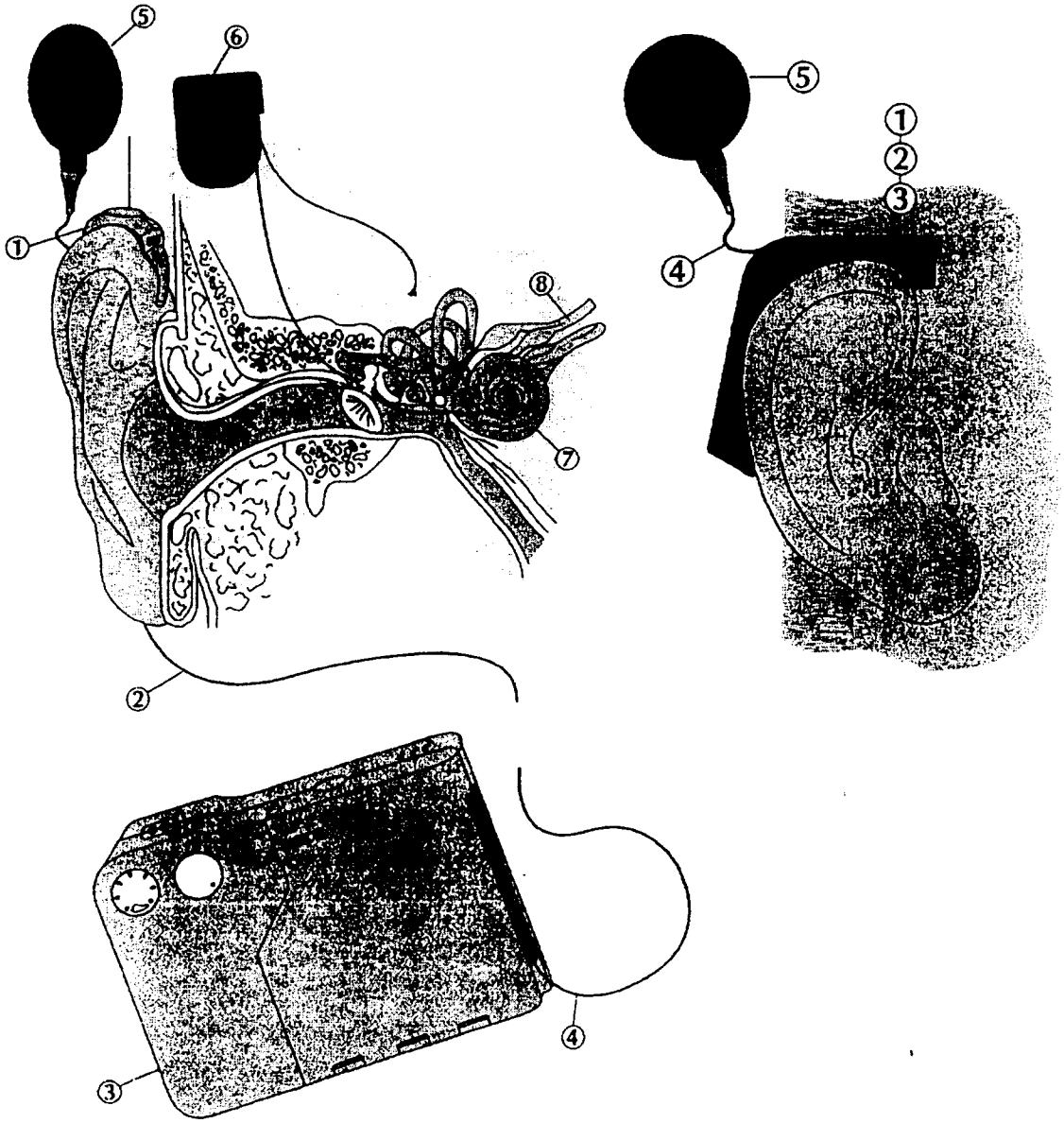


Figure 4: How the cochlear implant works

1. The microphone receives sound waves.

2. The signal from the microphone is sent to the speech processor.

3. The speech processor changes the sound into a coded signal that contains a very rapid pattern of small pulses.
4. The coded signal is sent along the cable to the coil.
5. The coil sends the coded signal via radio transmission through the intact skin to the implant.
6. The implant decodes the signal and sends a pattern of very rapid small electrical pulses to the electrodes in the cochlea.
7. The small pulses delivered by the electrodes stimulate the auditory nerve. Different parts of the nerve are stimulated according to the pitch of the sound waves received by the microphone. In response, the auditory nerve carries out its natural function and conducts nerve impulses to the brain.
8. The brain receives the nerve impulses and interprets them as sound. This is how the implant user receives sound.

The whole process takes place within a few milliseconds, corresponding to the time delay in the normally functioning ear.

2.1. People who Benefit from a Cochlear Implant

Adults and children can benefit from a cochlear implant if they have a severe or profound inner ear hearing loss and conventional hearing aids do not provide enough benefit - in particular if they do not help the person to understand speech.

Cochlear implants are suitable for individuals who are born with a hearing loss or who have lost their hearing, either slowly or suddenly.

Additionally, the individual must be medically healthy enough to undergo an operation and participate in programming and rehabilitation programs. It is very important that they and their families have realistic expectations of the cochlear implant and that these are discussed thoroughly with the Implant team.

3. THE COMBI 40+ COCHLEAR IMPLANT SYSTEM

3.1. The COMBI 40+ Implant

The implanted part of the COMBI 40+ System is called the COMBI 40+ Implant. It consists of a very *small implant package*, an *electrode array*, and a *reference electrode*. The implant is permanently implanted in the bone behind the ear, the electrode array is inserted into the cochlea, and the reference electrode is placed outside the cochlea. The surgical placement of the cochlear implant takes one to four hours on average and is described in section 6.3

All materials used in the construction of the COMBI 40+ Implant have been extensively tested for biological compatibility and durability.

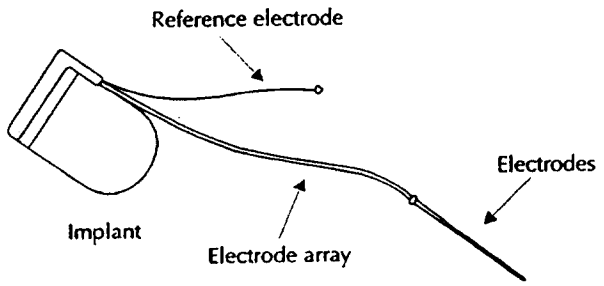


Figure 5: MED-EL COMBI 40+ Cochlear Implant

3.1.1. Ceramic Housing

All of the COMBI 40+ electronic components are sealed in a robust and compact ceramic case that is less than 4 mm in thickness. For young children it is ideal to have a small thin implant that can be easily recessed into the temporal bone. Although ceramic implant housings are very expensive to manufacture, they are increasingly becoming the materials of choice in many modern medical and electronic applications. The ceramic case does not interfere with signal transmission and allows large amounts of information to be transferred with low energy requirements. Besides favorable electrical characteristics, the ceramic material used in the COMBI 40+ Implant also has very high mechanical strength and is similar in hardness to the surrounding bone.

3.1.2. Electronics

The electronics of the COMBI 40+ Implant contain a powerful custom-made circuit that is capable of processing large amounts of information at a very rapid rate. It can generate over 18,000 pulses per second and has been designed according to highest safety and reliability standards. This high speed is part of what makes the implant compatible with a wide range of existing and future sound processing strategies. A telemetry feature enables the clinic to verify the functional status of the implant within a matter of seconds.

3.1.3. Electrode Array

The electrode array is attached to the ceramic implant package and is inserted into the cochlea during surgery. The 24 stimulating electrodes are arranged as 12 connected pairs and are well positioned for stimulating the auditory nerve. In order to stimulate deep within the cochlea with minimal trauma, the COMBI 40+ electrode array has an oval cross section and is approximately 31 mm long and has a unique design.

The reference electrode is on a separate carrier and is placed in a well-protected spot outside the cochlea.

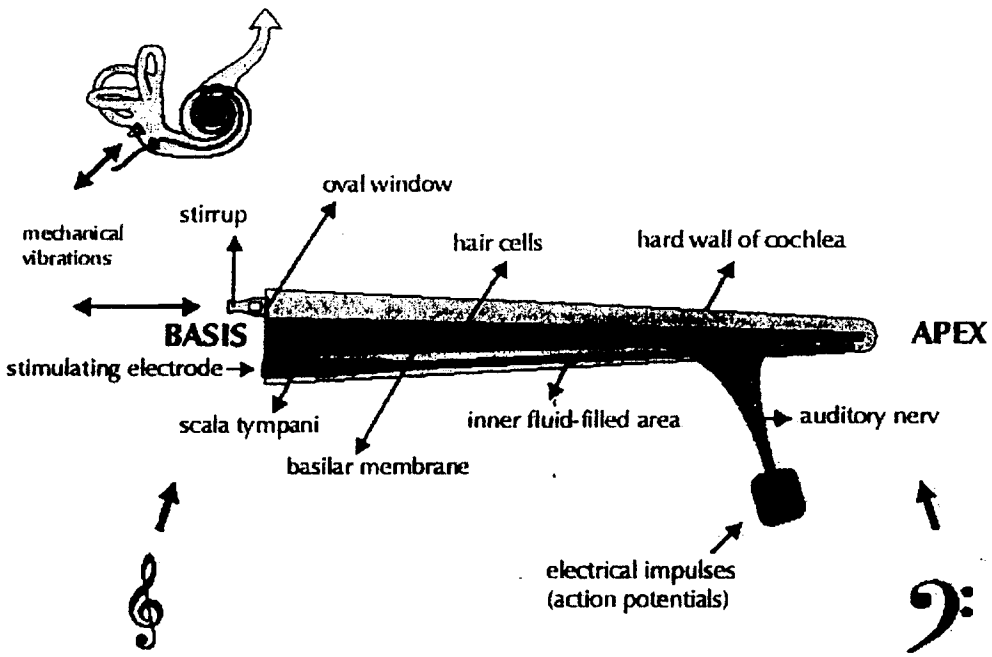


Figure 6: Uncoiled cochlea with electrode deep within the cochlea

3.2. TEMPO+: Behind The Ear (BTE) Speech Processor

The standard external components of the COMBI 40+ System consist of a TEMPO+ BTE Speech Processor, ear hooks, a coil and a coil cable (Figure 7). The entire processor and battery pack are small measuring approximately 67 x 8.3 x 13.5mm so it is ideal for adults and children alike.

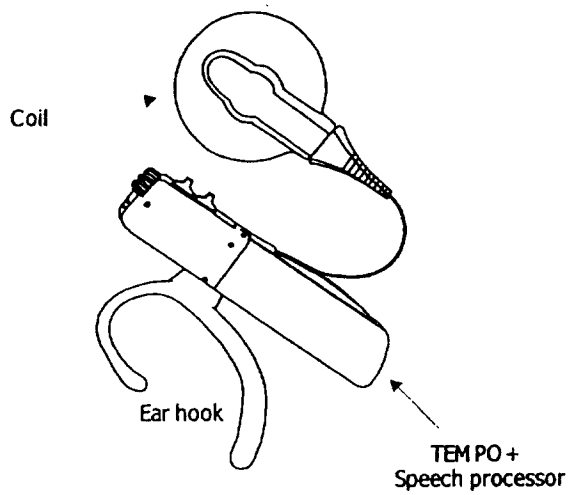


Figure 7: TEMPO+ BTE Speech Processor – with Straight Battery Pack.

