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**

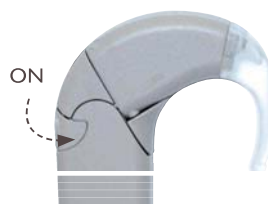
Fig. 3 The OPUS 2 speech processor in position OFF

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).

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.
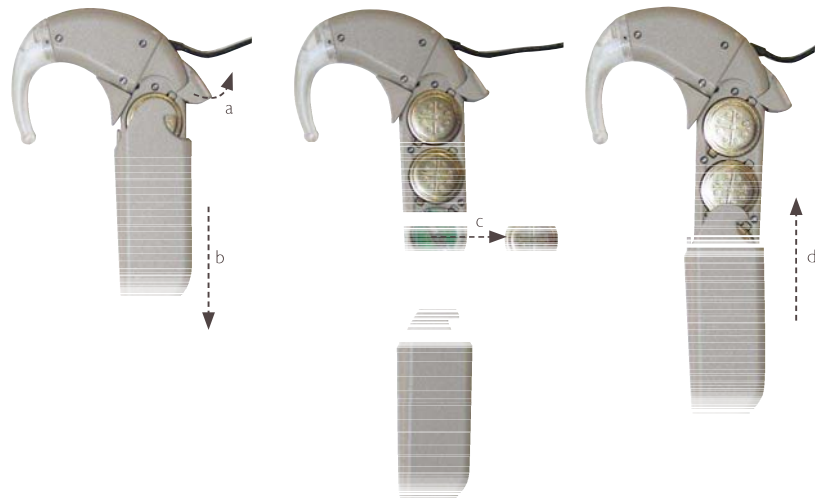
Fig. 16 Changing the batteries of your speech processor

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

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]
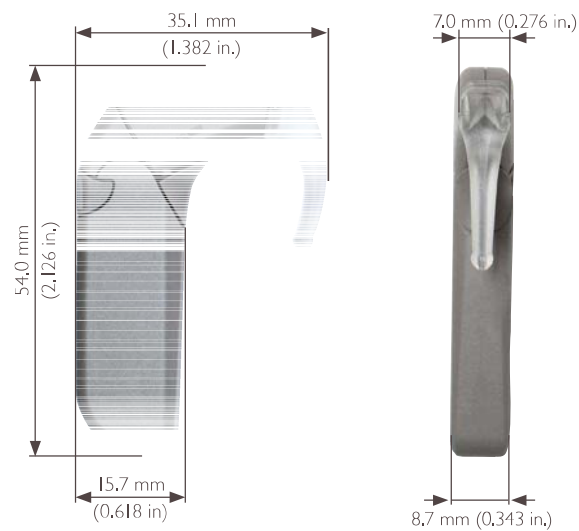
Weight [1]

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

- Short Range Device (SRD) according to ERC/REC 70-03 Annex 9 (band aa) and Annex 12 (band b)
- Equipment class 3

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

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

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

CE mark applied in 2005

SYMBOLS

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 obtainted 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

II.   APPENDICES

WARRANTY, GUARANTEE AND REGISTRATION CARD

Our warranty is in agreement with statutory warranty claims.

MED-EL grant 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 RoadSuite 100
Durham, NC 27713, USA
Tel: +1-919-572-22 22
Toll free: +1-888-633-3524
Fax: +1-919-484-92 29
Email: office@us.medel.com