OPUS 2

MED EL
MEDICAL ELECTRONICS

I. TABLE OF CONTENTS

2. INTRODUCTION

This user manual provides information and instructions regarding the MED-EL Cochlear Implant System with the OPUS 2 speech processor. It includes descriptions of available parts, wearing configurations, and accessories for the OPUS 2, as well as instructions for troubleshooting and proper care of the external cochlear implant equipment.

Your MED-EL Cochlear Implant System consists of the PULSAR_{CI}¹⁰⁰ or SONATA_{TI}¹⁰⁰ Implants, the external OPUS 2 speech processor (including FineTuner), the COMT+ P Coil, the external components and accessories, and the related external hardware and software used by your audiologist.

We recommend that you read this manual in its entirety.

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

The adjustment to a cochlear implant and adequate fitting of the device are gradual processes that occur over time. It is important to remember that your ability to hear with your new MED-EL system may take a little time while you become accustomed to this new method of hearing.

After your initial fitting, you will need to return to your CI center on a regular basis for reprogramming. Frequent reprogramming may be required during the first year of implant use. This is normal and necessary, and it reflects a learning process that occurs as you become more and more accustomed to stimulation through the implant. As more time passes, you will likely find that you may require fewer and fewer sessions. Most patients continue to need occasional adjustments for as long as they use their implant.

Please contact your CI center or MED-EL with any additional questions you may have.

3. INTENDED USE – INDICATIONS – CONTRAINDICATIONS

INTENDED USE

The OPUS 2 speech processor is part of the MED-EL Cochlear Implant System. The MED-EL Cochlear Implant System is intended to evoke auditory sensation via electrical stimulation of the auditory pathways for severely to profoundly hearing impaired individuals who obtain little or no benefit from acoustic amplification in the best aided condition.

INDICATIONS

The OPUS 2 speech processor is an external component of the MED-EL Cochlear Implant System and is indicated for use on patients who have been implanted with PULSAR$_{CI}$[100] and/or SONATA$_{TI}$[100] cochlear implants. The MED-EL Cochlear Implant System is indicated for:

- Adults eighteen (18) years of age or older who have bilateral, sensorineural hearing impairment and obtain limited benefit from appropriately fitted binaural hearing aids. These individuals typically demonstrate bilateral severe to profound sensorineural hearing loss determined by a pure tone average of 70 dB or greater at 500 Hz, 1000 Hz, and 2000 Hz. Limited benefit from amplification is defined by test scores of 40% correct or less in best aided listening condition on CD recorded tests of open-set sentence recognition (Hearing In Noise Test [HINT] sentences).

- Children aged twelve (12) months to seventeen (17) years eleven (11) months must demonstrate a profound, bilateral sensorineural hearing loss with thresholds of 90 dB or greater at 1000 Hz. In younger children, little or no benefit is defined by lack of progress in the development of simple auditory skills in conjunction with appropriate amplification and participation in intensive aural habilitation over a three (3) to six (6) month period. In older children, lack of aid benefit is defined as < 20% correct on the Multi-syllabic Lexical Neighbourhood Test (MLNT) or Lexical Neighbourhood Test (LNT), depending upon the child's cognitive ability and linguistic skills. A three (3) to six (6) month hearing aid trial is required for children without previous experience with hearing aids. Radiological evidence of cochlear ossification may justify a shorter trial with amplification.

As the OPUS 2 is a component of the MED-EL Cochlear Implant System, all indications stated for the Cochlear Implant System are applicable.

To obtain optimal benefit from the cochlear implant, candidates shall be sufficiently motivated and shall understand the importance of returning to the CI center for regular speech processor programming, assessment sessions and training.

CONTRAINDICATIONS

A patient must not receive an OPUS 2 speech processor if the individual is known to be intolerant of the materials used in the OPUS 2 control unit, battery pack, earhook, FM Battery Pack Cover or FineTuner. For details please refer to *Chapter 10, Technical data.*

As the OPUS 2 is a component of the MED-EL Cochlear Implant System, all contra-indications stated for the Cochlear Implant System are applicable.

The FineTuner is not intended to be used in environments where RF transmissions are prohibited.

NOTE:
Indications/contra-indications for the Cochlear Implant System are shipped to your clinic together with the implant. If you want to review this document, please contact MED-EL.

4. GETTING STARTED

THE PARTS OF THE SYSTEM

The MED-EL Cochlear Implant System is an active medical device that has internal (implanted) and external parts. The internal 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.
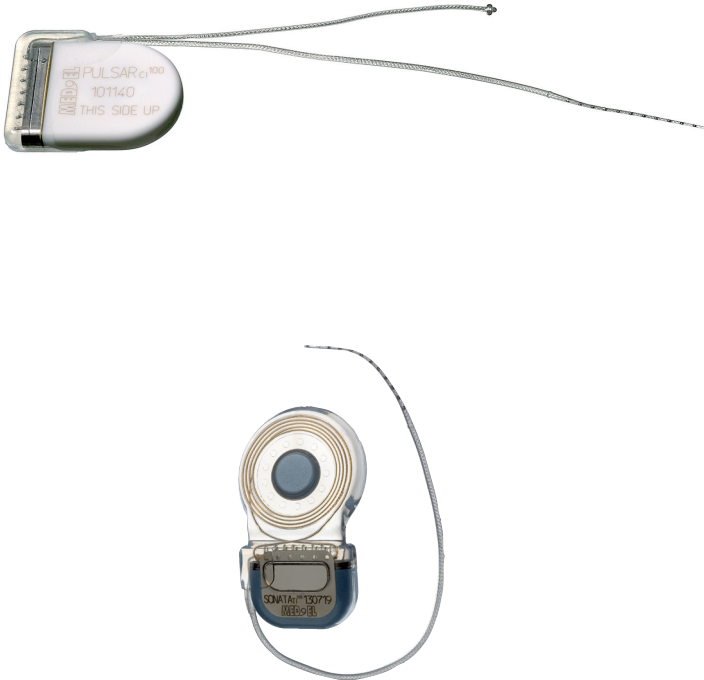

Fig. 1 PULSAR$_{CI}$^{100} and SONATA$_{TI}$^{100} cochlear implant

The external parts include the OPUS 2 speech processor and the speech processor accessories. In its basic configuration, the OPUS 2 speech processor consists of the control unit with the earhook attached, the battery pack frame and cover, the connecting piece, the coil and the coil cable. A device called a FineTuner facilitates access to various speech processor functions.

The coil is held in place by magnetic attraction to the implant.

The speech processor uses batteries that provide sufficient power for both the external and the implanted electronics. The implanted part does not contain batteries.

Fig. 2 Your OPUS 2 speech processor

5. OPUS 2 SPEECH PROCESSOR

CONTROL UNIT

Switching your processor ON and OFF

The battery pack lock functions as an ON/OFF switch.

You may select the following positions:
Battery pack lock open: **OFF**
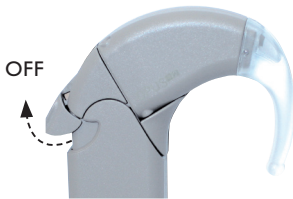Battery pack lock closed: **ON**

Fig. 3 The OPUS 2 speech processor in position OFF   Fig. 4 The OPUS 2 speech processor in position ON

After switching on the OPUS 2 speech processor, the red indicator light in the earhook will blink up to four times indicating the activated program (i.e. number of blink signals corresponds to the number of activated program). During this time the speech processor is already working.

In position OFF, the speech processor is turned off. No current is drawn in this position. Make sure to open the battery pack lock of your speech processor when not in use, as this prolongs the lifetime of the batteries (see also *Chapter 8, Care and maintenance*).

The OPUS 2 speech processor has an integrated telephone coil (telecoil). The telecoil picks up magnetic sound signals coming from telephone receivers or loop systems, which are installed in some public buildings, and converts them into electrical signals. When you switch on the speech processor, the microphone is active even if you had the telecoil selected before you switched off the speech processor. When the telecoil is active, you may hear buzzing sounds when operating a FineTuner key. The buzzing is normal and indicates that a command is being sent. To reduce interference with various electronic and electrical equipment when the telecoil is active, we recommend you reduce audio sensitivity (see *Chapter 5, OPUS 2 speech processor, FineTuner, FineTuner controls*).

FINETUNER

Your audiologist will program your OPUS 2 speech processor to your needs. The FineTuner is an accessory device to help you optimally use your speech processor in changing daily listening situations.

Your OPUS 2 speech processor has only an ON/OFF switch, all other functions are accessed with a separate device, the FineTuner, which transmits commands to your OPUS 2 speech processor via a radio frequency (RF) link. Its ergonomic design and larger size keys facilitate changing the settings of your OPUS 2 speech processor.

Keeping the FineTuner out of the reach of children prevents them from inadvertently changing the settings of their OPUS 2.

The FineTuner is not necessary for the function of your speech processor. When switched on, the OPUS 2 speech processor activates the same program, volume and audio sensitivity setting it had when it was switched off.

The FineTuner is configured for its designated target OPUS 2 speech processor, i.e. only the target OPUS 2 speech processor will execute the desired command when a certain key is pressed on the FineTuner. The typical maximum operating distance between the FineTuner and the OPUS 2 speech processor is approximately 80 cm (2.62 ft.). This range could be decreased close to electronic and electrical equipment even if this equipment complies with all applicable electromagnetic emission requirements.