There are four user friendly control buttons, a program and volume switch, an on/off switch and a microphone sensitivity control (Figure 8).

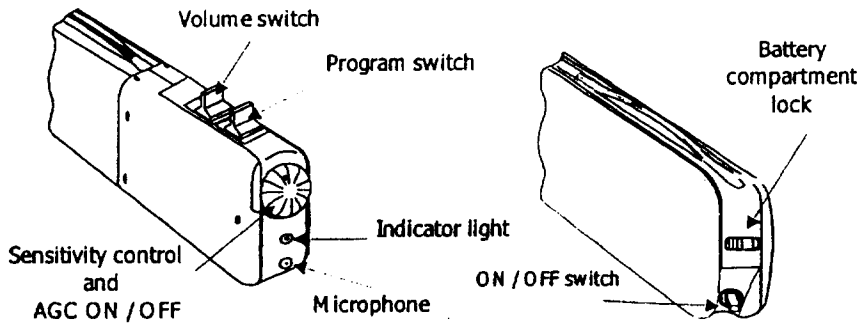


Figure 8: TEMPO+ BTE Speech Processor – controls

Other features include the availability of nine different programs, a status indicator light, a locking battery compartment and will have availability in a variety of different colors. The processor is provided with an angled, a straight and a children's ear level battery pack. These small battery packs use three zinc-air batteries. Additionally, the system comes with a body-worn remote battery pack that utilizes one standard AA rechargeable battery.

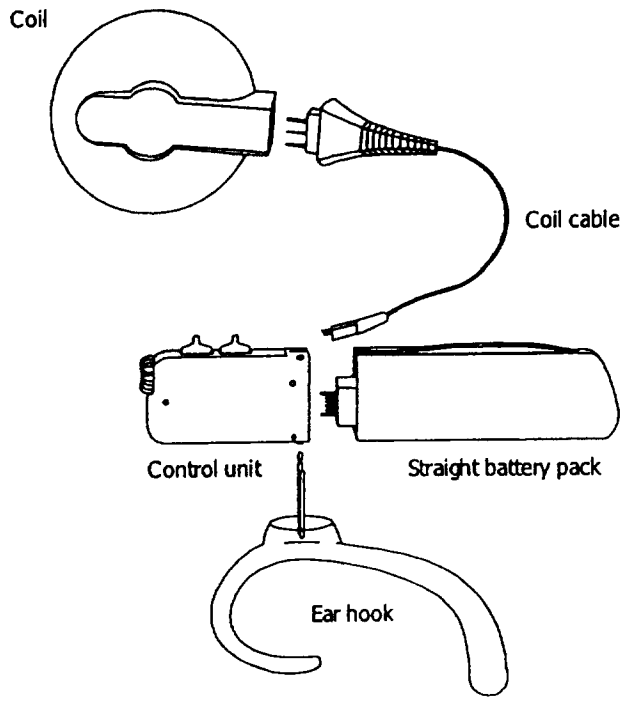


Figure 9: TEMPO+ BTE Speech Processor – individual components

The unique modular design of the TEMPO+ Speech Processor allows the behind-the-ear section, the control unit, to be separated from the battery pack so that it can be worn on the ear, with the battery pack worn elsewhere on the body (Figure 9). The entire processor or the battery pack can be worn in a number of different locations ...on the ear, on...glasses, on...a collar, on...a hat, etc. Ear hooks and accessory clips are provided to aid in fixation.

You do not have to sacrifice performance for size; the TEMPO+ has equal performance characteristics and is capable of stimulating at the same high-rate as the CIS PRO+ Body-worn Processor.[2] The TEMPO+ can also be connected directly to FM systems, a telephone, TV, Assistive Listening Devices, or other accessory equipment.

In choosing an implant system, it is important to know before the operation whether or not you will be able to use a BTE speech processor. The COMBI 40+ Implant and TEMPO+ Processor are highly power efficient. Due to this power efficiency, initial research indicates that all COMBI 40/40+ patients will be able to use the TEMPO+ Processor, regardless of stimulation levels.[3]

---

[2] Stoebich B., et al.: Comparison of performance of the MED-EL body- worn speech processor CIS PRO+ with the new MED-EL BTE Processor TEMPO+ in adults. Presented at the Second Congress of Asia Pacific Symposium on Cochlear Implant and Related Sciences, 1999.

[3] Stoebich B., et al.

3.3. The CIS PRO+ Speech Processor

The CIS PRO+ Speech Processor consists of the CIS PRO+ Headset, and the coil.

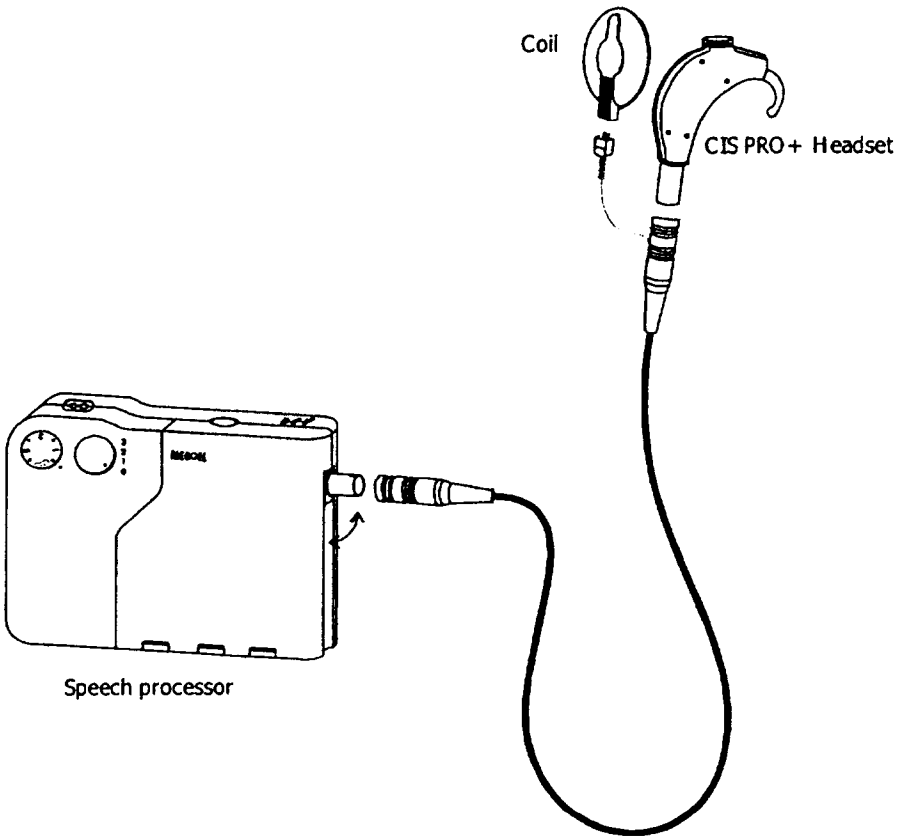


Figure 10: CIS PRO+ Speech Processor

The speech processor measures approx. 9.0 cm x 6.8 cm x 2.0 cm, about the size of a portable cassette recorder, and requires two rechargeable AA-type batteries for an average of one full day of operation. The processor continuously verifies that the microphone and coil cables are functioning. Two indicator lights and an alarm buzzer are available to give a visual or sound indication of the status of the processor, cable, and batteries. These self-check systems are helpful for adults and extremely important for children who are not able to monitor the status of their implant system. There are three control buttons readily accessible and designed for ease of use: volume, program selector, and microphone sensitivity selection. The sensitivity control is situated in the headset. Signal input is also provided for connection to external auditory systems.

The CIS PRO+ Headset is worn like a hearing aid. It is connected to the CIS PRO+ Processor through a cable. The sensitivity control, which can be used to adjust for different listening environments, is mounted on the CIS PRO+ Headset where it is easier to access than on the processor itself.

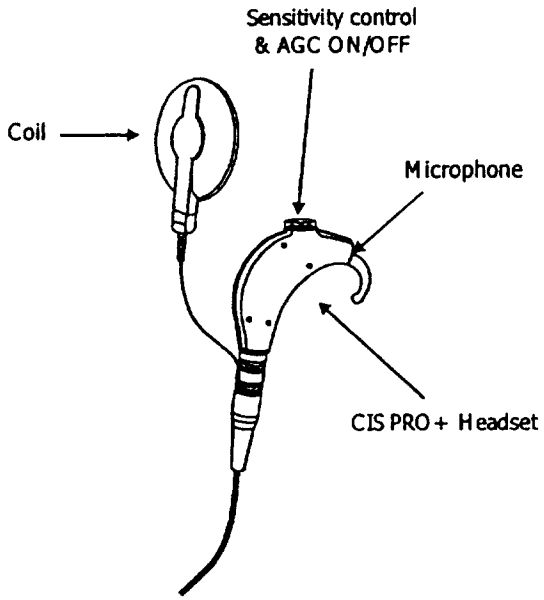


Figure 11: CIS PRO+ Headset and Coil

3.4. Special Characteristics of the COMBI 40+ System

The COMBI 40+ Cochlear Implant System is the result of many years of research and development in Europe and the USA. State-of-the-art technology has been used in the COMBI 40+ System to provide a uniquely advanced cochlear implant.

Some of the special technical features of the COMBI 40+ Implant System are given below. More detailed information can be provided by your Implant Center, or by contacting MED-EL Corporation.

3.4.1. Fast Stimulation Rate

The COMBI 40+ Implant is capable of generating 18,180 sequential pulses per second for a high-rate CIS or CIS+ speech processing strategy, or, alternatively, the system is flexible enough to implement the original fast n-of-m processing strategy. The fast stimulation sequence can provide a better representation of incoming sound to the nerve. The high-rate stimulation also allows the implementation of future processing strategies that are currently under development.

3.4.2. Low Power Consumption

The COMBI 40+ Implant and TEMPO+ BTE Processor have been specially designed to reduce power consumption. This is one of the reasons why the TEMPO+ BTE Speech Processor is able to provide speech processing that is equal to the body-worn processor.[4]

3.4.3. TEMPO+ the true BTE processor

The TEMPO+ BTE processor does not compromise performance for size.

---

[4] Stoebich, B., et al.

