

Neuro 2 Instructions for Use



Neuro – The Cochlear Implant System

CE 0459 (2018)

 NEURELEC

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MEDICAL

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Introduction

Congratulations on your new Neuro 2 sound processor from Oticon Medical. This manual is intended to the patient, the caregiver and the audiologist by providing important information and instructions on how to use the Neuro 2 sound processor.

- Patient : person implanted with a cochlear implant, non-healthcare professional, without relevant specialized training
- Caregiver: adolescent or adult with a minimum of 8 years of education, non-healthcare professional, without relevant specialized training
- Audiologist: healthcare professional with at least 3 years of studies in audiology, with specialized training in the usage of the device

The patient is an intended operator of the sound processor. Unless otherwise specified, every function related to the set-up, operation and maintenance of the sound processor described in the following can safely be performed by the operator.

Persons needing assistance (e.g: young patients) are expected to be assisted by a caregiver. Information that requires specific attention from the caregiver, or that is intended for the caregiver only, is indicated as such.

If you require assistance in setting up, using or maintaining Neuro 2 sound processor please contact your local Oticon Medical customer service or Oticon Medical distributor.



“Note”: indicating a note/tip



“Caution”: potential hazard that could result in patient/user temporary injury or hospitalization if not avoided.



“Warning”: potential hazard that could result in patient/user serious injury or death if not avoided.

Intended use

The Neuro 2 sound processor is the external part of the Neuro cochlear implant system, and is indicated for patients with Neuro Zti cochlear implant(s).

The Neuro Cochlear Implant System is intended to provide the opportunity to detect and recognize auditory information through electrical stimulation of the auditory nerve, for individuals with bilateral severe-to-profound sensorineural hearing loss, and adults with unilateral severe-to-profound sensorineural hearing loss, and who obtain limited benefit from appropriately fitted hearing aid(s).

Indications

The Neuro cochlear implant system is designed for children or adults who have severe to profound bilateral perceptive hearing loss or adults who have severe to profound unilateral perceptive hearing loss, and who gain limited benefit from appropriately fitted hearing aids, and have aided word recognition scores of less than 50% at 60 dB.

Contraindications

There is no contraindication to the use of the Neuro 2 sound processor and accessories. Contraindications stated for the Neuro Cochlear Implant System are applicable.

Undesirable Side effect

There is no known side effect related to the use of the Neuro 2 sound processor and accessories.





Intended User profile

The device is operated by the patient, the caregiver and the audiologist.

- Patient: person implanted with a cochlear implant, non-healthcare professional, without relevant specialized training
- Caregiver: adolescent or adult with a minimum of 8 years of education, nonhealthcare professional, without relevant specialized training
- Audiologist: healthcare professional with at least 3 years of studies in audiology, with specialized training in the use of the device

Compatibility

The Neuro 2 is compatible with the Neuro Zti implant and all accessories specified in this manual.

Neuro 2 model	Compatible with implants	Marking on the sound processor	Marking on the antenna
 <p>Neuro 2 (Zti)</p>	 <p>Neuro Zti</p>	 <p>Zti</p>	 <p>Zti – Neuro 2</p>



Note: The type and serial number of your Neuro 2 sound processor are indicated on the piece of the sound processor that serves as connector to the battery modules. To see this information, you need to detach the battery. The serial number has eight digits. It is recommended that you write it down for safekeeping, as you may need it in the future.



Warning: Do not use the sound processor with any other implant than the compatible one.



Warning: Do not use or connect accessories and cables other than those specified as part of the product or have been compatible with the product as this will be unsafe.

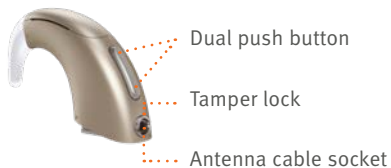
Overview of Neuro 2 sound processor

Neuro 2 main parts



Note: All parts indicated above are applied parts.

Neuro 2 detailed parts



Sound processor markings



Battery options:

Small rechargeable Li-Ion battery



Large rechargeable Li-Ion battery



Zinc Air battery cartridge



How Neuro 2 works

The cochlear implant system consists of an external part and an implanted (internal) part.