How to configure your FineTuner

The FineTuner is configured for your speech processor and cannot be used by another cochlear implant user. Your audiologist or clinical staff will configure the FineTuner to your needs. Sometimes it may be necessary that you synchronize your FineTuner and speech processor (e.g. if you purchase a backup FineTuner). Switch off your OPUS 2 speech processor and place the coil of the OPUS 2 speech processor system on the keyboard of the FineTuner (approximately over key MT). Then switch on your OPUS 2 speech processor. The speech processor and the FineTuner will be synchronized automatically. Successful synchronization is indicated by a short blinking signal of the two amber indicator lights on your FineTuner.

For bilaterally implanted users

If you want to use your FineTuner for both speech processor systems, your audiologist or clinical engineer has received the MAESTRO software manual with detailed programming information and will assign two speech processors to your dataset. Once your OPUS 2 speech processors are programmed correctly, the synchronization procedure described above should be performed with both speech processors.

FineTuner controls

The keyboard has 15 keys (see *Fig. 5*)

- **Volume keys:** Two keys to increase ⊕ or decrease ⊖ overall loudness. Loudness is increased or decreased continuously.

- **Sensitivity keys:** Two keys to increase 📶 or decrease 📶 the audio sensitivity. Audio sensitivity is increased or decreased continuously.

- **Default key:** This key ↩ sets overall volume and audio sensitivity to predefined values determined by your audiologist or clinical staff.

- **Program Selection keys:** Four keys ● ●● ●●● ●●●● to access four different programs.

- **Input Selection keys:** Three keys to select the microphone Ⓜ, the telecoil Ⓣ or the microphone and the telecoil (mix) ⓂⓉ as the signal source.

- **Processor Selection keys** (for bilateral patients only)**:** The Processor Selection keys allow selecting the left ◀, right ▶ or both processors ◀▶. These buttons are also required in programming mode, e.g. to activate or deactivate the keyboard lock (see ***Chapter 5, OPUS 2 speech processor, FineTuner, FineTuner functions - Automatic keyboard lock***).

All FineTuner controls can be selectively disabled by your audiologist or clinical staff by disabling the respective command in the control unit. Your FineTuner will still be able to transmit all commands, but your control unit will not execute disabled commands.

Fig. 5 FineTuner

FineTuner functions

Automatic keyboard lock: To avoid unintentional operation of a key, the FineTuner features an optional automatic keyboard lock. This function electronically locks the keyboard if no key is pressed for more than 10 seconds.

To activate the keyboard lock feature of your FineTuner, press the ◀▶ key for more than 5 seconds to enter the program mode (the red and both amber indicator lights on your FineTuner will both start blinking alternately indicating that you have successfully entered the FineTuner's program mode) and then the ▶ key to activate the automatic keyboard lock (the FineTuner will confirm successful activation of the automatic keyboard lock by a short blinking signal of the two amber indicator lights).

To deactivate the automatic keyboard lock enter the program mode just as described above and press the ◀ key. As above the FineTuner will confirm successful deactivation of the automatic keyboard lock by a short blinking signal of the two amber indicator lights.

ATTENTION:
To enter the program mode while the keyboard lock is active, the ◀▶ key must be pressed twice (second time for more than 5 seconds).

To activate a certain function while the keyboard lock is active, press the desired function key twice. The first click temporarily unlocks the keyboard, the second click executes the command. After 10 seconds without pressing another key, the keyboard lock is active again.

Battery low warning: The processor features an optical warning signal, which appears as a red indicator light flashing 3 times on the FineTuner. The signal is generated after pressing a key if the voltage level of the FineTuner reaches a critical lower limit (see also *Chapter 8, Care and Maintenance, Batteries, Changing the battery of your FineTuner*).

Transmitter time-out: The FineTuner stops transmitting after 3 seconds to save energy, even if the key is still pressed.

Your FineTuner does not have an ON/OFF switch.

Three indicator lights with different colors (2 amber, 1 red) indicate various conditions of the FineTuner. For a detailed description of their function see *Chapter 9, Troubleshooting.* The FineTuner does not affect connected Assistive Listening Devices (ALD's).

BATTERY PACK

The OPUS 2 battery pack consists of the battery pack frame holding 3 hearing aid batteries, and the battery pack cover. The battery pack cover slides over the battery pack frame and is held in place by the battery pack lock which also functions as the ON/OFF switch of the control unit (see *Fig. 3+4*). This configuration allows the entire speech processor to be worn at the ear and is the most common configuration for older children and adults.

Coil

Coil cable

Control unit

Earhook

Battery pack

Connecting piece
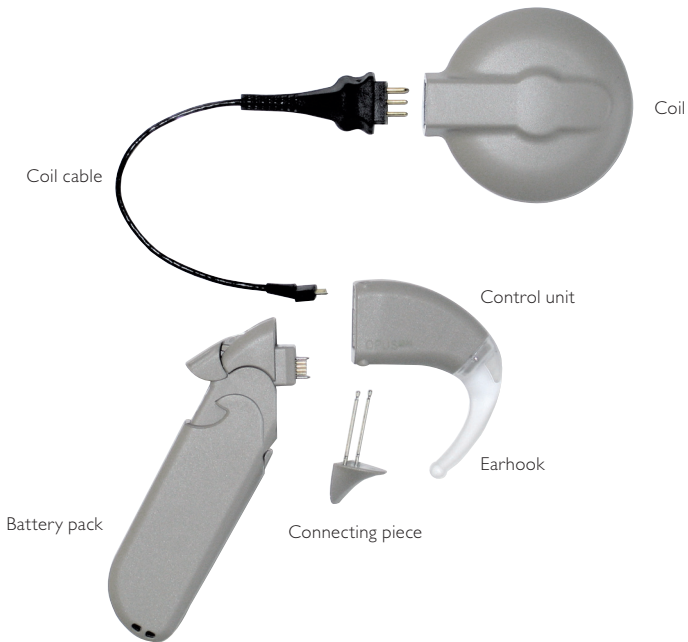
Fig. 6 How to assemble the control unit and battery pack

How to assemble your control unit and battery pack

1. Connect the 9.5 cm cable to the coil. 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 correct way to insert the cable into the coil (see *Fig. 6*).

2. Connect the opposite end of the cable into the control unit (see *Fig. 7*).

3. Add the battery pack frame with the cutout area positioned to accommodate the coil cable plug.

4. Insert the pins of the connecting piece into the small holes at the bottom of the control unit.

   If this configuration is used with children:

   For young children, it is mandatory to use the safety lock to prevent them from disassembling the speech processor (see Chapter 5, OPUS 2 speech processor, Safety lock).

   NOTE:
   It is not possible to attach or remove the connecting piece if the battery pack cover is not removed from the battery pack frame.

5. Add fresh batteries.

6. Add the battery pack cover and close the battery pack lock to switch the processor on.

7. The red indicator light in the earhook will blink up to four times indicating the activated program.

8. Position the speech processor on the ear and the coil over the implant.

9. Choose the desired program, volume and sensitivity settings with the FineTuner.

Only parents/adults are allowed to disassemble the device to change defective parts. Parents/adults must check the device frequently for damage or missing parts.

For more wearing options see *Chapter 5, OPUS 2 speech processor, Additional wearing options*.

An ear-mold may help keep the processor in position on the ear. Contact your CI center or audiologist for assistance.

COIL

The coil connects the OPUS 2 speech processor with the implant. It sends both energy and the coded acoustic signal through the skin to the implant.

A small magnet is located in the center of the coil to hold it in place on the head over the implant package. The magnet strength can be adjusted by your audiologist or clinical staff to meet your individual needs.

If you notice any signs of skin irritation around the coil, contact your clinic or CI center.

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 after surgery, you should regularly check the skin under the coil for irritation. As the child grows, skin thickness will increase and the magnetic attraction force will need to be adjusted by increasing the number of magnets. Your audiologist can adjust the magnet strength of the coil.

COIL CABLE

The coil and speech processor are connected by the coil cable. You have to unplug the cable for maintenance purposes or if you want to replace the cable. It is not necessary to disconnect the cable when changing the batteries.

Although the cable is designed for maximum durability and flexibility, this part of the MED-EL Cochlear Implant System is most likely to wear out.

If a cable fails, order a new one immediately.

Do not use the cable with devices other than the OPUS 2 speech processor.

How to replace the coil cable

Fig. 7 Connecting the coil cable

1. Open the battery pack lock and remove the battery pack cover.

2. Pull the connecting piece straight down until you feel a slight mechanical click. The connecting piece need not be removed completely but you may do so if you wish.

3. Disassemble the battery pack frame from the control unit.

4. Disconnect the coil cable from the control unit and the coil.

5. Connect the new coil cable to the coil.

6. Connect the opposite end of the new coil cable into the control unit. Make sure that the cable plug is correctly positioned. The slanting edge should face up. The cable should face diagonally upwards.

7. Reassemble the battery pack frame and the control unit. The coil cable plug rests in the small cutout section of the angled section of the battery pack.

8. Push the connecting piece back in place.

9. Slide the battery pack cover back on and close the battery pack lock. The speech processor is now active.

IMPORTANT

To prolong your cable's life, we recommend the following:
- **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.**
- **Do not use excessive force when unplugging the cable.**

CONNECTING ASSISTIVE LISTENING DEVICES

The additional components required for the connection of Assistive Listening Devices (FM Battery Pack Cover and Adapter Cable) are included in the **FM Extension Kit** which may be purchased separately.

A special battery pack cover is provided to connect your OPUS 2 speech processor to external, battery-powered audio devices, such as portable CD players, MP3 players, AM-FM radios, etc. The FM Battery Pack Cover is slightly longer than the standard cover to accommodate the integrated FM connector.