172

	TEMPO+BTE PROCESSOR	OTHER BTE PROCESSORS [5]
Performance equal to the body worn processor [6]	✔	NO
Designed to be used by **all** COMBI 40/40+ patients	✔	NO
Offers the CIS+ processing	✔	NO
Can stimulate at over 18,000 pps	✔	NO
Unique modular design	✔	NO
Can use rechargeable batteries	✔	NO
Provides 9 programs	✔	NO

3.4.4. Deep Insertion Electrode Array

The soft COMBI 40+ electrode array features special mechanical characteristics and was designed to facilitate deep electrode insertion into the cochlea with minimal trauma. The portion of the auditory nerve that is responsible for lower-pitched tones, which are a common feature of spoken language, is located toward the deeper end of the cochlea. Deeper electrode placement may facilitate stimulation of the low-pitch nerve fibers and thus contribute to enhanced speech understanding.[7]

The electrode array is very long so the stimulating electrodes can be widely spaced; this helps to minimize any interference between the different channels of information being sent to the cochlea.

3.4.5. Thin implant

The thin ceramic implant package contains all the electronic components including the receiver coil. This is helpful surgically and is particularly useful in the case of small children where thicker implants can cause large post-operative protrusions.

3.4.6. Choice of Speech Processing Strategies

"Continuous Interleaved Sampling" (CIS) and CIS+ represent the most promising processing strategy currently available. The COMBI 40+ System is also designed to implement other very fast strategies such as the original High Rate Spectral Peak Extraction Strategy, n-of-m.

---

[5] Cochlear implantation for infants and children – GM Clark, RS Cowan, RC Dowell, Singular Publishing Group – San Diego Houston, 1997, p.140, 141

http://www.cochlear.com/whynucleus/matrix_implant.html

http://www.cochlearimplant.com/compare_chat.html

Van de Heyning PH, D'Haese PS et al. (1998). Cochlear implantation: an overview of existing implants. Acta ORL Begica, 52: 91-103

[6] Stöbich B, et al.

[7] Gstoettner, et al.: Acta Otolaryngol (Stockh) 1997; 117:274 -277. Cochlear Implant Deep Electrode Insertion: Extent of Insertional Tauma.

3.4.7. Easy to upgrade

Because the COMBI 40+ has a flexible design, uses very little power and can deliver very high rates of stimulation, users will be able to take advantage of future generations of speech processing strategies and smaller processors as they are developed, without the need for another operation.

3.4.8. Multiple Safety features

The COMBI 40+ incorporates several safety features and meets all required international safety standards:

The implant case is designed to be as robust as the surrounding bone and is air tight to protect the electronics.

The unique electronic and system design provides highly effective protection from damage by static electricity.

All electrodes have individual coupling capacitors, which prevent harmful direct current (DC) from damaging the hearing nerve.

The advanced telemetry system allows your implant center to check the functional status of the COMBI 40+ Implant in a matter of seconds.

The Diagnostic Interface Box (DIB) permits advanced testing of muscle and brain wave responses to electrical stimulation through the implant.

Before deciding for or against a cochlear implant, we recommend that you talk to hearing-impaired people who have experience using modern cochlear implants. Seeing the results for yourself will help you to make a better-informed decision.

4. PROCESSING STRATEGIES

While the COMBI 40+ System can support several different speech processing strategies, the most commonly chosen strategy is High-Rate Continuous Interleaved Sampling (CIS/CIS+).

4.1. High-Rate Continuous Interleaved Sampling CIS/CIS+

The High-Rate Classic CIS/CIS+, provided in TEMPO+ and CIS PRO+ Speech Processors are not the same as CIS–like strategies offered in other devices. The COMBI 40+ System was designed specifically around the CIS processing strategy, and provides CIS stimulation faithful to how it was designed to be implemented. Other implant systems have not been designed with CIS as the main strategy, but rather have added a CIS-like strategy in order to be able to offer something in addition to their original processing strategies. [8]

The principle of CIS is to present the information from all of the filters in the filter bank to the inner ear, rather than representing only a few higher energy filters. This allows the brain to process all incoming information, similar to the process of the normal hearing ear.

CIS operates by first converting the incoming sound to a digital signal in much the same way music is converted to a digital signal when recorded on a compact disc. The sound

---

[8] Kiefer J, et.at.: Speech Understanding in Quiet and Noise with the CIS Speech Coding Strategy (MED-EL COMBI 40) Compared to the Multipeak and Spectral Peak Strategies (Nucleus). ORL 1996, 127-135.

is then divided into its different frequency (or pitch) ranges by the filter bank. The frequency ranges are designed to follow the natural organization of the cochlea. The amount of sound energy in each filter is measured, controlling the amplitude of the stimulation pulses and the output is adjusted for each individual. This information is then sent to the corresponding electrodes in the inner ear one at a time, at a maximum rate of 18,180 sequential, non-overlapping pulses per second. Independent electrode stimulation coupled with high speed provides the advantage of a very accurate representation of the sound pattern while minimizing interaction between electrodes.

The TEMPO+ BTE Speech Processor supports the new CIS+ coding strategy, which incorporates several technological enhancements to speech processing. This new CIS+ strategy uses the Hilbert transform for obtaining more accurate envelope, i.e. Loudness information.

4.2. High-Rate n-of-m Strategy

The COMBI 40+ System also supports a family of High-Rate Spectral Peak n-of-m strategies as an alternative to the CIS strategy. The n-of-m strategy operates in a similar fashion to CIS in that it also divides the incoming sound signal by means of a bank of filters that correspond to the various pitch regions along the cochlea. The energy of the information in each filter is measured as it is with CIS. However, the n-of-m strategy only stimulates the electrodes that have the most energy, rather than representing the entire spectrum of sound.

The number of filters to be chosen in each stimulation cycle (n), out of the total (m), is flexible and can be determined by the clinic during device programming. Your clinician will chose the processing strategy and program the speech processor to maximize your hearing perception with the COMBI 40+ System.

5. BENEFITS, LIMITATIONS AND RISKS

Results that are reported with currently marketed cochlear implants indicate increased speech understanding. Benefit from a cochlear implant is most readily measured by the percentage of speech a cochlear implant user can understand in a laboratory setting without lip-reading. Although open-set speech understanding is a very important measure of hearing ability, it is by no means the only benefit cochlear implant users report. The perception of environmental sounds, door bells, music, birds, or alarm signals can make a substantial difference to the life of a severely hearing impaired person.

5.1. Benefits expected with the Cochlear Implant

Published data suggest that most cochlear implant users can perceive speech and environmental sounds at normal listening levels and show a substantial improvement in lip-reading with their cochlear implant.[9] Many post-lingually deafened users of modern devices understand at least some speech without lip-reading. Usually, the ability to understand speech improves over time as experience is gained in interpreting sounds and "hearing" with the cochlear implant. Active participation in a hearing and speaking environment is an important factor for success with the cochlear implant.

5.2. Level of benefit

Although it is not possible to predict exactly how much benefit a particular person will be able to get from using a cochlear implant, certain factors are agreed to have a direct effect, including:

- how long the person has had a severe to profound hearing loss; the shorter the time the better, especially for very young children learning to listen and talk,
- how much experience of hearing and spoken language the person had before developing a severe to profound hearing loss,
- if the person can remember sound, especially speech sounds,
- how well the auditory nerve is working; the implant relies on the nerve to pass the sound information to the brain,
- how committed the individual and his/her family are to the implant process, including participation in the rehabilitation program.

---

[9] Helms J, et. al.: ORL 1997; 59:23 -35. Evaluation of Performance with the COMBI 40 Cochlear Implant in Adults: A Multicentric Clinical Study.

Figure 12 and Figure 13 show the results of two multi-center trials, carried out on users with the COMBI 40 and the COMBI 40+ Implants. The speech recognition tests were performed without lip-reading. [10]

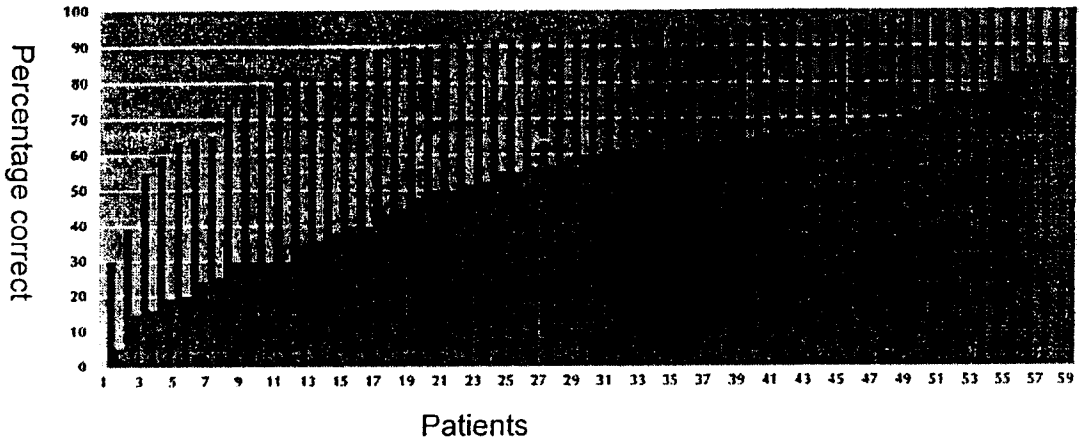


Figure 12: COMBI 40 sentence and monosyllabic word understanding at 12 months post first fitting

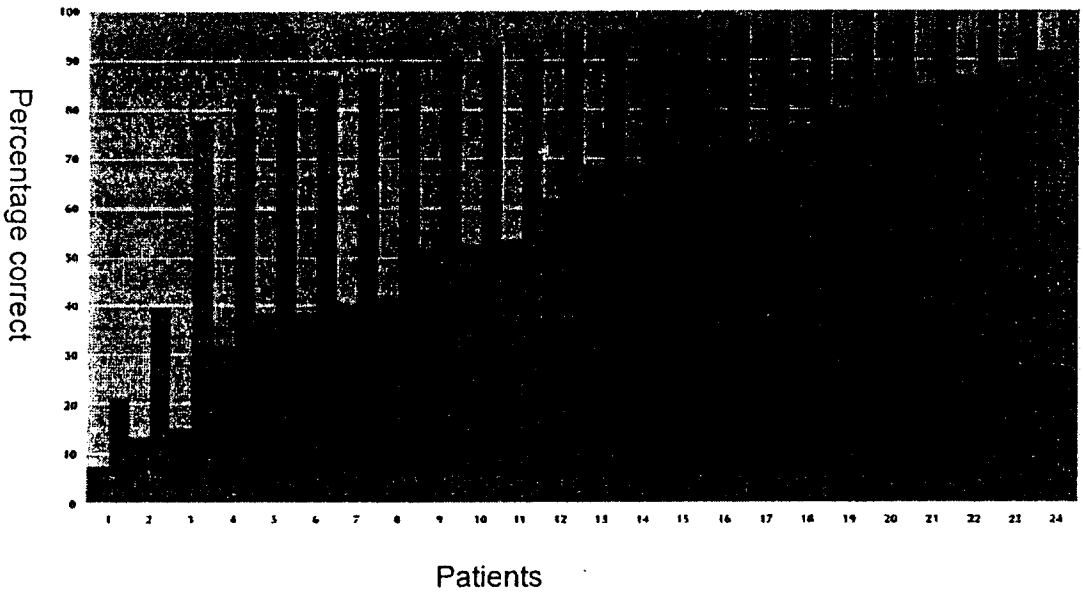


Figure 13: COMBI 40+ sentence and monosyllabic word understanding at 12 months post first fitting

Monosyllabic word understanding

Sentence understanding

[10] Helms J, et. al.: ORL 1997; 59:23-35. Evaluation of Performance with the COMBI 40 Cochlear Implant in Adults: A Multicentric Clinical Study.