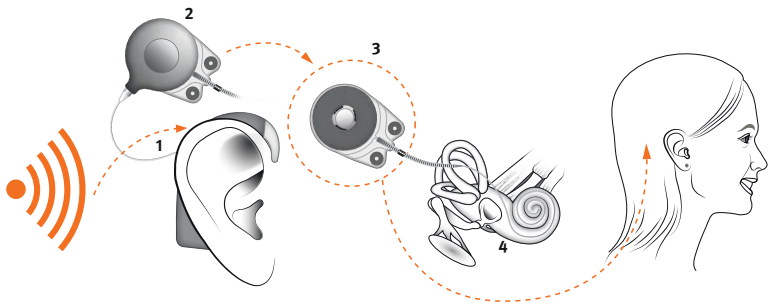
External part

The Neuro 2 hearing device consists of a sound processor (1) placed behind the ear connected to an antenna (2) that is placed over the implanted part (3).

The sound processor (1) acquires sound from the environment, digitally processes it and sends wirelessly from the antenna through the skin to the implanted part.












Implanted part

The implant is a small casing (3) placed under the skin. It contains an electronic stimulator, which distributes the sound to the electrodes placed in the cochlea (4).



Note: Please keep the cochlear implant patient card provided by your implant centre in a safe place as you may need to show it at medical examinations and treatments.

Packaging content

 <p>Neuro 2 (Zti) sound processor mounted with a Zinc Air battery cartridge and a hook</p>	 <p>Neuro 2 Antenna (Zti)</p>	 <p>Neuro 2 Hook</p>	 <p>Neuro 2 Antenna cable</p>
 <p>Protective case</p>	<p>Neuro 2 Care Kit containing: Pin tool, Carrying pouch, Cleaning cloth, Hook pins</p>	 <p>Desiccation drying system</p>	 <p>Blisters 6 Zinc Air batteries</p>
 <p>Neuro 2 Magnet</p>	<p>← Optional content →</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div data-bbox="478 547 692 626">  <p>Neuro 2 Rechargeable battery</p> </div> <div data-bbox="785 557 963 613">  <p>Neuro 2 Charger</p> </div> <div data-bbox="1063 551 1292 644">  <p>Power supply</p> </div> </div>		
 <p>USB memory stick</p>	 <p>Neuro 2 Tamper tool</p>	<p>Documentation Neuro 2 Instructions for Use Neuro 2 Product registration Neuro 2 Warranty Certificate/Extension Return envelope</p>	

Pictures are not contractually binding. Quantities can vary according to markets and local regulations.

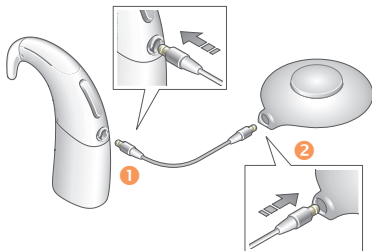


Note: All parts indicated above are applied parts.

Preparing Neuro 2 for use

Connecting and changing the antenna and the antenna cable

- Connect the antenna cable to the sound processor by simply pushing it in (1).
- Connect the other end of the antenna cable to the antenna (2). Push the antenna cable plug firmly into the antenna socket. A firm push is needed as the antenna socket is designed to be tamper proof.
- To disconnect the antenna from the antenna cable or to disconnect the antenna cable from the sound processor (the antenna may remain connected), wind the antenna cable around a finger and pull it out. **Do NOT pinch the cable with your nails as it may damage the cable.**





Note: During normal use, we recommend that you store your sound processor with the antenna cable connected to the antenna in the protective case.

Several antenna colours are available. Check availability in the order form and contact your local Oticon Medical customer service or Oticon Medical distributor.

Marking on the antenna:



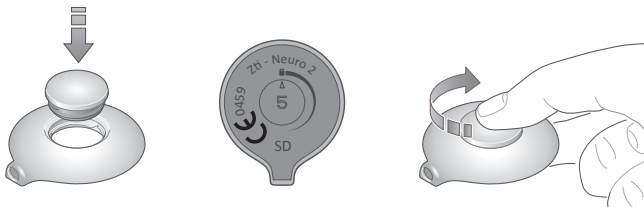
Placing and changing the magnet in the antenna

The antenna is maintained in contact with the implant using a magnet.

The strength of the magnet (indicated at the bottom of the magnet) determines how firmly the antenna is held in place over the implant.

To change the magnet, follow the below instructions:

- Hold the antenna by grasping the magnet cap by its top and bottom. The triangle symbol of the magnet should be aligned with the lock symbol marked on the antenna.
- Screw the magnet by turning it clockwise.
- Unscrew the magnet by turning it counter clockwise.