To assemble the FM Battery Pack Cover, proceed as follows:
- Open the battery pack lock.
- Remove the battery pack cover.
- Slide on the FM Battery Pack Cover.
- Close the battery pack lock.

Connect the three-pin connector of the Adapter Cable (grey end) to the openings at the bottom of the FM Battery Pack Cover. Mind the orientation of the three pins and do not use excessive force when connecting the cable.

Connect the audio phone plug (yellow or red end) to the audio output of the battery-powered device.

Fig. 8 Connecting the FM cable and FM receiver

Direct-link FM systems (e.g. Phonic Ear/Oticon Lexis) may be connected to the FM Battery Pack Cover without an Adapter Cable. Connecting direct-link FM systems will decrease battery life of your OPUS 2 speech processor.

IMPORTANT

The provided cable is intended for the connection of battery-powered audio devices, such as portable CD players, MP3 players, AM-FM radios, etc. For connection of FM or infrared systems, use the respective manufacturers' adapter cables.

WARNING

Do not use cables longer than 1 m (3.28 ft.) as these cables may result in increased electromagnetic emissions or decreased electromagnetic immunity of your speech processor system.

Cables from MED-EL are available for unilateral and bilateral implant use and for Mix and Ext mode. For more information, please contact your local MED-EL office.

Mix mode:
When connected to an external device, the OPUS 2 microphone remains active. You will hear inputs from the external device and the speech processor.
Mix cables are indicated by a yellow 3.5 mm plug.

Ext mode:
When connected to an external device, the OPUS 2 microphone is deactivated. You will hear input from the external device only.
Ext cables are indicated by a red 3.5 mm plug.

ADDITIONAL WEARING OPTIONS

BabyBTE™/ActiveWear

MED-EL's signature wearing option for infants and young children is the BabyBTE™. The BabyBTE™ has the advantage of allowing a young child to begin using the same ear-level speech processor that he or she will use for the long term, while still accommodating a baby's small ear and activity level. For this wearing option, the entire BTE processor is placed on the clothing, and only the coil is placed over the implant on the head. This configuration is also referred to as ActiveWear for users who participate in sports or other activities where a very secure placement is desired.

For activities that require wearing a helmet, using this configuration allows the microphone of the speech processor to be positioned outside the helmet, with only the coil and cable fitting underneath.

When using the BabyBTE™ or the ActiveWear configuration, it is important to be aware of the position of the microphone; it should be positioned in such a way that the majority of sound will be directed at the microphone port (i.e. facing forward). The microphone should not be covered or positioned where jewellery and/or clothing could obstruct input to the microphone.

Fig. 9 How to assemble the BabyBTE™/ActiveWear
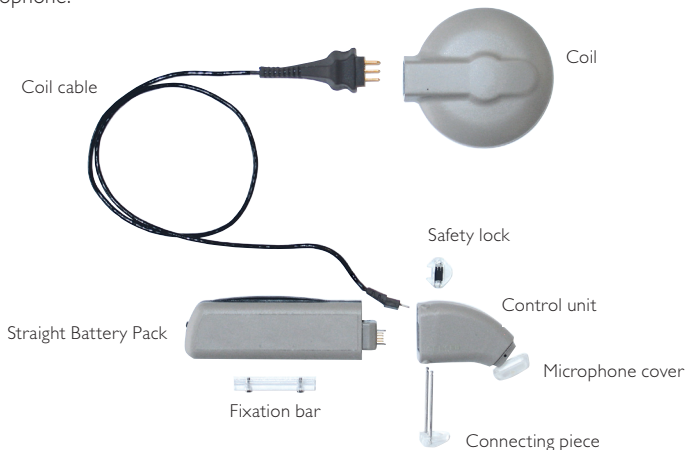
How to assemble your BabyBTE™/ActiveWear configuration

The additional components required for the BabyBTE™ assembly and the ActiveWear configuration (Straight Battery Pack, 28 cm coil cable, microphone cover, connecting piece, safety bar, screw-on fixation bar and fixation clip) are included in the **BabyBTE™/ActiveWear Extension Kit** which may be purchased separately.

1. Exchange the earhook with the microphone cover: Remove the earhook fixation pin (when used) and pull off the earhook as shown in *Fig. 13 + 14.*

2. Attach the microphone cover to the control unit as shown in *Fig. 14.* You will hear or feel a soft click when the microphone cover is attached properly.

3. Attach the screw-on fixation bar or the fixation clip to the Straight Battery Pack.

4. Connect the 28 cm coil cable to the coil.

5. Connect the opposite end of the cable to the control unit.

6. Connect the Straight Battery Pack to the control unit.

7. Insert the pins of the connecting piece for safety lock into the small holes at the bottom of the speech processor. Secure the assembly by attaching the safety lock as shown in *Fig. 15.*

   For young children, it is mandatory to use the safety lock to prevent them from disassembling the speech processor (see Chapter 5, OPUS 2 speech processor, Safety lock).

8. To insert batteries, open the battery pack lid of the Straight Battery Pack by pushing the lever at the back of the device as shown in *Fig. 18* and hold it in this position. Now push the battery pack lid backwards about 3 mm, then remove it by pushing it to the front.

9. Add fresh batteries.

10. To close the battery pack lid, put it on the housing so that it overhangs the back of the Straight Battery Pack by about 3 mm. Gently push the battery pack lid onto the housing. When the battery pack lid is positioned correctly, it can be pushed forward, where it snaps in place easily. Never put the battery pack lid on the very back of the housing, pushing it forward by force. This could damage the Straight Battery Pack. Do not use excessive force when closing the battery pack.

11. Switch on the speech processor at the back of the Straight Battery Pack.

12. The red indicator light behind the microphone cover will blink up to four times indicating the activated program.

13. Attach the speech processor to the clothing so that the microphone is generally pointing in the desired direction, and then place the coil over the implant.

14. Choose the desired program, volume and sensitivity settings with the FineTuner.

Fig. 10 OPUS 2 BabyBTE™/ActiveWear

Children's Battery Pack

The control unit is worn at the ear, which provides optimal microphone placement and easy visibility of the red indicator light in the earhook. A cable allows the battery pack to be attached directly to clothing. This cable is hard-wired into the battery pack and cannot be disconnected or replaced. If the cable is damaged, the entire battery pack should be replaced.

The additional components required for the Children's Battery Pack assembly (Children's Battery Pack, children's connecting piece, safety lock, screw-on fixation bar and fixation clip) are included in the **Children's Extension Kit** which may be purchased separately.
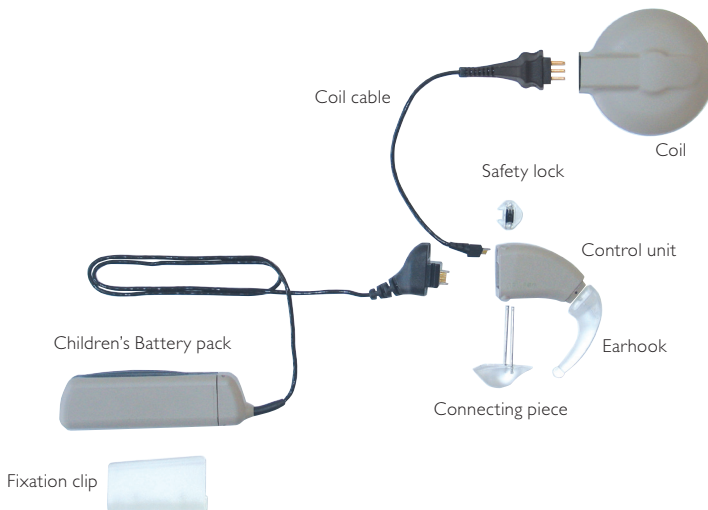
Fig. 11 How to assemble the Children's Battery Pack

How to assemble your Children's Battery Pack

1. If you were using the BabyBTE™ assembly before, exchange the microphone cover with the regular earhook. Carefully pull off the microphone cover and attach the earhook to the control unit as shown in *Fig. 14*. You will hear or feel a soft click when the earhook is attached properly. It is recommended to insert the earhook pin. The earhook pin will make it difficult for children to remove the earhook.

2. Attach the screw-on fixation bar or the fixation clip to the Children's Battery Pack.

3. Connect the 9.5 cm coil cable to the coil.

4. Connect the opposite end of the cable to the control unit.

5. Connect the cable of the Children's Battery Pack to the control unit.

6. Insert the pins of the children's connecting piece for safety lock into the small holes at the bottom of the speech processor: Secure the assembly by attaching the safety lock (see *Fig. 15*).

   For young children, it is mandatory to use the safety lock to prevent them from disassembling the speech processor (see Chapter 5, OPUS 2 speech processor, Safety lock).

7. To insert batteries open the battery pack lid of the Children's Battery Pack by pushing the lever at the back of the device as shown in *Fig. 18* and hold it in this position. Now push the battery pack lid backwards about 3 mm, then remove it by pushing it to the front.

8. Add fresh batteries.

9. To close the battery pack lid, put it on the housing so that it overhangs the back of the Children's Battery Pack by about 3 mm. Gently push the battery pack lid onto the housing. When the battery pack lid is positioned correctly, it can be pushed forward, where it snaps in place easily. Never put the battery pack lid on the very back of the housing, pushing it forward by force. This could damage the Children's Battery Pack. Do not use excessive force when closing the battery pack.