COMBI 40+ multi-center trial (submitted)

178

5.3. Limitations of a Cochlear Implant

5.3.1. Adapting to Sound through the Implant

A cochlear implant does not restore normal hearing but rather can give the user a sensation of hearing. Some users find the sound quite natural from the beginning, but others may describe it as 'mechanical' sounding at first. However, with a little time, the user gets used to the sound and will usually find it more natural.

Whilst excellent results are achievable, not all implant users reach the same level of performance and anyone wishing to have a cochlear implant must have realistic expectations of the benefits they might gain.

A cochlear implant has the following limitations:

- Usually only one ear is implanted and it is difficult for cochlear implant users to recognize which direction sound comes from.
- As with a conventional hearing aid, the presence of background noise makes speech understanding with a cochlear implant more difficult. The fast MED-EL CIS strategy has been designed to provide the best possible speech understanding in background noise for cochlear implant users.
- The degree of benefit obtained with the CI may vary greatly from user to user. This is due to several factors, some unknown. There are no tests currently available that can accurately predict the degree of speech understanding that will be possible after implantation for any given candidate.
- The cochlear implant is a technical device and it requires battery power for operation. When the batteries in the speech processor are empty, the implant stops working.
- As with conventional hearing aids, the speech processor of the cochlear implant contains parts that need occasional servicing or replacing. These include the cable, as well as mechanical switches and connectors. When a connector, a switch, or some other part of the processor is broken, the user may be without hearing until a spare processor has been received from the clinic or from a MED-EL service center.
- Contact sports that could produce severe blows to the head should be avoided as they could damage the implant. The cochlear implant does not prevent the user from engaging in most everyday activities, including non-violent sports. Baths, showers and swimming are not affected, but the external parts of the system must be removed during such activities.
- Additional information can be found in the TEMPO+ or CIS PRO+ User Manual.

- **WARNING:** Implantees with the COMBI 40+ Cochlear Implant System should not be subjected to MRI, should not enter the MRI suite, or come into close proximity to the source of the magnetic field. MRI involves the use of very strong magnetic fields, the effect of which could possibly dislodge the implant or demagnetize the internal implant magnet.

5.4. Risks involved in cochlear implantation

5.4.1. Risks of surgery

Research and experience indicate that the risks involved in cochlear implant surgery are minimal and comparable to other routine surgical procedures of the middle ear. There are some general risks associated with anesthesia but problems and complications are rare. You should ask your doctor and anesthetist for further details on these.

Very few complications have occurred after thousands of cochlear implant surgeries. Complications that do occasionally occur are generally non-serious and temporary. Such complications include some delay in healing of the scar, temporary pain or numbness of the tissue around the implant, and a possible temporary change in taste.

Perhaps the most common surgical 'limitation' would be the inability to get the entire electrode array into the cochlea. Bony or fibrous growth within the cochlea, sometimes undetected before the operation, can prevent the electrode from going fully into the cochlea. However, even if the surgeon is only able to insert part of the electrode array into the cochlea, the user can derive great benefit and may not be disadvantaged.

5.4.2. Risk of the implant failing

MED-EL multi-channel implants have proven to be highly reliable. However, the electrical or mechanical components of even the most advanced implant designs may fail due to technical reasons. In the rare event of a failure of the internal device, it may need to be replaced. On occasions when this has been necessary, experience shows that replacement surgery is highly successful.

In general, researchers have concluded that the benefits that cochlear implants provide significantly outweigh any risks.

6. THE COCHLEAR IMPLANT PROCESS

The cochlear implant process is made up of several stages. In general the process is as follows:

- Stage 1: Finding out about cochlear implants
- Stage 2: Assessment procedures and preparation
- Stage 3: Cochlear implant surgery
- Stage 4: Initial Device Fitting
- Stage 5: Rehabilitation program
- Stage 6: Follow-up program

6.1. Stage 1: Finding out about cochlear implants

Reading this booklet is part of stage 1. People considering having a cochlear implant for themselves or their child should have access to plenty of information on cochlear implants. This information should not only be about what cochlear implants are and how they work but also about the experiences of people who have had an implant. Your Implant Center will be able to supply you with information and put you in touch with those who have already a cochlear implant, or whose child has been implanted.

One of the most important parts of the information seeking stage is that you take time to think about any questions that you might have. Ask the doctors, clinicians and rehabilitation staff of the Implant teams anything you are unsure about.

6.2. Stage 2: Assessment procedures and preparation

Very thorough assessments need to be carried out to establish whether a cochlear implant would be the best means of improving a person's hearing. These will depend on local practice but will include careful hearing assessment, usually with and without hearing aids. Objective hearing measurements (such as auditory brainstem response testing) that help to find out which part of the ear is damaged are often performed. A medical examination and scan of the ears are essential.

The person should be professionally counseled and assessed as being psychologically ready and able to go through the cochlear implant process successfully. Realistic expectations of what possible benefits the implant may provide must be established. These assessments will normally involve the family and obviously this is essential for children.

This process will establish whether a person is suitable for our implant, or if hearing aids or another type of management would be a better choice. These assessments may take place over a period of time to ensure that reliable results are obtained and may involve the patient trying out different hearing aids.

This time can also be used to help parents develop listening skills with their children.

6.3. Stage 3: Cochlear Implant Surgery

An operation is necessary to implant the cochlear stimulator and electrodes. A general anesthetic is required for children and most adults and the surgery usually lasts between

one and four hours. The specially trained doctor who performs the surgery will discuss the details of the surgery with you.

During the operation the doctor makes an incision in the skin behind the ear and forms a bed for the implant in the bone. The electrode array is then fed into the cochlea through an opening made during the operation. The reference electrode is positioned under the muscle behind the ear.

After the operation, patients do not usually have a lot of pain, but painkillers can be given. Some patients may feel dizzy and possibly sick for a short period; this can be due to the effect of the anesthesia or a result of surgery to the cochlea.

Following surgery, most patients make a very quick recovery and are able to get up the same day. The usual length of stay in hospital varies from one to five days. Typically patients can return to normal activities within a few days of the surgery.

Additional question you may have on the surgical technique, outcome risks and side effects relating to the cochlear implant, the operation and the time after the operation should be addressed directly with your ear doctor during the assessment period.

6.4. Stage 4: Initial Device Fitting

About four to six weeks after the surgery, when the incision has completely healed and any swelling has gone down, the speech processor can be first activated, or switched on. The implant cannot provide any sound information until the speech processor is programmed, turned on and the coil placed on the head over the implant.

The speech processor has to be set up, or programmed, for each patient individually. To do this, the patient's processor is plugged into the clinic's computer. The patient wears a coil over the implant site. The audiologist or clinician can send signals from the computer to the patient. He or she will measure the quietest level that the patient hears on each electrode (Threshold-T), and the loudest level that the patient finds comfortable (Most Comfortable Level - MCL) on every electrode.

These Threshold and Most Comfortable Levels are different for every individual and are used to make programs in the speech processor. Essentially, each electrode is set to operate between these two levels, so that sounds are loud enough to be perceived by the patient, but are not so loud that they are uncomfortable. Patients are encouraged to actively participate in the fitting process. In order to find the best program the audiologist will ask adult patients to describe the sound of various tones and signals. Once an initial speech processor program is found, the user can try listening to environmental sounds and speech through the cochlear implant.

The first fitting of the processor is often an emotional time for all involved, and patients may wish to be accompanied by a close friend or a relative. Many successful cochlear implant users report that the sound of speech through the cochlear implant seems strange and confusing at first, especially for patients who have been deaf for a significant portion of their lives. It is important to understand that a patient's first experience with the speech processor will probably bear little resemblance to the eventual benefit from the cochlear implant. The time required to become comfortable with the new sound, and for the brain to learn to effectively interpret the signal, varies for each individual.

At the first fitting session you will be given your TEMPO+ or CIS PRO+ User Manual. Please read through it carefully as it contains detailed information about how the external components operate and how to optimize the use of your cochlear implant.

6.5. Stage 5: Rehabilitation Programs

Once the processor has been switched on for the first time, a new and exciting time begins as the user can experiment with new sounds; a rehabilitation program will help the user, or the parents in the case of a child, to monitor their progress with the implant system.

A rehabilitation program will help the user make the most of the newly available sound through guidance and a range of therapies including hearing therapy, auditory training and speech and language therapy. Every user's needs will be different and therapists and educators working for or with the Implant Team will identify, with the implant user, what help or training is needed. For instance, implant users who have some memory of speech have different needs to a young child who was born deaf or who lost its hearing before having much experience of speech.

When first using the implant system it may be a great achievement for the user to be able to detect any sound at all. They must learn how to recognize what a sound is, such as the difference between a dog barking and the telephone ringing.

For speech sounds, being able to tell how many syllables there are in a word, following rhythm and the intonation of speech are all skills, which are very valuable in helping with lip-reading. The rehabilitation staff will monitor the patient's progress and make suggestions for improvement.

Speech and language therapists can help the user work on speech production and also monitor improvements over time.

Each cochlear implant user needs to be fully committed to the rehabilitation program in order to obtain the most benefit from their device. For children, the parents' involvement and participation is crucial. Parents usually spend more time with their children and are in communication with them more than anyone else, and thus are in the best position to help the child to learn to use the sound the implant can provide.

6.6. Stage 6: The follow-up program

The follow-up program is normally made up of regular medical checks, re-programming sessions and a rehabilitation program. It is very important that anyone considering having a cochlear implant be fully committed and able to participate in the follow-up program.

It takes a number of clinical programming sessions in order to ensure that the program is optimal for the user. For children it can take a much longer time, depending on number of factors including how reliable and co-operative they are during the process. For children, the programming sessions can be made into an enjoyable experience as games and play situations can be used to obtain the information required.

At first, the clinician may set the volume deliberately low, especially for children, so that the user can begin to get used to stimulation through the implant, and not become overwhelmed by too much sound all at once. At this stage, the user may only be able to

respond to louder sounds in speech and their surroundings. With time, they should be able to detect a much broader range of sounds.

While a cochlear implant user is getting acquainted with the new sensations of sound, the perception of loudness may change slightly. Larger changes are more common during the first few weeks following initial programming. Adjustments of the volume settings may help the user to compensate for smaller daily fluctuations in loudness perception. In addition, your hearing ability may change and a different processor setting or strategy may be of advantage. Therefore, the implant center may require occasional programming sessions and examination of the implant site.

Adjustments and fine-tuning of the program/s in the speech processor usually take place several times during the first year and once a year following initial fitting. However, this may vary from clinic to clinic. On average, a programming session takes about 45 minutes to one hour.

Maintenance of the speech processor and other external components:

Occasionally a fault may arise with the external equipment as it is subject to wear and tear. Users are provided with spare batteries, cables and other accessories. If the processor is at fault, the Implant Center will arrange to send the patient a replacement so he/she is not without a fully functioning system for a long period of time.