Note: In the middle of the magnet, the strength is mentioned. Several strengths are available, please check the Oticon Medical order form for availability and ordering.

You can adjust the distance between the skin and the magnet at any time by screwing or unscrewing the magnet. The magnet should never be unscrewed more than half a turn (triangle symbol at the bottom, opposite to the lock symbol).

If the antenna does not stay on the skin properly, a higher magnet force is recommended. If all the supplied magnets are too weak, contact your implant centre for advice on the suitable force. Several strengths and colours are available. Check availability on the order form and contact your local Oticon Medical customer service or Oticon Medical distributor.



Warning: Check and monitor on a regular basis the head skin over the implant site for signs of skin redness or irritation, blistering, or skin breakdown. In case of blistering or skin breakdown, stop using the sound processor until the wound site is assessed by a clinician. In case of skin redness or irritation, unscrew the magnet or change the magnet to a lower force. If problem persists, stop using the sound processor until the wound site is assessed by a clinician.

Connecting and changing the battery module

Two types of battery modules can be connected to the Neuro 2 sound processor:

- Rechargeable Li-Ion battery modules
- Zinc Air battery cartridge



Note: The type of battery is indicated on the module (120mAh for the small rechargeable battery or 200mAh for the large rechargeable battery). You also can find the serial number of the battery and the type of your device (Neuro 2).

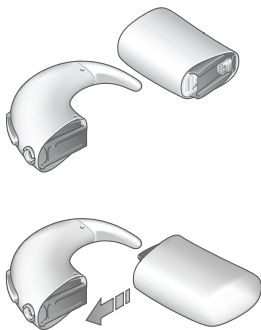
If needed, refer to the "Locking and unlocking the battery module" section to deactivate the tamper-proof system.

- Slide the depleted battery module off
- Slide the charged battery module on

If needed, refer to the "Locking and unlocking the battery module" section to reactivate.

When to replace the battery

The Neuro 2 sound processor will notify you when the battery is running low on power.



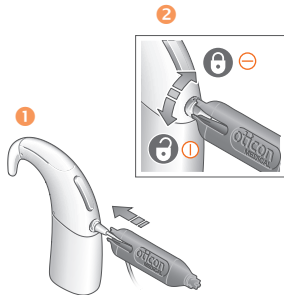
To make sure the Neuro 2 is always working, use fully charged rechargeable batteries or new disposable Zinc Air batteries. We also recommend you carry spare batteries with you.

Locking and unlocking the battery module

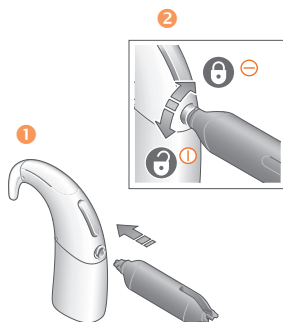
This section is intended for the caregiver of infants and young children.

The sound processor is equipped with a tamper-proof system, which secures the connection between the sound processor and the battery module or the battery cartridge to avoid any hazardous disconnection. Using this security system may be enabled or disabled at any time using the tamper tool device. It does not replace adult supervision.

- To activate the tamper-proof system keeping the antenna cable connected: Place the open side of the tamper tool on the lock ring (1) situated around the antenna socket and turn clockwise (2).
- To deactivate the tamper-proof system keeping the antenna cable connected: Place the open side of the tamper tool on the lock ring (1) situated around the antenna socket and turn the lock ring counter clockwise (2) using the tamper tool to deactivate.



- To activate the tamper-proof system without the antenna cable connected: Place the screwdriver end of the tamper tool on the lock ring (1) situated around the antenna cable socket and turn the lock ring clockwise (2).
- To deactivate the tamper-proof system, turn the lock ring counter clockwise (2).



User instructions for using Zinc Air battery

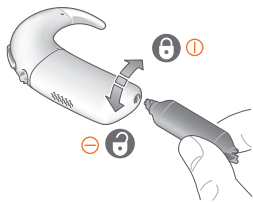
You can choose to use them as a primary power source for Neuro 2 or as a backup for the rechargeable batteries when they run out of power.



Important: Only use "675" (European designation) or "PR44" (international designation) Zinc Air batteries recommended by your implant centre or Oticon Medical. Using another type of battery can affect the functioning of Neuro 2 and cause reduced battery life or sound processor power supply problems. Your local Oticon Medical customer service or Oticon Medical distributor can help you get hold of new batteries if needed.