10. Switch on the speech processor at the back of the Children's Battery Pack.

11. The red indicator light in the earhook will blink up to four times indicating the activated program.

12. Attach the Children's Battery Pack to the clothes, put the control unit on the ear and place the coil over the implant.

13. Choose the desired program, volume and sensitivity settings with the FineTuner.

*An ear-mold may help keep the processor in position on the ear. Contact your CI center or audiologist for assistance.*

Fig. 12 OPUS 2 Children's Battery Pack

Locking lever

The Children's Battery Pack, in contrast to the other battery pack versions, is provided with a locking lever. With this lever, the battery door can be opened only by using a ballpoint or other pointed object. Thus, a small child is not able to open the battery pack lid to take out the batteries and possibly swallow them.

EARHOOK/MICROPHONE COVER

How to remove the earhook pin

Your OPUS 2 speech processor is shipped with a pin securing the earhook to the control unit. This configuration is recommended when the user is a young child.

To remove the earhook pin, push the pin through the holes (see *Fig. 13*) using the supplied tool, then grab it and pull it out completely.
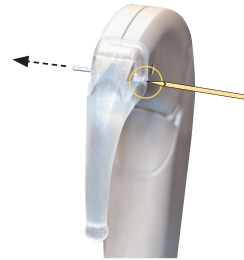
Fig. 13 How to remove the earhook pin

How to remove the earhook or microphone cover

To exchange the earhook or replace it with the microphone cover, gently push the earhook downwards (a, b) to remove it from the control unit. Attach the new earhook or microphone cover over the rib in the lower part of the control unit and push it gently upwards (c, d) until it snaps in place (see *Fig. 14*). To remove the microphone cover from the control unit, push against the top rib of the cover (e, f).
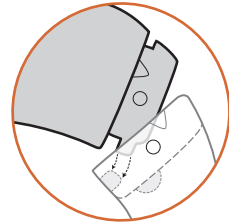
Fig. 14 How to remove the earhook or microphone cover

Make sure to insert the earhook pin when attaching the earhook to prevent children from removing the earhook. Keep the supplied pin removal tool away from children.

SAFETY LOCK

The safety lock prevents small children from disassembling their speech processor, therefore it is mandatory to use it for children. After attaching the safety lock, check that the safety lock is positioned properly.

Insert the connecting piece for safety lock (with long pins) and place the safety lock on the protruding pins. The coil cable plug rests in the cutout section. Slide the black lever into the shown direction using a pointed object (e.g. ballpoint) to secure the safety lock. To open the safety lock, move the black lever in the other direction.

Fig. 15 Safety lock

6. SPECIAL CONSIDERATIONS FOR YOUNG CHILDREN

The OPUS 2 speech processor has several features that are particularly designed for young children. Among them:

- **Locked earhook:** The earhook is secured to the control unit with a small pin.

- **Safety lock** to prevent small children from disassembling the speech processor, therefore it is mandatory to use it for children.

- **Wearing configurations for small ears** that remove the speech processor from the head and place it securely on the clothing.

- **Deactivation of certain FineTuner controls:** To prevent accidental program, volume or sensitivity changes, it is possible to deactivate these FineTuner controls. Please contact your CI center for assistance.

- Only parents/adults are allowed to disassemble the device to change defective parts. Parents/adults should check the device frequently for damage or missing parts.

7. GENERAL PRECAUTIONS AND WARNINGS

This section contains information on the safe use of your Cochlear Implant System. Please read this information carefully. Your CI center 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.

Expected performance with the cochlear implant cannot be predicted accurately. Past experience with the MED-EL Cochlear Implant System may provide some general guidelines. 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 the MED-EL Cochlear Implant System with any device other than those listed in this manual or approved by MED-EL. If you have problems with any component of the system, refer to *Chapter 9, Troubleshooting*.

IMPORTANT

If you ever experience uncomfortable hearing sensations, we strongly recommend that you no longer wear your external system components. Please contact your clinic or CI center immediately.

If your child refuses to wear the system or indicates uncomfortable hearing sensations, remove the system immediately and have your child's system checked at your clinic or CI center.

GENERAL PRECAUTIONS FOR YOUR COCHLEAR IMPLANT SYSTEM

The OPUS 2 speech processor and other parts of the system contain sophisticated electronic components, which need special precautions regarding electromagnetic compatibility (EMC). When activating your OPUS 2 speech processor always follow the guidelines outlined in this section and *Chapter 10, Technical data, Guidance and manufacturer's declaration.*

The electronics are durable but must be treated with care.

• Never open the housing of your OPUS 2 speech processor. Unauthorized opening invalidates the warranty. To change the batteries or clean the battery contacts, remove only the battery pack cover as described in *Chapter 8, Care and maintenance*.

• Before switching on the OPUS 2 speech processor, check the external parts of the MED-EL Cochlear Implant System for proper mechanical condition, e.g. for loose or broken parts. In case of problems, the speech processor may/should not be switched on. Read *Chapter 9, Troubleshooting* or contact your CI center or MED-EL.

IMPORTANT

When operating the MED-EL Cochlear Implants with an OPUS 2 speech processor, we recommend using a coil with the suffix "P" in its serial number. Using the MED-EL OPUS 2 speech processor with a coil without the suffix "P" could – under extreme environmental conditions (when exceeding the specified operational temperature range of the OPUS 2 speech processor) – cause the MED-EL Cochlear Implants to switch off. In this case, the implant will stop stimulation; wrong stimulation or over-stimulation is impossible. As soon as the operational temperature is reached again, the implant will continue to stimulate.

Everyday life

The implant package and the electrodes are located directly under the skin. In order to avoid damage to the implant you/your child should not unnecessarily move and extensively scratch the skin above the implant site and should also avoid mechanical pressure on the site. When brushing or styling the hair at the site of implantation, you should be careful not to harm the skin (at the site of the implant there may be a slight bulge).

For the external components, please observe the following:

- Your OPUS 2 speech processor, FineTuner and coil do not require regular maintenance by clinic personnel or other experts.

- The defined operating temperature range is between +10°C and +45°C (+50°F and +113°F) for the OPUS 2 speech processor and the FineTuner. Normally, when the OPUS 2 speech processor is worn on the body, natural body heat helps maintain this temperature range.

- Do not leave the speech processor or FineTuner in direct sunlight (particularly inside a car).

- If you ever experience loud or uncomfortable sounds, please remove your coil immediately: this will stop stimulation at once.

- Do not use the speech processor or FineTuner of another cochlear implant user. Your speech processor and FineTuner have been adjusted to your individual needs. Using another speech processor or FineTuner may cause painful or uncomfortable stimulation.

- Avoid getting your speech processor or FineTuner wet as this may impair its function. Always remove and switch off the external parts of your implant system and keep them in a dry place before bathing, showering or engaging in other water-related activities.

- If the external parts become wet, switch off your speech 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 for at least 12 hours in the supplied drying kit to allow moisture inside the speech processor to dry. If in doubt, extend the drying period to a day or longer. If the FineTuner becomes wet, wipe it off with a dry tissue.

- You also have to take care of the external components of your/your child's Cochlear Implant System. They should not be dropped or subjected to dangerous areas (machines or high voltage) which could result in damage to the components.

- Do not use the OPUS 2 speech processor and the FineTuner in environments where radio frequency (RF) transmissions are prohibited.

- Do not try to shape the earhook by hot air.

Children shall be instructed not to swallow or put any components of their Cochlear Implant System into their mouths and not to play with any components. For young children, it is mandatory to use the safety lock to prevent them from disassembling the speech processor (see Chapter 5, OPUS 2 speech processor, Safety lock).

Technology in everyday life

Metal Detectors and Anti-Theft Systems
Metal detectors, some anti-theft security systems and other RF transmitters may produce a buzzing sound heard by the implant user, when you are near or walking through the magnetic field emitted by these systems. To avoid the buzzing sound, switch your OPUS 2 speech processor off when walking through metal detectors and anti-theft systems. Please note that your FineTuner will not be able to communicate with your processor until the processor is switched back on. In rare cases, a cochlear implant may trigger a security system alarm, so make sure that you always carry your MED-EL ID card with you in order to identify yourself as a cochlear implant user.

Airport/Airplane
In airplanes it is required that computers and other electronic devices are switched off during takeoff and landing. Electronic devices may interfere with the communication system and the airplane's electronic equipment. Your OPUS 2 speech processor is an electronic device and should therefore be switched off during takeoff and landing, even if interference is unlikely.

Interference with reception of TV
In rare cases, your speech processor may interfere with reception when using certain TV sets (sets with an indoor antenna). You can reduce the amount of interference by moving away from the TV set and turning the antenna.

Mobile phones
Mobile phones and other portable and mobile RF communications equipment may interfere (perceived as a buzzing sound) with the external parts of your Cochlear Implant System if they are used within a distance of less than 3 meters (9.84 ft.).

TV, radio, FM systems, etc.
The speech processor should never be connected directly to any equipment connected to an electrical outlet of any kind, including a power strip. Galvanic isolation systems, such as an infrared system or FM system, should always be used if you want to connect to a device that plugs into an electrical outlet. Battery operated devices can be directly connected to the speech processor. Special cables may be needed (e.g. for connection to FM systems). For further information please contact MED-EL.

Electrostatic discharge (ESD)

Electronic devices are influenced by electrostatic discharge (ESD). Although the MED-EL Cochlear Implant System has several internal safety features designed to reduce ESD, there is a small risk that the external or internal equipment can be damaged if the static discharge flows through the external equipment. Switching off your speech processor will not prevent damage from occurring. In rare cases, the user may experience uncomfortably loud hearing sensations, however, the most likely occurrence in case of an ESD event is a short interruption of stimulation or a controlled speech processor shutdown.