MED-EL has long-standing experience and dedication in providing quality service and support to cochlear implant users worldwide. MED-EL speech processors have been designed for maximum reliability and easy serviceability.

7. CLOSING REMARKS

The MED-EL COMBI 40+ Implant combines the latest in cochlear implant research with state-of-the-art technology. Clinical results continue to confirm its effectiveness in helping users to perceive and understand speech.

The COMBI 40+ System has been especially designed to be flexible - users will be able to take advantage of new developments without the need for a further operation.

If you have any questions or would like to further explore the option of cochlear implantation, contact your local Implant Center or MED-EL Corporation.

7.1. Declaration of Conformity

MED-EL Elektromedizinische Geräte Ges.m.b.H. (Fürstenweg 77A, A-6020 Innsbruck, Austria) is the manufacturer of the products listed below:

COMBI 40+ Implant

COMBI 40 Implant

TEMPO+ Speech Processor

consisting of
- Control unit
- Battery pack
- Coil
- Cables

CIS PRO+ Speech Processor

consisting of
- Speech Processor
- Headset
- Coil
- Cables

As manufacturer of the products listed herein, MED-EL declares that these products correspond to the EC Directive on Active Implantable Medical Devices 90/385 EEC (AIMD) and the Essential Requirements in Annex I of the Directive.

Conformity assessment was certified by the notified body. For use within the EU, in children and adults, the device is marked with the CE-mark.

CE

0123

1999

The device was developed per the requirements of the Standards listed below:

EN ISO 9001 (1994): Quality Systems - Model for quality assurance in design, development, production, installation and servicing

EN 46001 (1996): Quality systems- Medical devices - Particular requirements for the application of EN ISO 9001

CAN/CSA ISO 13485-98: Quality Systems – Medical devices – Particular requirements for the application of ISO 9001.

8. REFERENCES

(1) Helms J, et. al.: ORL 1997; 59:23-35. Evaluation of Performance with the COMBI 40 Cochlear Implant in Adults: A Multicentric Clinical Study.

(2) Kiefer J, et. al.: Speech Understanding in Quiet and Noise with the CIS Speech Coding Strategy (MED-EL COMBI 40) Compared to the Multipeak and Spectral Peak Strategies (Nucleus). ORL 1996; 127-135.

(3) Gstoettner, et al.:Acta Otolaryngol (Stockh) 1997; 117:274-277. Cochlear Implant Deep Electrode Insertion: Extent of Insertional Trauma.

(4) Stoebich B., et al: Comparison of performance of the MED-EL body worn speech processor CIS PRO+ with the new MED-EL BTE Processor TEMPO+ in adults. Presented at the Second Congress of Asia Pacific Symposium on Cochlear Implant and Related Sciences, 1999.

(5) Wilson, et. al.: Better Speech Recognition with Cochlear Implants, Nature 236-238 1991

(6) Wilson, et. al.: Comparative Studies of Speech Processing Startegies for Cochlear Implants, Laryngoscope 88: 1069-1077.

(7) Wilson B., et al: First Quarterly Progress Report, Research Triangle Institute NIH Contract N01-DC-5-2103, 1995, page 14.

(8) Wilson B., et al: Third Quarterly Progress Report, Research Triangle Institute NIH Contract N01-DC-5-2103, 1996.

(9) Brill S, et. al.: Optimization of Channel Number and Stimulation Rate for the Fast Continuous Interleaved Sampling Strategy in the COMBI 40+. The American Journal of Otology, Inc.; 18: S7-10, 1997.

(10) COMBI 40+ multi-center trial (submitted)

(11) International Standard, Implants for surgery: cardiac pacemakers. Part 2: Reporting of the clinical performance of populations of pulse generators. ISO 5841/2-1986.

(12) Richard S. Tyler (ed.): Cochlear Implants. San Diego, California: Singular Publishing Group, 1993.

(13) Cochlear implantation for infants and children – GM Clark, RS Cowan, RC Dowell, Singular Publishing Group – San Diego Houston, 1997, p.140, 141

(14) http://www.cochlear.com/whynucleus/matrix_implant.html

(15) http://www.cochlearimplant.com/compare_chat.html

(16) Van de Heyning PH, D'Haese PS et al. (1998). Cochlear implantation: an overview of existing implants. Acta ORL Begica, 52: 91-103

ADDRESSES

MED-EL HEADQUARTERS
MED-EL ELEKTRO-MEDIZINISCHE GERÄTE GMBH.
FÜRSTENWEG 77A
A-6020 INNSBRUCK, AUSTRIA
TEL: +43-512-28 88 89
FAX: +43-512-29 33 81
E-MAIL: office@medel.com

MED-EL DEUTSCHLAND GMBH.
TRUHENSEEWEG 2
D-82319 STARNBERG, GERMANY
TEL: +49-8151-77 03
FAX: +49-8151-77 03 23
E-MAIL: info@medel.de

MED-EL UK LIMITED
BRIDGE MILLS, HUDDERSFIELD ROAD
HOLMFIRTH, HD7 2TW, UK
TEL.: +44-1484-68 62 23
FAX: +44-1484-68 60 56
E-MAIL: office@medel.co.uk

MED-EL LATINOAMERICA S.R.L.
SARMIENTO 212 / 5 „A"
(1041) BUENOS AIRES, ARGENTINA
TEL: +54-11-4342 3071
FAX: +54-11-4343 9078
E-MAIL: matkinson@sinfomed.org.ar

MED-EL SUCURSAL EN ESPAÑA
C/RONDA DE PONIENTE 16,
ALA DERECHA, PLANTA BAJA L
E-28760 MADRID, SPAIN
TEL: +349-1-80 41 527
FAX: +349-1-80 44 348
E-MAIL: jrodrigomedel.co@mad.servicom.es

MED-EL ASIA PACIFIC REGIONAL HQ
SUITE 1501 RICHVILLE CORPORATE TOWER
INDUSTRY ROAD, MADRIGAL BUSINESS PARK,
AYALA ALABANG, 1702 MUNTINLUPA CITY,
METRO MANILA, PHILIPPINES
TEL.: +63-2-807 8780
FAX: +63-2-807 4163
MAIL: medelasiamueller@vasia.com

MED-EL BÜRO WIEN
WÄHRINGER STRASSE 6-8/4/17
A-1090 VIENNA, AUSTRIA
TEL: +43-1-31 72 400
FAX: +43-1-31 72 400-14
E-MAIL: medel@vienna.at

MED-EL CORPORATION
2222 EAST NC HWY 54, SUITE B-180
DURHAM, N.C. 27709, USA
TEL: +1-919-572 2222
FAX: +1-919-484 9229
E-MAIL: medelci@aol.com

MED-EL MIDDLE AMERICA
19436 EAST COUNTRY CLUB DRIVE
AVENTURA, FLORIDA 33180, USA
TEL: +1-305-792 7597
FAX: +1-305-792 7598
E-MAIL: bryanmrees@compuserve.com

MED-EL FRANCE SARL
34, RUE DE PENTHIÈVRE
F-75008 PARIS, FRANKREICH
TEL: +33-1-53 89 64 45
FAX: +33-1-53 89 64 48
E-MAIL: medel.france@wanadoo.fr

MED-EL MIDDLE EAST
PO BOX 54320
DAFZ DUBAI
UNITED ARAB EMIRATES
TEL.: +971-4-299 4700
FAX: +971-4-299 4255
E-MAIL: Medeluae@emirates.net.ae

MED-EL JAPAN LIAISON OFFICE
11TH FLOOR AKASAKA DAIICHI BUILDING
9-17 AKASAKA 4-CHOME
MINATO-KU, TOKYO 107-0052
JAPAN
TEL.: +81-3-5414 5353
FAX: +81-3-5414 5388
E-MAIL: BQV00055@nifty.ne.jp

MED-EL HONGKONG OFFICE
INTERNATIONAL TRADE CENTER, RM. 1106/7,
11-19 SHA TSUI ROAD, TSUEN WAN, N.T.
HONGKONG
MOBILE: +85-291-701734
FAX: +85-224-379883
E-MAIL: medelhkg@asiaonline.net

MED-EL CORPORATION

Version 1.0

HELPING YOUR CHILD TO HEAR

A guide to the COMBI 40+ Cochlear Implant System

1976
First implant developed by the founders of MED-EL

1978
Vienna/Hochmair hybrid multi-channel cochlear implant developed

1989
Introduction of the Comfort Cochlear Implant which contained both the antenna and electronic components inside a single robust ceramic case

1991
Further development of the Comfort led to the world's first behind-the-ear Speech Processor

1994
The COMBI 40 system introduced as the world's first multichannel high speed cochlear implant

1995
MED-EL CISLINK system developed to provide High-Rate CIS stimulation for users of the Ineraid Cochlear Implant

1996
Introduction of the COMBI 40+ Implant, a very thin CI system specifically designed for children

1997
The COMBI 40+ GB* split electrode achieves unprecedented results in ossified cochleae

* Note: The COMBI 40+ GB is an investigational device.
Caution: Limited by Federal (US) law to investigational use only.

1998
The TEMPO+ (BTE) Speech Processor combines modern design and the latest sophisticated technology

---

Introduction

As a parent, you make many decisions to help your child have a happy and fulfilling life. The parents of a hearing-impaired child have even more decisions to make, including how best to bring more sound into their child's world.

Whether this can be best achieved with a cochlear implant is a question you must work through with a Cochlear Implant Team. As part of MED-EL's commitment to the hearing impaired, this guide has been produced to help you find the right answer for your child. It includes information from parents, children, doctors, educators and researchers who have real-life experiences with cochlear implants.

Within this booklet we have included some of the questions, which are most commonly asked by parents. We have also included an explanation of various medical and technical terms, which may not be familiar to everyone. These can be found in Appendix 1.

Please do not hesitate to ask an experienced ear specialist (Otologist) or other member of a Cochlear Implant Team for additional information. You can also call MED-EL for further information or for a list of experienced implant centers in your area.

Five Steps to Finding Out More

This easy to follow 5 step guide can assist you in the decision of whether or not your child is suitable for and can benefit from a MED-EL COMBI 40+ Cochlear Implant System:

Step 1:
Exploring the world of sound for your child

Step 2:
Finding out if a cochlear implant will be suitable for your child

Step 3:
Understanding the benefits and limitations of cochlear implants

Step 4:
Choosing the best cochlear implant for your child

Step 5:
Preparing your child and family for cochlear implantation and beyond

---

Step 1:
Exploring the world of sound for your child

The first thing that you will want to understand is what a cochlear implant is and how it can help people hear.

"How do we hear?"
In normal hearing ears, sound waves cause changes in air pressure in the ear canal, which make the eardrum vibrate. These vibrations pass into the inner ear or cochlea, which is filled with fluid. The cochlea is rather like a snail shell in shape, and if you imagine it rolled out it is like a piano keyboard in that it has low notes at one end and high notes at the other.

All along the healthy cochlea there are thousands of very sensitive cells called hair cells. When a sound is made, the fluid in the cochlea moves and stimulates these hair cells to send a small electrical charge to the hearing nerve (the auditory nerve). This small electrical current passes along the nerve to the brain, where it is understood as sound.

"What causes a hearing loss?"
If any one part of the complicated hearing system is not working properly, hearing loss can result. People with severe or profound losses usually have a problem in the cochlea, commonly due to damage or absence of the sensitive hair cells; this can be the result of illness or injury, or the problem may be present at birth. Hearing aids can help by making sounds louder if the damage to the cochlea is not extensive.

"How does a cochlear implant work?"
If the cochlea has very damaged hair cells it will no longer be able to effectively change sound vibrations into an electrical current. A cochlear implant makes up for the lack of intact hair cells by placing an electrode array (with several electrode contacts) within the cochlea. This delivers sound and speech information directly to the auditory nerve by means of small, safe electrical currents.

1. Sound waves are picked up by a small microphone
2. Signal sent to Speech Processor
3. Speech Processor codes the signal
4. Coded signal sent to coil
5. Signal sent through intact skin to implant
6. Implant decodes the signal
7. Electrodes stimulate the auditory nerve
8. Nerve impulses sent to the brain

Step 2:
Finding out if a cochlear implant will be suitable for your child
Your local doctor or physician should arrange for your child to be seen by an ear specialist within an Implant Team, who has experience with the MED-EL cochlear implant. He or she can give advice and arrange for a thorough evaluation.
If your local physician cannot refer you to such a center, contact the clinical team at MED-EL and we will refer you to an experienced Implant Team in your area.

"Who are the members of an implant team?"
Members of an Implant Team may include Otologists, Audiologists, Educators and Speech and Language Therapists who will evaluate your child's health, hearing and speech skills. MED-EL provides clinics with special evaluation materials called EARS (which stands for Evaluation of Auditory Responses to Speech) to help in these assessments.

"Is a cochlear implant appropriate for my child?"
There are many factors, which need to be considered when answering this question. The main questions are whether the hearing level is poor enough to need a cochlear implant and whether there are any medical, educational or other reasons that an implant would not be in the child's best interest.

Cochlear implants are suitable for both children and adults, whether they have been born with a hearing loss or they have lost their hearing, through injury or illness. If your hearing-impaired child is old enough, you will want them to have information about the implant and be involved in the decision-making process.

"How deaf must you be to qualify for an implant?"
Anyone with a severe to profound hearing loss may qualify for a cochlear implant, but very thorough assessment needs to be carried out to establish both the hearing level and the child's potential to use conventional hearing aids. This assessment may be undertaken over a period of time in order to get accurate and consistent results.

"Will other tests be necessary?"
A medical examination and a scan of the ears will be required and objective hearing measurements (such as auditory brainstem response testing) are often performed.

"How much will a cochlear implant cost?"
The cochlear implant is about as expensive as a new, medium-sized family car. As in any highly specialized technological field, costs of research, development, and manufacturing are high. As technology continues to move forward, further developments not already outlined in this guide may become available at additional cost.

"After comparing devices I realized it's results that really count... That's why I chose MED-EL."

The cost of the implant, the surgical procedure and associated care, are covered by many health-care providers and insurance companies throughout the world. Recent investigations by independent researchers have clearly demonstrated that cochlear implants provide a significant gain in quality of life for most users. In fact, the benefit vs. cost ratio was rated to be higher for the cochlear implant than for many other, more common, medical procedures. The integration of implant users into hearing society can represent a significant economic saving for society as a whole.
For more detailed information, or for help regarding reimbursement matters, please do not hesitate to talk to professionals at your clinic or to contact MED-EL directly.

"Why might my child not be considered appropriate for a cochlear implant?"
The most common reason for not being offered a cochlear implant is that the child's hearing is "too good". If the audiologists and doctors feel that there is a good chance that the child can hear most of everyday speech through well fitted hearing aids this will be the recommendation. There are some medical conditions, such as absence of an auditory nerve, or specific kinds of malformations of the cochlea, which may mean that surgery is not possible.

"How can I find out more?"
If the Implant Team finds that a cochlear implant may benefit your child, they will discuss the issues and the steps involved for your child and family. They can also answer many of your questions and may provide names of families or support groups experienced with cochlear implants.

"What is the first step?"
You should ask to be referred to a specialist implant center as soon as possible if your child:

- has a severe to profound hearing loss,
- gets minimal benefit from hearing aids and is making little or no progress with speech understanding.

Pre-implant Counseling:
Acting promptly to have a team of professionals diagnose your child's hearing loss and explain your options is crucial. Research demonstrates that early intervention can be extremely important in ensuring that a child receives full benefit from a hearing aid or cochlear implant.

"Our little girl was born deaf but we didn't realize she was eligible for a cochlear implant until she was four years old. She was five when she finally had the operation. Although it might have been easier for her being that bit older and able to understand what was going on, I wish she could have had it earlier. She may have made even more progress by now."

Technical information

COMBI 40+ Cochlear Implant
The COMBI 40+ Implant system consists of the COMBI 40+ Implant, an electrode array and a reference electrode. The implant is permanently placed in the bone behind the ear, the electrode array is inserted into the cochlea, and the reference electrode is placed between the bone and the muscle behind the ear. The surgical placement of the cochlear implant generally takes two to four hours and is described later in this handbook.

All materials used in the construction of the COMBI 40+ Implant have been extensively tested for biological compatibility, durability and sterility. The energy required to power the implant is provided by the external Speech Processor. The implant contains no batteries.

Ceramic Case

The COMBI 40+ Implant housing is very small (approx. 33.5 x 23.4 mm and only ~ 4 mm thin). All of its electronic components are contained in a robust and compact ceramic case. Although ceramic implant housings are very expensive to manufacture, they are increasingly becoming the choice in many modern medical and electronic applications. Unlike metallic housings, the ceramic case of the COMBI 40+ Implant does not interfere with signal transmission and allows the transmission of a large amount of information with low energy requirements. Besides favorable electrical characteristics, the ceramic material used in the COMBI 40+ implant also has very high mechanical strength and is similar in hardness to the surrounding bone. MED-EL has a long history of experience with ceramic implant housings, having used this material since 1989.

Electronics

The electronics of the COMBI 40+ Implant contain a powerful custom-made chip that is capable of processing large amounts of information at a very rapid rate. It can generate over 18,000 sequential, non-overlapping stimulating pulses per second and has been designed according to the highest safety and reliability standards. These characteristics make the implant capable of utilizing a wide range of speech processing strategies, with the ability to incorporate future developments in speech processing.

Electrode array

The electrode array, attached to the header of the implant, is inserted into the cochlea during surgery. The COMBI 40+ Implant electrode array has been designed to enable deep placement, with minimal trauma, up to 31mm into the top of the cochlea where the low frequency (speech) region is located. The 24 stimulating contacts (electrodes) are arranged as connected pairs for 12-channel high-rate stimulation. The contacts are mounted on the electrode array so they are optimally positioned for stimulating the auditory

nerve. The reference electrode is placed in a well-protected spot outside the cochlea. In addition to this standard electrode, MED-EL also offers two other electrode options, the short compressed electrode• and the split electrode•, designed for use in ossified or malformed cochleae.

•Note: The C 40+ S - Compressed Electrode, and the C40+ GB - Split Electrode, are investigational devices.
Caution: Limited by Federal (US) law to investigational device use only.

CIS PRO+ Speech Processor
The CIS PRO+ is actually a small, wearable computer! It measures 90x68x20 mm, about the size of a small cassette recorder and requires two rechargeable AA-size batteries for an average of one full day of operation. The processor fits conveniently into a pocket or may be worn on the belt in a carrying pouch. Small children often wear the processor in a harness on their back or chest. A variety of carrying pouches are available.

Two programmable indicator lights and an alarm buzzer are available to give a visual or auditory indication of processor, program, cable, and battery status. Volume and program selection controls are provided for the user. Although the control buttons are readily accessible and designed for ease of use, they are especially designed to prevent small children from adjusting them inadvertently. The processor memory holds up to three different programs, which can meet a variety of patient needs related to different preferences and listening situations.

The CIS PRO+ also has an audio input port for connection to assistive listening devices, such as compatible FM-systems. When an assistive listening device is connected to the audio input port, an input-mixing selector is available to allow the user to choose between hearing from the assistive device alone, or to mix the information with the signal coming in from the headset. For example, you might choose to have your child hear the teacher through the FM-system alone, or through the FM-system and the headset, which may allow better monitoring of his or her own voice and the questions asked by other children in the classroom.

Microphone and coil

The headset is worn like a hearing aid and is connected to the CIS PRO+ Speech Processor by a single, detachable cable. The sensitivity control, which can be used to adjust for different listening environments, is mounted on the headset to allow easy access. The sensitivity control can be disabled for small children. Sound is picked up by the microphone and then converted into a "sound signal" by the Speech Processor. This "sound signal" is then transmitted to the COMBI 40+ Implant by the CIS PRO+ coil. The CIS PRO+ coil is small and is worn under the hair behind the ear. It is held on the head by magnetic attraction to the implant. The coil is available in a variety of colors designed to blend with the color of the hair.

Long-term care

The MED-EL COMBI 40+ Cochlear Implant is designed to be reliable and durable. Many children wear their Speech Processors during play and sports just by taking a little extra care to ensure that the external parts and the implant site are secure and protected. As with hearing aids, the external components of the cochlear implant system contain parts that need occasional servicing or replacing. These include the cable, as well as mechanical switches and connectors. Each child is provided with a spare cable. If a connector, switch or some other part of the processor is broken, a spare processor may be supplied from your clinic or a MED-EL service center.

TEMPO+: Behind The Ear (BTE)

The new TEMPO+ Speech Processor is an ear level device with a unique design. The processor is modular so it can be worn in a number of different locations ... on the ear, on ... glasses, on a collar, on a hat, etc. Two ear hooks, a clothing clip and an accessory clip are provided to aid in fixation.

The entire processor and battery pack(s) are small, measuring approximately 67 x 8.3 x 13.5mm (straight version) so the TEMPO+ is ideal for adults and children alike. The TEMPO+ Speech Processor is provided with an angled and a straight ear level battery pack. Furthermore, a children's battery pack is available, too. The behind the ear section can be separated from the battery pack so that the control unit can be worn on the ear and the battery pack worn elsewhere on the body. The standard battery

pack permits over 36 hours of continuous use with three small zinc-air batteries. Additionally, the system will include a remote battery pack that utilizes one standard AA rechargeable battery.

FM-Systems and other assistive listening devices can be connected to the TEMPO+ by use of the angled and the remote battery packs.

Scientific studies have shown that the performance of the TEMPO+ is equal in performance to the CIS PRO+ body-worn processor. Both are fully digital, contain an indicator light for process status checking and are capable of stimulating at over 18,000 pulses per second. The TEMPO+ Speech Processor provides your child with additional features such as up to nine user selectable programs and the new CIS+ processing strategy. The TEMPO+ Speech Processor incorporates the latest technical enhancements available to help your child to hear.