Following the listed guidelines can reduce the probability of electrostatic discharge.

- If you believe that you or your child is statically charged, discharge by touching a radiator, a water tap, or any grounded metal object.

- Do not allow another person to touch the external parts of your implant system unless both you and the other person are "discharged".

- You should always discharge before taking off or putting on the OPUS 2 speech processor. To do this, use this two step approach:

  (A) When removing another person's speech processor:

  Step 1   Touch the person's body

  Step 2   Touch the processor

  (B) When picking up the speech processor from a table or other surface:

  Step 1   Touch the table

  Step 2   Pick up the processor

- You or your child should always be "discharged" when leaving the car. Touching the car door is a good way to discharge. The speech processor or cables should neither touch the car door nor other parts of the car body.

- Use an antistatic spray for upholstery, TV or computer screens to reduce static build-up. These sprays are also available for carpets or clothing.

- Always remove your speech processor before dressing and undressing, especially if garments include synthetic fibers. Generally, cotton and natural fibers are less likely to cause ESD problems. Fabric softeners might also help reduce static electricity. When getting dressed, put your OPUS 2 speech processor on last, and remove it first when undressing.

- Always remove the OPUS 2 speech processor and coil before touching plastic play equipment (e.g. children's slides). Switching off the speech processor may not be enough to prevent ESD damage. Completely remove the speech processor from the body. Afterwards, do not touch the site of the implant. Make sure that you or your child "discharge" before touching the speech processor. If you have any doubt about a particular material, it is best to be cautious by removing the OPUS 2.

- Always remove the OPUS 2 speech processor and coil when experimenting with static electricity and "high" voltage. Van de Graaff generators, as found in school science departments, should never be used by cochlear implant users because they produce very high levels of static electricity.

- When working at a computer, make sure the computer is grounded and use an anti-static mat under your work area to reduce static build-up. Never directly touch the screen of a computer or TV. The risk of problems from computer screens is very small but may be further reduced by attaching an anti-static screen to the computer.

- If your speech processor stops working and you suspect an ESD is the cause, switch off the speech processor, wait for a few minutes and switch it on again.

Sports and play

It is important to protect the implant from sources of direct impact. Accidents like falling out of a chair or bumping into furniture with your head could damage the implant. As with any child, parents should take measures to prevent these accidents by using child seats and child locks where appropriate and by supervising outside play.

Avoid contact sports that might result in severe blows to the head or continuous pressure on the implant, since this could damage the implant. Other physical activity is generally allowed. Make sure that you wear the OPUS 2 securely (see *Chapter 5, OPUS 2 speech processor, Additional wearing options*) to protect it from physical damage. Sports that require a helmet are okay as long as they do not exceed the given capabilities of the user. Use a helmet whenever necessary to protect the implant site from any blows. Your/your child's helmet should be high quality and may need to be modified to meet your individual needs. For specific questions about contact sports, contact your CI center. Most water sports should cause no problems as long as the external parts of the implant system are removed. If goggles are worn, care must be taken to ensure that the strap is not tight over the site of the implant. In any case consult an experienced physician about personal restrictions when participating in water sports. Consult with your implant surgeon before snorkelling and scuba diving.

If you have any concerns or questions, ask your physician for advice about performing sports and limitations caused by your/your child's health status.

PRECAUTIONS FOR MEDICAL PROCEDURES

Neurostimulation or diathermy
Neurostimulation or diathermy must not be carried out 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.

Electrosurgery
Monopolar electrosurgical instruments must not be used close to the cochlear implant. Instruments used in electrosurgery can produce high-frequency voltages which may induce currents in the electrodes of the cochlear implant. Such currents may damage the implant and/or the surrounding tissue.

Electroconvulsive therapy
Electroshock or electroconvulsive 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
Any necessary ionizing radiation therapy should be carefully considered and the risk of damage to the cochlear implant has to be carefully weighed against the medical benefit of such therapy. Switch off and remove your OPUS 2 speech processor in the vicinity of strong ionizing radiation like X-ray diagnosis machines to prevent any possible interference with the electronics.

MRI
Only 0.2T MRI scanners should be used on patients who have PULSAR$_{CI}$[100] or SONATA$_{TI}$[100] implants. There is no need to remove your implant's internal magnet, but you should always remove your OPUS 2 speech processor before undergoing a MRI scan. Most 0.2T MRI machines are "open MRI". Unlike other tube-like MRI scanners, the open MRI machines have a clear, unobstructed space on one or more sides allowing patients to see and talk to imaging personnel and loved ones during the exam. If you have difficulty locating 0.2T MRI scanners, MED-EL can provide a list of scanners and their locations.

Please have your radiologist contact MED-EL Corporation for details on the appropriate scanning techniques with the PULSAR$_{CI}$[100] or SONATA$_{TI}$[100] implants before scheduling your exam. The following is a list of some of the most important information that your radiologist should know before s/he begins your scan:

CAUTION: MED-EL must be consulted prior to conducting a 0.2T MRI examination on any patient with a PULSARCI[100] or SONATATI[100] Implant.

- Do not, under any circumstances, scan a PULSARCI[100] or SONATATI[100] patient with field strengths greater than 0.2T.

- When scanning at 0.2T, confirm that the patient is positioned so that the magnetic field of the internal magnet is in the same orientation as the magnetic field of the scanner. This is necessary to minimize torque on the internal magnet and induced voltage in the receiver.

- Straight orientation of the head is acceptable for bilaterally implanted patients.

- Please note that there exist many types of 0.2T MRI scanners. In some, the head coil used for head imaging is attached to the MRI bed. Further counseling and recommendations will be provided to the cochlear implant professional and radiologist in the event of head imaging.

MED-EL has prepared a MRI Examination Request Form containing precise information on device parameters (magnetic field strengths) and guidelines for a MRI examination under safe conditions. The MRI Examination Request Form must be completed by the requesting physician in cooperation with the applicable radiology department and reviewed and approved by MED-EL prior to performing the MRI examination for safety reasons and to avoid loss of warranty coverage. External equipment should not enter or be in close proximity to the MRI machine.

Other treatments
The effects of a number of treatments are unknown, e.g. radioactive radiation (cobalt, linear accelerator) or electrical examinations in the dental area. Please contact your clinic.

Ear infections
Infections in the implanted ear must be treated promptly by a physician who will prescribe antibiotics as necessary. Prophylactic use of antibiotics is recommended for all patients unless medically contraindicated. The surgeon should prescribe adequate dosing for each patient's condition. Please inform your CI center of such infections.

Electrical lice combs
Cochlear implant users should not use these devices.

Meningitis vaccine and prevention
Bacterial meningitis is rare but has the potential to be serious. The risk of contracting meningitis after your CI surgery can be reduced by the meningitis vaccine, by using antibiotics before and after CI surgery and by using the surgical technique recommended by MED-EL. As with all cochlear implant surgery, preventative antibiotic usage is recommended for all patients unless medically contraindicated. Talk to your surgeon about this. Your surgeon should prescribe adequate antibiotic dosing for you or your child and should check your or your child's immunization status before your implant surgery.

8. CARE AND MAINTENANCE

MAINTENANCE

Your OPUS 2 speech processor is designed for durability and reliability. When handled with sufficient care, it will function for a long time. The battery pack and particularly 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 speech processor. Do not use aggressive cleaning agents. Prevent water from running into the speech processor via the connectors, controls, or the battery pack.

Protect your OPUS 2 speech processor from water (see also *Chapter 7, General precautions and warnings*).

Do not try to repair electronic parts of your OPUS 2 speech processor 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. Cover the air openings on the top with adhesive tape when storing the batteries to avoid self-discharge. Also remove the batteries when drying the speech processor in the enclosed drying kit.

Handle your FineTuner with care. Avoid getting the FineTuner wet. Do not clean the FineTuner in or under water. Use a damp cloth to gently clean the FineTuner. Do not use aggressive cleaning agents.

BATTERIES

In its current version, the OPUS 2 speech processor requires three 675 zinc air batteries.

These batteries supply the external and internal components with energy.

If you want to get more information on batteries, please contact your local MED-EL representative or CI center.

The battery pack cover has two air holes on each side of the bottom end. Do not cover these holes as this may shorten battery life. If the holes are contaminated, remove the battery pack cover and carefully clean the holes with the enclosed cleaning brush.

IMPORTANT

Always remove used batteries immediately to avoid leaking and possibly damaging the device.

Dispose of used batteries according to local regulations. Generally, batteries are collected separately and not discarded with the household garbage.

To prevent children from swallowing or choking on batteries, always keep new and used batteries out of the reach of children. Children should be instructed not to swallow or put any components of their Cochlear Implant System into their mouths and not to play with any components. For young children, it is mandatory to use the safety lock to prevent them from disassembling the speech processor (see Chapter 5, OPUS 2 speech processor, Safety lock).

Changing the batteries of your OPUS 2 speech processor

When the red indicator light in the earhook blinks continuously (⎍⎍⎍), the battery set must be replaced (see also **Chapter 9, Troubleshooting**).

To change the batteries, proceed as follows

1. Remove the coil from your head and switch off the OPUS 2 speech processor before replacing the batteries.

2. Open the battery pack lock (a) and remove the battery pack cover (b).

3. Replace the used battery set (c) 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 outward, i.e. the "+" sign is still visible when the batteries are inserted.