The COMBI 40+ Implant and TEMPO+ Speech Processor are highly power efficient so you know before surgery that your child will be able to use the TEMPO+ processor. In choosing an implant system for your child it is important for you to be able to select a system that allows all patients to be able to use an ear level processor.

Step 3
Understanding the benefits and limitations of cochlear implants

MED-EL's High Rate COMBI 40+ Cochlear Implant System incorporates a number of technological advancements that are designed to provide increased benefit for children and adults. Clinical research studies have included detailed testing and evaluation and demonstrate outstanding results for the COMBI 40+ Implants:

1. Hearing everyday sounds
Virtually everyone hears environmental sounds with their implant. The implant allows them to hear traffic, car horns, emergency vehicles, and their name being called. This is very important for children because it could alert them of hazardous situations.

2. Hearing and understanding speech

The sound information received by your child gives them the potential to understand speech and to lipread more easily. This is invaluable for children who are learning to speak.

3. Helping to improve your child's own speech
Your child can hear the speech of others as well as his or her own voice and begin to fine tune his or her own speech. Having understandable speech can open new social, educational and eventually career opportunities for your child interacting in a hearing world.

4. Using the phone can become a reality!
Some children who receive a cochlear implant use the device so effectively that they can understand speech without lipreading and can even have an interactive conversation over the telephone.

5. Reducing the influence of background noise
As with a conventional hearing aid, the presence of background noise can make understanding speech with a cochlear implant more difficult. The fast stimulation rate and advanced design of the COMBI 40+ Cochlear Implant system allows it to provide outstanding speech recognition even in the presence of background noise.

It is important to understand that not all implant users get the same degree of benefit from a cochlear implant. A number of factors influence how quickly each child will learn to use the implant and the ultimate level of benefit that he or she will receive, including:

- how well the auditory nerve is working,
- how long the child has had a severe to profound hearing loss (generally the sooner a child is implanted after a severe-to-profound hearing loss is determined, the better),
- how much experience of hearing and spoken language the child had before developing a severe-to-profound hearing impairment,
- how committed a child and his or her family are to the rehabilitation process.

There are currently no tests available that can accurately predict how much a child's understanding of speech or his or her speech production will improve if they have a cochlear implant. Results show that most children have benefited from implantation independent of whether the deafness is congenital or acquired.

"I was amazed how quickly my child progressed with high speed CIS speech processing."

Step 4

Choosing the best cochlear implant for your child

You will want to discuss this with the Implant Team. You may well decide that the COMBI 40+ Implant is the best choice for your child because it incorporates advanced features that benefit children, many of which are not available in other implant devices.

Proven results

Clinical results and research investigations show outstanding speech understanding results.

Easy to upgrade

The flexibility of the system ensures that future upgrade developments will be available for your child without the need for further surgery.

Most advanced processing strategies

Classic CIS, High-rate CIS, Jitter CIS, CIS+ and spectral peak representation ('n of m').

Behind-the-ear processor BTE

Your child can use the miniaturized TEMPO+ ear level processor with no reduction in processor performance.

Fast stimulation

The advanced CIS speech coding strategy uses fast stimulation to maximize speech understanding.

Compatibility
With the COMBI 40/40+ Implants you can be confident that your child will be able to use the TEMPO+ ear-level processor.

Strong robust implant
Strong ceramic implant case with hardness similar to the bone in the child's skull.

Unique electrode designs
The COMBI 40+ Implant has a very long electrode to provide stimulation across most of the cochlea.

Extra safety features
- The air-tight sealed casing protects the implant's delicate electronics.
- The implant system's design prevents damage from static electricity.

Slim profile
At approximately 4mm thin it is ideally suitable for a child's small head.

Parent friendly monitoring
The TEMPO+ has a red light, and the CIS PRO+ has 2 lights and a buzzer alarm. These features alert parents to problems like low batteries or other processor problems.

MRI
MRI is contraindicated.

> **WARNING:** Implantees with the COMBI 40+ Cochlear Implant System should not be subjected to MRI, should not enter the MRI suite, or come into close proximity to the source of the magnetic field. MRI involves the use of very strong magnetic fields, the effect of which could possibly dislodge the implant or demagnetize the internal implant magnet.

Easy internal device check
The system has a feature called 'telemetry' which allows the Audiologist to automatically test that the implanted part of the device is working properly in a matter of seconds.

MED-EL Service Support
The processor is designed for maximum reliability and ease of service; the whole system is backed by the MED-EL Service Charter - providing you with superior, fast and reliable service.

...and into the future...
...the COMBI40+ is designed to provide significant benefits now and take your child into the future.

The COMBI 40+ Implant uses today's most advanced technology and processing strategies. It can stimulate at fast or slow speeds and is designed to incorporate future processing strategies.

The COMBI 40+ Implant's unique feature of low energy requirements will support future generations of Speech Processors that are even smaller and easier to wear. Unlike other cochlear implants all users selecting a COMBI 40+ Implant will be able to use an ear-level processor providing uncompromised performance. The new TEMPO+ Speech Processor is designed for all current and future users. It is the only behind-the-ear Speech Processor capable of:

- implementing high-rate CIS* - the speech coding strategy proven to provide unparalleled results in noisy and quiet listening situations,
- holding up to nine different programs with an uncompromised performance,
- allowing versatile placement.

* over 18,000 pps.

"The surgeon gave us a choice of implants and explained the key features of each. We felt that the MED-EL implant technology was the most advanced, so our decision to opt for the COMBI 40+ for our daughter was quite straightforward."

Step 5

Preparing your child and family for cochlear implantation and beyond
If you and your Implant Team decide that a COMBI 40+ Cochlear Implant will benefit your child and you would like to proceed, you should understand and prepare for the process.

You'll want to know the costs involved regarding the cochlear implant procedure. Your Implant Center will discuss the arrangements, which apply in your country and whether government assistance or insurance will cover some or all of the costs.

You should also ask the Implant Team to describe what will take place during follow-up visits where programming and teaching your child how to effectively use his or her device is done. The Implant Team will work with you and your child's teachers, when possible, to ease the transition into a world of sound. Commitment is required from everyone involved, however, parents overwhelmingly report that the benefits of the implant in helping their child prepare for the future are well worth the investment of both time and resources.

If you decide to proceed, your Implant Team will schedule the surgery. In the meantime, if your child is very young, the Implant Team may work with him or her to teach or 'condition' them to respond to sound or other stimuli such as vibration. This will help the Audiologist to program the device for your child after implantation.

The Surgery
An operation is necessary, requiring general anesthesia for children and most adults. The details will be discussed with you by the specially trained doctor who performs the surgery. Briefly, the internal implant is placed into a hollow bed in the bone behind the ear, the electrode array is fed into the cochlea. The operation typically takes about two to four hours. Children are usually up and about the next day, with little or no pain, and can resume normal activities within a few days.

"The surgery was the most difficult time, I felt awful sending her down for the operation. She was very happy going down to the operating theatre. I coped by trying to put my own feelings of anxiety aside and focusing on the future - reminding myself of all the benefits that she might get once the

operation was over and the implant was switched on. That's what kept me going."

Risks Associated with Surgery
Research and experience indicate that the risks of cochlear implant surgery are minimal and comparable to other routine surgical procedures of the middle ear. Complications from anesthesia are rare, but there are some associated general risks. Please ask your Surgeon and Anesthetist for details.

No life-threatening conditions or other major complications have ever been reported following a MED-EL Cochlear Implant surgery. Complications that do occasionally occur after implantation (independent of the device used) include: dizziness, delay in the healing of the scar, temporary pain or numbness of the tissue surrounding the implant, temporary change in taste, facial nerve damage, meningitis, poor location of the implant in surgery requiring a revision of surgery, increase in tinnitus. Residual hearing in the implanted ear will most likely be impaired. In general, researchers have concluded that the benefits cochlear implants provide significantly outweigh any risks.

Fitting and customizing the external device
The Speech Processor initial 'fitting' or 'tuning' takes place about four weeks after the surgery, after all stitches have been removed and swelling has subsided. An Audiologist or other specially trained Clinician programs the external parts of the device so that the sounds are comfortable for your child. This procedure is very much like having a hearing test and for young children it can be done using games and play situations.

When working with your child, the Audiologist finds the lowest level of stimulation on each channel that gives a hearing sensation - this is known as the threshold. The loudest level, which is comfortable, the most comfortable level (MCL), also needs to be measured. Each channel is then programmed to operate etween these two levels, so that incoming sounds will be audible, but not too loud. When several channels have been programmed in this way and are switched on together, the settings are known as a program.

Like all other cochlear implant systems, the programs of the Speech Processor will need to be readjusted or fine-tuned. This is because the sensitivity of the hearing nerves changes over time as they begin to get accustomed to stimulation from the implant. Your implant center will require that your child return at regular intervals to have the program and surgical site checked. The regularity of these fitting sessions will be decided by your implant center. On average, a programming session takes between one and three hours. The sessions will be more frequent during the first year following surgery, and may be required annually thereafter. Most patients need occasional adjustment of the program for as long as they use the implant.

"The first program Sarah had in her processor was a very conservative one but she cried when she first put it on and that made me want to cry too. I had to remain positive about the processor and have confidence in the clinicians who programmed it who assured me it was comfortable for her. She could pick up loads of sounds with it though, and very quickly got to like it. Now, after just a few months, Sarah runs to answer the door and the telephone. Now I know that my perseverance was all worthwhile."

Programming

Many programming sessions are carried out in order to refine the settings, which are different for each person. At first, the program may be set deliberately low for your child, so that he or she can begin to get used to the stimulation and not become overwhelmed by too much sound all at once. At this stage, your child may only respond to louder sounds in speech and in his or her surroundings. With time, your child will be able to detect a much broader range of sounds as the program is developed.

Regular programming and monitoring of the implant and processor takes place into adulthood. Eventually, most children only require an annual review, but it can take young children a long time to reach this 'maintenance' stage.

Learning to use the implant

A new, exciting world opens as you work with your child to identify new sounds and to learn how to use the device. The Implant Team and Educators will provide special training to help your child get the most benefit from the

device. They will show you and your family how to help your child use the new sounds to understand speech and develop and refine his or her own speech.

Every conversation can be a new learning experience for your child. It is important to be patient and remember that your child is learning a new way of listening to the world. Maintain reasonable expectations. Improvements with the implant will happen over time as you, the Implant Team, and your child's teachers help your child learn how to use the device.
The rehabilitation process is long and will require a tremendous commitment on the part of your family. Although it will demand a good deal of time it can be a lot of fun!

The Audiologist and Implant Team will monitor your child's progress and adjust the implant's program, as necessary, so that your child is receiving maximum benefit from the device.

The Implant Team may have the opportunity to work with your child's teachers so that the learning process will continue in school and during everyday activities. MED-EL's Speech Processors, both the body worn and the ear-level device, are fully compatible with commonly used external auditory systems such as FM-Systems, devices widely used in schools to help hearing impaired children overcome any difficulties due to the effects of distance from the teacher and background noise.

"His teachers are over the moon with the progress he has made with his implant in just 6 months. He has come on in leaps and bounds and his reading skills have really excelled."