5. Slide the cover over the battery pack frame (d) and close the battery pack lock.

Fig. 16 Changing the batteries of your speech processor

Changing the battery of your FineTuner

When your FineTuner generates an optical battery low warning signal (see also **Chapter 5, OPUS 2 speech processor, FineTuner, FineTuner functions**), it is recommended to replace the battery of your FineTuner.

To change the battery, proceed as follows

1. Open the lid on the back of the FineTuner with a small screwdriver.

2. Replace the used button battery (type CR2025) by removing it with the coil magnet or by gently shaking it into your hand. Try not to touch the battery contacts.

3. Insert the new battery with the "+" sign facing up.

4. Close the lid by carefully inserting it on the right side, then sliding it in place and tightening the screw.

Fig. 17 Changing the battery of your FineTuner

Changing the batteries of your
BabyBTE™/ActiveWear and Children's Battery Pack

When changing the batteries for the BabyBTE™/ActiveWear and Children's Battery Pack options, proceed as described for the OPUS 2 speech processor. The only difference will be how to remove and attach the battery pack cover:

1. To open the battery pack, push the lever at the back of the BabyBTE™/ActiveWear and hold it in this position (a). Use a pointed object to open the locking lever at the back of the Children's Battery Pack. Now push the lid on the battery pack backwards about 3 mm (b) and remove it by pushing it to the front (c).

2. To close the battery pack, put the lid on the housing so that it overhangs the back of the speech processor by about 3 mm (d). Gently push the lid onto the housing. When the lid is positioned correctly, it can be pushed forward (e), where it snaps in place easily. Never put the lid on the very back of the housing pushing it forward by force. This could damage the battery pack. Do not use excessive force when closing the battery pack.
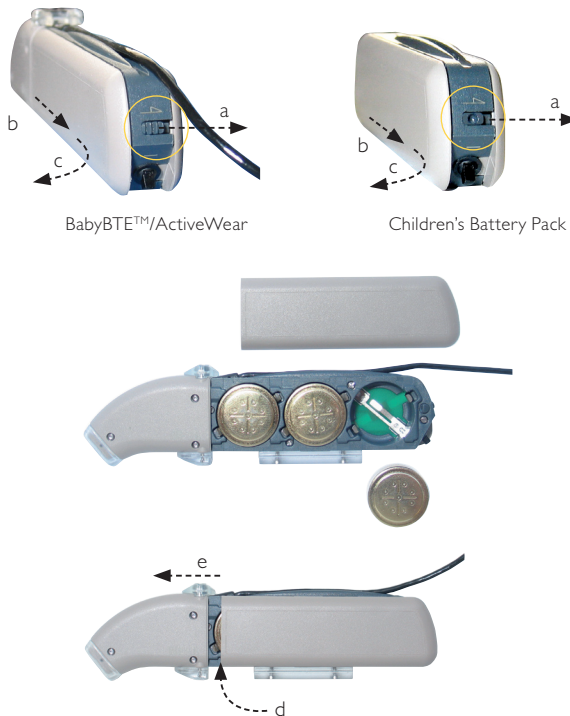

BabyBTE™/ActiveWear   Children's Battery Pack

Fig. 18 Changing the batteries of your BabyBTE™/ActiveWear and Children's Battery Pack

WEEKLY MAINTENANCE OF YOUR OPUS 2 SPEECH PROCESSOR

Thoroughly wipe the external parts of your OPUS 2 speech processor with a tissue and let them dry completely.

Drying your OPUS 2 speech processor

The speech processor system includes a drying kit (drying box) and 4 drying capsules.

Make sure that the drying box is completely dry. Remove a drying capsule from the blister pack to activate it, and place it in the drying box.

Remove the batteries from your OPUS 2 speech processor and, if possible, cover the removed batteries with the stickers they were originally packed with. Place your OPUS 2 speech processor in the drying box and close the box carefully.

The speech processor need not be completely disassembled.

We recommend that you dry your OPUS 2 speech processor once a day (preferably overnight), although how often you will need to dry your equipment depends on the humidity in your environment. Excessive perspiration or high humidity in the air will require frequent use of the drying kit.

After use, make sure to keep the activated drying capsule in the carefully closed box. This will prolong its use.

Do not swallow the capsules!

For further information, please read the user manual for the drying kit.

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.

Using cables or plugs not recommended or delivered by MED-EL may damage your Cochlear Implant System or cause uncomfortable stimulation and the warranty may void. If you have any questions or problems, please get in touch with your CI center or nearest MED-EL office.

Switching the speech processor on or off can cause a soft sound. You can remove the coil before operating the switch if this bothers you.

IMPORTANT

If this troubleshooting does not eliminate the problem and you do not hear sound with your Cochlear Implant System, please contact your clinic or CI center immediately.

SPEECH PROCESSOR TEST DEVICE

Red indicator light
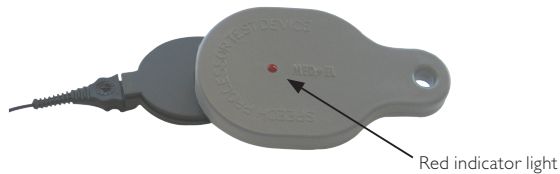
Fig. 19 Speech Processor Test Device

For your convenience you have been provided with a small grey Speech Processor Test Device.

The Speech Processor Test Device is a simple, optional troubleshooting tool for MED-EL speech processors intended to be used by cochlear implant users or other persons interacting with cochlear implant patients (parents, audiologists, teachers, etc.).

The Speech Processor Test Device is not necessary for the function of your speech processor, it is just intended to help detect most common functional speech processor problems like defective coil cables, defective speech processor microphones, weak batteries or other minor defects that might cause improper functioning of the speech processor.

If you suspect a malfunction of your speech processor, contact your CI center or MED-EL or try the following procedure:

Switch on the OPUS 2 speech processor and make sure that it is supplied with batteries. Place the coil underneath the Speech Processor Test Device (see *Fig. 19*). 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 red light does not light or is on constantly, try the following steps:

•   Adjust the volume setting. By using the appropriate loudness setting, you should be able to recognize the flickering of the LED in the rhythm of your voice.

•   Change the batteries.

•   Replace the existing cable with a substitute cable.

We recommend you try these steps independent of the use of your Speech Processor Test Device. If these measures are not successful, immediately contact your CI center or MED-EL. Do not try to open the speech processor or to disassemble the coil as this will cause damage to the device and immediately voids any warranty.

The Speech Processor Test Device should be handled with care to achieve maximum lifetime and ensure proper function. Do not expose your Speech Processor Test Device to conditions other than those suitable for your OPUS 2 speech processor (see also *Chapter 7, General precautions and warnings*).

FINETUNER

The FineTuner transmits commands to the OPUS 2 speech processor via a radio frequency (RF) link. If the **OPUS 2 does not respond to FineTuner commands**, the below describes potential reasons for this occurring and provides information to assist you in solving the problem:

•   The OPUS 2 is out of the FineTuner's operating distance. To overcome this you should move the FineTuner closer to the OPUS 2.

•   The FineTuner keyboard lock is active. In this case follow the instructions for the unlocking function as described in *Chapter 5, OPUS 2 speech processor, FineTuner, FineTuner functions*.

•   Interference from other electronic or electrical equipment is present that blocks the transmission. To eliminate this interference you need to move the FineTuner closer to the OPUS 2 and/or go to a different location.

•   The OPUS 2 and the FineTuner are not synchronized. In this case you need to refer to the section described in *Chapter 5, OPUS 2 speech processor, FineTuner, How to configure your FineTuner*.

•   In the case of a suspected malfunction of the FineTuner you need to remove the battery and re-insert it after a few minutes as described in *Chapter 8, Care and maintenance, Batteries, Changing the battery of your FineTuner*.

- The FineTuner battery is low. In this case you need to replace the battery as described in *Chapter 8, Care and maintenance, Batteries, Changing the battery of your FineTuner*.

- The desired command in the OPUS 2 has been disabled by your audiologist during fitting. To enable this command you will need to contact your clinic, CI center or MED-EL.

- The red indicator light in the OPUS 2 has been disabled by your audiologist during fitting. To enable the red indicator light you will need to contact your clinic, CI center or MED-EL.
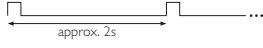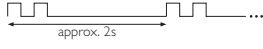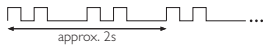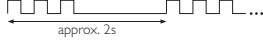
Additional troubleshooting information:

- If you or your child have used the T (telecoil) or MT (microphone and telecoil) settings and are unable to return to the M (microphone) signal source input with the FineTuner, you need to switch the speech processor off and on. When the speech processor is switched on again it will automatically start with the M (microphone) setting activated.

- If you or your child have lost the FineTuner please contact your clinic, CI center or MED-EL immediately and ask for a replacement.

OPUS 2 RED INDICATOR LIGHT

The red indicator light on the front of the speech processor flashes with different patterns to indicate different conditions. If the indicator light begins flashing, use the following tables to determine the cause.

Your audiologist can deactivate the blinking signals permanently (except error and program change patterns) if you prefer this.

Error patterns

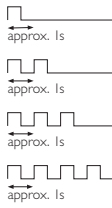| Blinking pattern	Meaning	Action to take	Remarks
approx. 2s	Electronic problem or temporary processor disturbance	Switch processor off. Switch processor back on.	If the blinking persists, the speech processor must be replaced.
approx. 2s	Selected position is not programmed, or there has been a program failure	Select another position.	If the blinking persists, the processor should be reprogrammed by the clinic.
approx. 2s	Electronic problem or program failure	Switch processor off. Switch processor back on.	If the blinking persists, the processor must be reprogrammed.
approx. 2s	Electronic problem or temporary processor disturbance	Switch processor off. Switch processor back on.	

Warning patterns

Blinking pattern	Meaning	Action to take	Remarks
approx. 1s	Batteries empty	Switch processor off. Change the batteries. Switch processor back on.	If the processor is not switched off, the red indicator light will continue to blink.
	Maximum or minimum value of volume or audio sensitivity range reached	Stop pushing button(s) on FineTuner.	
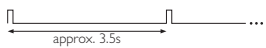
Confirmation pattern

Blinking pattern	Meaning	Action to take	Remarks
Brief flash of red indicator light	FineTuner command received and accepted	None	IMPORTANT: Pressing the Default button ⟳ on your FineTuner only affects volume and audio sensitivity. The program position does not change.

Program change pattern

Blinking pattern	Meaning	Action to take	Remarks
approx. 1s approx. 1s approx. 1s approx. 1s	Program 1 to 4 selected	None	The red indicator light will blink depending on the selected program position. IMPORTANT: These blinking patterns start like the battery empty pattern.

Status pattern

Blinking pattern	Meaning	Action to take	Remarks
approx. 3.5s	The processor is intialized and working	None	A clicking sound may be perceived with active telecoil whenever the indicator light blinks.

PRIVATE ALERT

The private alert feature allows adding an acoustic warning signal to the audio signal. This added signal is audible only to the user of the speech processor and can be adjusted in 8 loudness steps. Your audiologist will set the loudness accordingly.

Battery low warning signal
If the battery voltage falls below a certain level, four short warning beeps will be generated approximately every 14 seconds. You are still able to hear, but should change the batteries of the OPUS 2 speech processor as soon as possible.

End of range reached warning signal
If a maximum or minimum value of volume or audio sensitivity has been reached, a continuous beeping signal is audible for the user as long as the key of the FineTuner is pressed.

Confirmation signal
If a command from the FineTuner has been executed successfully by the OPUS 2 speech processor, a confirmation beep is audible for the user of the speech processor.

The two warning signals and the confirmation signal may be deactivated permanently by your audiologist if your prefer this.

FINETUNER INDICATOR FUNCTIONS

Three indicator lights with different colors (left and right: amber; center: red [warnings]) indicate various conditions of the FineTuner.

Keyboard locked
If you press a key while the keyboard is locked, the red indicator light comes on. For power saving reasons the red indicator light goes off after 5 seconds even if the key is still pressed.

Transmitting
If a key is accepted and the FineTuner transmits commands to the speech processor, the left or right or both indicator lights (depending on the current side mode of the FineTuner) blink synchronously to the transmitted signals. To save energy, the FineTuner stops transmitting (and the indicator light blinking) after 3 seconds even if the key is still pressed.

Switch to side
If the FineTuner is programmed for two different speech processors (i.e. in case of bilateral users), the left indicator light illuminates when pressing ◀, the right indicator light illuminates when pressing ▶ and both indicator lights illuminate when pressing ◀▶. To save energy, any indicator light goes off after 5 seconds even if the key is still pressed (if ◀▶ is pressed for more than 5 seconds, the FineTuner enters the program mode, see below).

Low battery
The FineTuner checks the battery status after each transmission to the speech processor. If a low battery status is detected, the red indicator light (center) blinks in a regular pattern (⌐_⌐_⌐ - red indicator light on your FineTuner goes on 3 times).

Configuration successful
If configuration of your FineTuner (see **Chapter 5, OPUS 2 speech processor, FineTuner, How to configure your FineTuner**) was successful, or if the automatic keyboard lock feature was successfully activated/deactivated, both amber indicator lights will illuminate for approximately one second.

Program mode
If ◀▶ is pressed for more than 5 seconds (must be unlocked; see **Chapter 5, OPUS 2 speech processor, FineTuner, FineTuner functions** for locking/unlocking instructions), the FineTuner enters the program mode. The three indicator lights start flashing. When the red indicator light is on, the two amber indicator lights are off and vice versa. Flashing stops and the program mode is left after 5 seconds or earlier when a correct key is pressed.

10. TECHNICAL DATA

SPEECH PROCESSOR

Dimensions of OPUS 2 speech processor (mm)[1]

35.1 mm
(1.382 in.)

7.0 mm (0.276 in.)

54.0 mm
(2.126 in.)

15.7 mm
(0.618 in)

8.7 mm (0.343 in.)
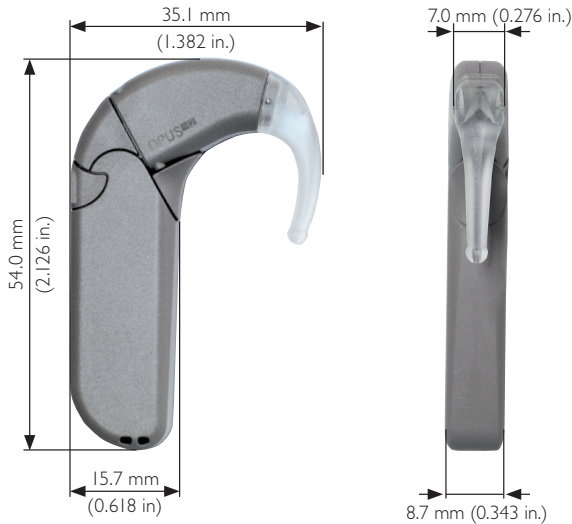
Weight [1]
12.4 g (0.437 oz)   (including batteries)

[1] typical values

Power supply
3 hearing aid batteries type 675 zinc air (1.4 V)

Hardware
- Fully digital signal processing
- Various parameters programmable
- 4 programs selectable
- Up to 12 band pass filters; filter characteristics programmable
- Non-linear amplification programmable
- Frequency range: up to 10,000 Hz
- Speech processor self test: checksum on programs, continuous parity check
- Automatic Gain Control (AGC) configurable
- FineTuner commands can selectively be disabled

Audio Input
- Via FM Battery Pack Cover
- Hearing aid type three pin connection (Euro-Audio) acc. to IEC 60118-12
- Sensitivity   -61.4 dBV[1] (corresponds to 70 dB SPL at 1 kHz)
- Impedance   2.9 kΩ[1]

[1] typical values

Controls/Indicators
- ON/OFF switch
- Indicator light: 1 red LED for alarm and indicator functions

Materials
- Mixture of polycarbonate and acrylonitrile-butadiene-styrol polymer (PCABS): speech processor, battery packs, all colors
- Polyamide (PA): earhook, microphone cover

Temperature and humidity range

Operating temperature range	10°C (50°F) to 45°C (113°F)
Storage temperature range	-20°C (-4°F) to 60°C (140°F)
Relative humidity range	10 % to 90 % (at or above 31°C/ 88°F)
	10 % to 93 % (below 31°C/88°F)

Radio frequency (RF) link (FineTuner)

Frequency band of reception	9.07 kHz (±3%)

FINETUNER

Dimensions [1]

Length	85.5 mm	(3.336 in.)
Width	54 mm	(2.126 in.)
Height	6.3 mm	(0.248 in.)
Weight	33 g	(1.164 oz) (incl. battery)

[1] typical values

Controls / Indicators

- Default key
- Volume keys
- Sensitivity keys
- Program selection keys
- Input selection keys
- Processor selection keys
- Indicator lights: 1 red LED for alarm and 2 amber LEDs for indicator functions

Power supply

- One lithium/manganese dioxide battery type CR2025 (3 V)
- Typically, battery life is expected to be more than 6 months.

Classification

- 47 CFR Part 15 Low Power Transmitter below 1705 kHz – US
- Short Range Device (SRD) according to ERC/REC 70-03 Annex 9 (band aa) and Annex 12 (band b) – EU
- Equipment class 3 – EU

Materials

Mixture of polycarbonate and acrylonitrile-butadiene-styrol polymer (PCABS)

Temperature and humidity range

Operating temperature range	10°C (50°F) to 45°C (113°F)
Storage temperature range	-20°C (-4°F) to 60°C (140°F)
Relative humidity range	10 % to 90 % (at or above 31°C/ 88°F)
	10 % to 93 % (below 31°C/88°F)

Radio frequency (RF) link

Carrier frequency	9.07 kHz (±0.7%)
Type of modulation	phase shift keying (PSK)
Maximum RF output power	11.7 dBμA/m @ 10 m
Maximum operating distance	~ 1.15 m (3.77 ft.)

Applicable in Canada only:

This Category II radiocommunication device complies with Industry Canada Standard RSS-310.

Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Ce dispositif de radiocommunication de catégorie II respecte la norme CNR-310 d'Industrie Canada.

L'utilisation de ce dispositif est autorisée seulement aux deux conditions suivantes : (1) il ne doit pas produire de brouillage, et (2) l'utilisateur du dispositif doit être prêt à accepter tout brouillage radioélectrique reçu, même si ce brouillage est susceptible de compromettre le fonctionnement du dispositif.

Applicable in the USA only:

This device complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Warning: Changes or modifications made to this equipment not expressly approved by MED-EL may void the FCC authorization to operate this equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
• Reorient or relocate the receiving antenna.
• Increase the separation between the equipment and receiver.
• Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
• Consult the dealer or an experienced radio/TV technician for help.