Additional information

Warranty

The implant itself carries a warranty of 10 years. As with conventional hearing aids, the Speech Processor and headset contain parts that may occasionally require repair or replacement. MED-EL´s Service Policy states replacement equipment will be provided to you or your clinic the next business day after a problem is reported. After the warranty has expired,

MED-EL offers a choice of optional extended warranties or service contracts.

Limitations of a cochlear implant
A cochlear implant provides a very good sensation of hearing but cannot restore normal hearing. To gain the most benefit from the implant it should be used fully throughout all or most of the day.

By exercising a little caution and common sense, children with cochlear implants can continue to participate in most everyday activities, including non-violent sports. Contact sports that could result in severe blows to the head and deep water diving should be avoided as they may damage the implant. Children should simply remove the external parts of the implant for baths, showers, swimming and water sports.

MED-EL multichannel implants have proven to be highly reliable; however, the electrical or mechanical components of even the most advanced implant designs may fail due to technical reasons. In the rare event of a failure of the internal device, it may need to be replaced. On the rare occasions when this has been necessary, experience indicates that replacement surgery is highly successful.

Testing after implantation using MED-EL´s EARS (Evaluation of Auditory Responses to Speech) protocol.

MED-EL´s commitment to you
Our commitment to supporting patients and clinics is second to none.
MED-EL offers fast and efficient service for a lifetime of cochlear implant use.
MED-EL brings you local service with over 13 regional offices and many representatives worldwide.

A Sound Commitment
MED-EL is committed to providing you with fast and convenient service. MED-EL service staff will assist by troubleshooting minor problems and handling repairs.

MED-EL's commitment to High- Technology Products
MED-EL as a company is a leader in advanced technology with an impressive record for innovation. MED-EL developed the first behind-the-ear Speech Processor in 1991. In 1994 the first specially designed processor with a multichannel fast coding strategy (called CIS) was introduced and the first high-rate multichannel ear-level processor was launched in 1999.
MED-EL's researchers will continue their focus on developing new coding strategies and technologies to improve your child's performance and miniaturize the system.

If you have any questions or would like to contact an Implant Team in your area, or wish to receive literature on experience with MED-EL CI-systems, please get in touch with your nearest MED-EL office where our staff will be happy to help.

We at MED-EL wish you well in your decision regarding cochlear implantation for your child.

"The MED-EL company is totally committed to supporting MED-EL cochlear implant users throughout their lifetime, to continue to develop leading edge cochlear implant technologies and to pass the benefits of these developments on to the cochlear implant user".

Dr. I. Hochmair, CEO MED-EL International

Glossary of Terms

Audiologist:
Clinician specializing in hearing assessment and rehabilitation.

Auditory nerve:
The nerve of hearing leading from the cochlea (inner ear) to the brain.

CIS (Continuous Interleaved Sampling) and CIS+:
The highly advanced, fast rate speech processing strategies used to code speech sounds into electrical pulses for the implant to deliver to the auditory nerve.

Cochlea:
The snail-shaped inner ear containing delicate cell structures (including hair cells) vital to the hearing process. The normal cochlea changes sound from vibrations into electrical pulses, which are passed up the auditory nerve to the brain.

Coil:
A disc-shaped unit, which attaches to the head over the implant site, by means of magnetic attraction to a magnet in the implant. The coil sends the coded impulses through the skin to the implant.

Electrode array:
The tail-shaped portion of the cochlear implant containing electrodes and conducting wires sealed in a flexible, biocompatible material.

Hair cell:
Hair cells are situated in the cochlea. Their function is to change vibrations into small electrical currents, which are passed up the auditory nerve to the brain.

Implant:
That portion of the implanted part of the cochlear implant, which contains electronic components. Its function is to pick up the signal sent by the coil through the skin.

Most Comfortable Level (MCL):
A term in audiology used to express the most comfortable sound for a patient. It is measured for each channel individually.

Otologist:
A doctor specializing in conditions of the ear. Other titles which you may come across are Ear, Nose and Throat Surgeon, Otorhinolaryngologist and Audiological Physician.

Program:
The 'program' in the Speech Processor is the combination of Thresholds and Most Comfortable Levels together with other parameters for each channel. When activated, this 'program' ensures that the processor stimulates the user at a level, which is loud enough for them to hear, but not uncomfortably loud. Everyone's program is individual to them.

Processor:
This is the TEMPO+ ear-level speech processor. Its function is to change the incoming electrical signal from the microphone into coded pulses. The MED-EL body worn Speech Processor is called the CIS PRO+ and is the size of a personal cassette player.

Spectral peak representation ('n of m'):
A speech processing strategy used with the CIS PRO+, which codes speech sounds into electrical pulses for the implant to deliver to the auditory nerve.

'Switch-on':
The time when the implant is first activated, usually 3 or 4 weeks after surgery.

Threshold:
A term used in audiology to express the level at which a person can just hear a sound. For cochlear implants an electrical threshold is measured for each channel. This is not directly comparable to the sound threshold, which is normally measured through headphones or through hearing aids.

Test your cochlear implant knowledge!

1. What level of hearing loss can benefit from a cochlear implant?

a) mild to moderate
b) severe to profound
c) any level

2. What causes of hearing loss can be helped with a cochlear implant?

a) any cause
b) glue ear
c) any primarily affecting the inner ear

3. Can children with additional medical or learning difficulties qualify for a cochlear implant?

a) yes
b) no

4. What does a cochlear implant do?

a) restore normal hearing
b) give bionic hearing
c) give a sensation of hearing

5. Where does the electrode of a cochlear implant go?

a) in the outer ear
b) in the cochlea
c) in the middle ear

6. How long is the family's commitment to tuning and rehabilitation?

a) 3 to 12 months
b) 3 to 12 years
c) a lifetime

7. Can born deaf people benefit from cochlear implants?

a) yes
b) no

8. Once a child has an implant, will he or she drop sign language (if used)?

a) yes, immediately
b) not necessarily
c) no

9. Can an implanted child have an MRI scan without the need for a second operation?

a) no, because of the strong magnetic field required, MRI is contraindicated
b) yes, if they have a COMBI 40+ Implant and CI teams contact MED-EL first

10. The COMBI 40+ Implant stimulates the auditory nerve:

a) as fast as an eye can blink (10 blinks per second)
b) as fast as a humming bird can flap its wings (80 flaps per second)
c) with more than 18,000 pulses per second

See over for the answers to the quiz

Answers to the quiz

1. b: Mild to moderate losses benefit from conventional hearing aids.

2. c: Hearing losses which are primarily due to middle ear or nerve problems are not suitable for a cochlear implant.

3. a: A child with additional medical or learning difficulties can qualify for a cochlear implant subject to the same assessment criteria applied to all children (e.g. the child needs to be medically well enough to undergo surgery and the tuning/rehabilitation process).

4. c: A cochlear implant will not restore normal hearing, but rather provide a range of benefits from assisting lipreading to allowing the children to understand speech.

5. b: The electrode array is placed in the inner ear, or cochlea, from which position it can pass electric current to the nerve of hearing.

6. c: Cochlear implantation is a lifetime commitment. The child will normally take over responsibility for attending such appointments when he or she reaches adulthood.

7. a: Born deaf people can benefit from cochlear implantation. Those profoundly deaf may obtain more limited benefit because their hearing system has not been stimulated for a long time.

8. b: Some implant users either want or need to continue to use sign language. Many very young children continue to use sign or gesture whilst spoken language is developing and then, as speech becomes the predominant language, they may use less sign. It is important that children with cochlear implants are spoken to as much as possible in order for them to gain the most from their hearing through the implant.

9. a: no, because of the strong magnetic field required, MRI is contraindicated

10. c: The COMBI 40+ Implant is able to stimulate at more than 18,000 pulses per second, speeding towards natural sound.

Score 8-10: Well done!

Score 4-8: There are some gaps in your knowledge - more homework to do!

Score 0-4: Oh dear! You need to read this brochure again and/or ask questions to an experienced professional!

MED-EL Company headquarters are located in Innsbruck, Austria. The company has 13 subsidiaries or regional offices which support implant centers in more than 50 countries, and has over 250 employees worldwide. The company annually invests approximately 30% of its revenues in research and development. The philosophy of the organization is to bring technological advances to the patient as soon as possible, so the patient may benefit from state-of-the-art developments. MED-EL is committed to a flexible system that can incorporate future developments with ease; thus, the COMBI 40+ Implant is designed with the capability for future upgrades in conjunction with current technology standards, to meet your child's needs now and in the future.

MED-EL mission statement
MED-EL is a high-technology company with an effective quality system. We strive to be an efficient, motivated, flexible, creative, and well-organized cooperative team.

Our mission is:

• the production of high quality, highly reliable cochlear implant systems,

• the supply of the entire spectrum of cochlear implant candidates world-wide,

• the efficient, personalized support of and partnership with cochlear implant patients and professionals.

Locations Worldwide
MED-EL Headquarters
Fürstenweg 77a
A-6020 Innsbruck, Austria
Tel. +43-512-28 88 89
Fax +43-512-29 33 81

MED-EL Deutschland GMBH
Münchner Straße 15B
D-82319 Starnberg, Germany
Tel. +49-8151-77 03
Fax +49-8151-77 03-23

MED-EL Vienna Office
Währinger Strasse 6-8 / 4 / 17
A-1090 Wien, Austria
Tel. +43-1-31 72 400
Fax +43-1-31 72 400-14

MED-EL UK Limited
Bridge Mills
Huddersfield Road
Holmfirth
HD7 2TW, UK
Tel. +44-14 84-68 62 23
Fax +44-14 84-68 60 56

MED-EL GMBH Sucursal en España
C/Ronda de Poniente 16
Ala Derecha, Planta Baja L
E-28760 Madrid, Spain
Tel +349-1-80 41 527
Fax +349-1-80 44 348

MED-EL France Sarl
34, Rue de Penthièvre
75008 Paris, France
Tel. +33-1-53 89 64 45
Fax +33-1-53 89 64 48

MED-EL USA Corp.
2222 East NC Hwy 54, Suite B-180
Durham
N.C. 27713, USA
Tel. +1-919-572 2222
Fax +1-919-484 9229

MED-EL Latin America
Sarmiento 212 / 5 „A"
1041 Buenos Aires, Argentina
Tel. +54-11-4342 3071
Fax +54-11-4343 9078

MED-EL Middle America
19436 East Country Club Drive
Aventura, Florida 33180, USA
Tel. +1-305-792 7597
Fax +1-305-792 7598

MED-EL Asia Pacific
Suite 1501, Richville Corporate Tower
Industry Road
Madrigal Business Park
Ayala Alabang
1702 Muntinlupa City
Metro Manila, Philippines
Tel. +63-2-807 8780
Fax +63-2-807 4163

MED-EL Middle East
P.O. Box 54320, 54321
DAFZ
Dubai, United Arabic Emirates
Tel. +971-4-299 4700

Fax +971-4-299 4255

MED-EL Tokyo Office
11th Floor, Akasaka Daiichi Building
9-17 Akasaka 4-Chome
Minato-Ku, Tokyo 107-0052
Japan
Tel. +81-3-5414 5353
Fax. +81-3-5414 5388