SPEECH PROCESSOR TEST DEVICE

The Speech Processor Test Device is in compliance with EU Directive 89/336/EEC (Electromagnetic Compatibility/EMC).

CE mark applied in 2005

SYMBOLS

CE 0123 — The OPUS 2 speech processor and the FineTuner are in compliance with EU Directive 90/385/EEC (Active Implantable Medical Devices/AIMD).

CE mark applied in 2006

The OPUS 2 speech processor and the FineTuner (RF link) comprise "Class 2" radio equipment under the R&TTE directive.

Hereby MED-EL declares that the OPUS 2 speech processor and the FineTuner (RF link) are in compliance with the essential requirements and other relevant provisions of EU Directive 1999/5/EC (Radio Equipment and Telecommunications Terminal Equipment/R&TTE). The Declaration of Conformity can be obtained directly from MED-EL Worldwide Headquarters (for address see *Chapter 11, Appendices*).

Caution, consult accompanying documents (manual)

Type BF
(IEC 60601-1 / EN 60601-1)

Non-ionizing radiation (FineTuner)

Applicable in Bulgaria only:
The OPUS 2 speech processor and the FineTuner (RF link) are in accordance with the Ordinance for essential requirements and conformity assessment of radio equipment and telecommunications terminal equipment.

Fragile; handle with care

Relative humidity; moisture content

Temperature limit

The OPUS 2 speech processor, the FineTuner and the Speech Processor Test Device are in compliance with EU Directive 2002/96/EC (Waste Electrical and Electronic Equipment/WEEE).

The WEEE logo (⌧) on the product or in this user manual indicates that this product must not be disposed of or dumped with your other household waste. *You are liable to dispose of all external components of your MED-EL Cochlear Implant System by returning them to your local MED-EL subsidiary or distributor.* Isolated collection and proper recovery of your electronic and electrical waste equipment at the time of disposal will allow us to help conserving natural resources. Moreover, proper recycling of the electronic and electrical waste equipment will ensure safety of human health and environment.

Applicable in Europe only:
The OPUS 2 speech processor and the FineTuner (RF link) may be operated in:

AT	BA	BE	BG	CH	CY
CZ	DE	DK	EE	ES	FI
FR	GB	GR	HR	HU	IE
IS	IT	LI	LT	LU	LV
MK	MT	NL	NO	PL	PT
RO	SE	SI	SK	TR	YU

GUIDANCE AND MANUFACTURER'S DECLARATION

Tables according to IEC 60601-1-2 for OPUS 2

Table 201 – Guidance and manufacturer's declaration
Electromagnetic emissions for all equipment and systems

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

Table 202 – Guidance and manufacturer's declaration

Electromagnetic immunity – for all equipment and systems

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

Table 204 – Guidance and manufacturer's declaration

Electromagnetic immunity – for equipment and systems that are not life-supporting

Guidance and manufacturer's declaration – electromagnetic immunity			
The OPUS 2 is intended for use in the electromagnetic environment specified below. The customer or the user of the OPUS 2 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the OPUS 2, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.17 * \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.17 * \sqrt{P}$ 80 MHz to 800 MHz $d = 2.33 * \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the OPUS 2 is used exceeds the applicable RF compliance level above, the OPUS 2 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the OPUS 2.			
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 206 – Guidance and manufacturer's declaration

Recommended separation distances between portable and mobile RF communications equipment and the OPUS 2 – for equipment and systems that are not life-supporting

Recommended separation distances between portable and mobile RF communications equipment and the OPUS 2		
The OPUS 2 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the OPUS 2 can help prevent electromagnetic interference (resulting in the perception of a "buzzing sound") by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the OPUS 2 as recommended below according to the maximum output power of the communications equipment.		

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.17 * \sqrt{P}$	80 MHz to 800 MHz $d = 1.17 * \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33 * \sqrt{P}$
0.01	0.12 (0.39 ft.)	0.12 (0.39 ft.)	0.23 (0.75 ft.)
0.1	0.37 (1.21 ft.)	0.37 (1.21 ft.)	0.74 (2.43 ft.)
1	1.17 (3.84 ft.)	1.17 (3.84 ft.)	2.33 (7.64 ft.)
10	3.70 (12.14 ft.)	3.70 (12.14 ft.)	7.39 (24.25 ft.)
100	11.70 (38.39 ft.)	11.70 (38.39 ft.)	23.30 (76.44 ft.)

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

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

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

II.   APPENDICES

WARRANTY, GUARANTEE AND REGISTRATION CARD

Our warranty is in agreement with statutory warranty claims.

MED-EL grants a three-year guarantee for the OPUS 2 speech processor system.

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 is completed and returned to MED-EL within 30 days of the initial fitting for newly purchased systems. The warranty period for the OPUS 2 speech processor system begins with the date of first speech 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 within 30 days.

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 (CI patient card), and return them to MED-EL via registered mail.

MANUFACTURER ADDRESS

MED-EL Worldwide Headquarters
MED-EL Elektromedizinische 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 distributor in the U.S.:
MED-EL Corporation
2511 Old Cornwallis Road, Suite 100
Durham, NC 27713, USA
Tel: (919)-572-2222
Fax: (919)-484-9229
Tollfree: (888) MED-EL-CI (633-3524)
E-Mail: implants@medelus.com

Contacting MED-EL

MED-EL Worldwide Headquarters

Fürstenweg 77a, A-6020 Innsbruck, Austria
Tel.: +43-512-28 88 89, Fax: +43-512-29 33 81
office@medel.com

MED-EL GmbH Niederlassung Wien
Währinger Str. 3/1/9
1090 Wien, Austria
Tel.:   +43-1-317-2400
Fax: +43-1-317-2400-14
office@at.medel.com

MED-EL Deutschland GmbH
Moosstr. 7 / 2. OG
82319 Starnberg, Germany
Tel.:   +49-8151-77 03-0
Fax: +49-8151-77 03-23
office@medel.de

MED-EL Deutschland GmbH Büro Berlin
Schloßstr. 57
14059 Berlin, Germany
Tel.:   +49-30-383779-50
Fax: +49-30-383779-55
office-berlin@medel.de

MED-EL Unità Locale Italiana
Via Maso della Pieve 60/A
39100 Bolzano (BZ), Italy
Tel.:   +39-0471-250131
Fax: +39-0471-234200
ufficio.italia@medel.com

MED-EL GmbH Sucursal España
Centro Empresarial Euronova
Ronda de Pontiente num.2, 2°A Tres Cantos
28760 Madrid, Spain
Tel.:   +34-91 80 41 527
Fax: +34-91 80 44 348
office@es.medel.com

MED-EL GmbH Sucursal em Portugal
Av. Sá da Bandeira, 77 – 1° Dt° Fte.
3000 – 351 Coimbra, Portugal
Tel.:   +351-239-098-804
office@pt.medel.com

MED-EL UK Ltd
Great Cliffe Court, Dodworth
Barnsley, S75 3SP, UK
Tel.:   +44-12 26-24 28 74
Fax: +44-12 26-77 10 56
office@medel.co.uk

MED-EL Corporation (North America)
2511 Old Cornwallis Road, Suite 100
Durham, NC 27713, USA
Tel.:   +1-919-572-2222
Fax: +1-919-484-9229
Toll Free: (888) MED-EL-CI (633-3524)
implants@medelus.com

MED-EL Latino America S.R.L.
Viamonte 2146 P 9
(C1056ABH) Capital Federal, Argentina
Tel.:   +54-11-4954-0404
Fax: +54-11-4954-0404
medel@medel.com.ar

MED-EL Middle East FZE
Dubai Airport Free Zone
P.O. Box 54320, 54321
Dubai, United Arab Emirates
Tel.:   +9714-299 4700
Fax: +9714-299 4255
medeluae@emirates.net.ae

MED-EL India Private Ltd
#505 Pragati House
47-48 Nehru Place
New Delhi, 110019 India
Tel.:   +91-11-4160 7171
Fax: +91-11-4164 2800
implants@medel.in

MED-EL China Office
2110 Unit, Tower A, SOHO New Town,
NO.88, Jian Guo Road, Chao Yang District,
Beijing, China 100022
Tel.:   +86-10-85893527/28/29
Fax: +86-10-85893530
office@medel.net.cn

MED-EL Singapore Regional Service Office
41 Science Park Road
The Gemini, Lobby B #04-03A
Singapore Science Park II
Singapore 117610
Tel.:   +65-677888 14
Fax: +65-677888 12
office@sg.medel.com

MED-EL Philippines
Regional Headquarters
1501 Richville Corporate Tower
Industry Road, Madrigal Business Park
Ayala Alabang, Muntinlupa City
RP-1702 Philippines
Tel.:   +632-807-8780
Fax: +632-807-4163
office@ph.medel.com

MED-EL Hong Kong Office
Room 703, Austin Tower
22-26 Austin Avenue, T.S.T Kowloon
Tel.:   +852-2730 5818
Fax: +852-2730 5009
kenneth.leung@medel.com

MED-EL Japan Co., Ltd
7F TIK Bldg., 3-2-3 Hongo, Bunkyo-ku
Tokyo, 113-0033 Japan
Tel.:   +81-3-5842-8580
Fax: +81-3-5842-8582
info@medel.co.jp

VIBRANT MED-EL
Hearing Technology France
Village d'Entreprise Green Side
400 av Roumanille - BP 309
06906 Sophia-Antipolis Cedex, France
Tel.:   +33-4-9300-1124
Fax: +33-4-9300-1125
office@fr.medel.com

CE 0123

www.medel.com