Locking and unlocking the Zinc Air battery cartridge

This section is intended for the caregiver of infants and young children. Locking the Zinc Air battery cartridge protects access to the battery cells. The Zinc Air battery cartridge is equipped with a tamper-proof system, which prevents infants and young children accessing and accidentally swallowing the Zinc Air batteries, and keeps the battery cartridge closed while wearing or if the sound processor is dropped. This security system may be activated or deactivated at any time using the tamper tool. Please note that this does not replace adult supervision.

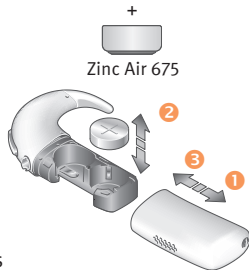


Warning: In case of swallowing, you must contact the nearest medical center.

- To activate the tamper-proof system: Make sure that the battery cartridge is correctly connected to the sound processor and that battery cells are inserted. With the help of the screwdriver end of the tamper tool, turn the screw situated at the bottom of the battery cartridge clockwise to its locked position.
- To deactivate the tamper-proof system: Turn the screw counter clockwise to its unlocked position with the tamper tool. You can now freely open and close the battery cartridge.


Inserting/changing Zinc Air batteries


- If locked, unlock the battery module.
- Pull the sleeve off (1).
- Remove the used batteries and place two new batteries (2) (remove the protective film) in the compartment observing the polarity indicated on the compartment ("+" side facing up).
- Slide the sleeve on (3).
- If needed, lock the battery module.



The sound processor will automatically switch on when new batteries are in place.

When not in use it is recommended that you keep the batteries in a cool and dry place away from direct sunlight and heat and observe the expiry date indicated on the packaging. Make sure you insert batteries of the same type and change both at the same time.

 **Warning:** Change the two batteries when they are running out, as discharged batteries could leak corrosive liquid that may damage the sound processor. Regularly clean the battery compartment to prevent the deposit of any substance, to ensure a proper ventilation through the holes.

 **Warning:** Remove Zinc Air batteries from the battery cartridge when they run out and when your sound processor is not being used for a prolonged period of time.

The Zinc Air batteries cannot be recharged and are for single-use. They must not be thrown away but should be returned to a collection point (point of sale, waste disposal site, etc.) or in the containers provided for this purpose. Refer to local rules.

User instructions for connecting rechargeable Li-Ion battery



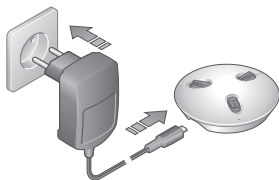
Warning: Do not try to dismantle, damage or open a Li-Ion battery. When the battery is not connected to the sound processor, there is a risk that it can be swallowed. In case of swallowing, you must contact the nearest medical center. Fitting and using should be done under the supervision of a caregiver. The Neuro 2 Li-Ion batteries should only be recharged with the Oticon Medical charger connected to the compatible power adaptor. Do not short-circuit. Do not carry or store the battery with metal objects (such as wire, chain necklace or hairpins). If the battery is short-circuited, excessive large current can flow and may cause a defective battery by deep discharge. Dispose of the battery according to local and environmental rules. Never burn or heat the battery (>65°C). Never touch a leaking battery. In case of chemical leakage in contact with the skin, you must contact the nearest medical center. Never nail anything into the battery, hit it with a hammer, or tread on it. Do not place the batteries in microwave ovens, high-pressure containers or on induction cookware. Immediately stop using the battery if, while using, charging, or storing the battery, the battery emits an unusual smell, feels hot or moist, changes colour, changes shape, or appears abnormal in any other way. Remove the battery module if it is not likely to be used for some time.

Charging a rechargeable battery








Important: Before using a rechargeable battery for the first time make sure it is fully charged. Failure to do this may degrade the battery capacity and performance.

- Assemble the charger by connecting the power supply cable to the charger. Then plug the power supply cable to a domestic wall power socket.
- Place the rechargeable battery on the charger by sliding it onto one of the battery charger slots.



The charger is equipped with indicator lights:

	Short green light: once power supply is connected
	Short repeated green light: battery is charging
	Continuous green light: battery is fully charged
	Short repeated red lights: ambient temperature is too high or too low. Try to use the charger in a temperature range of 10°C to 45°C.
	Continuous orange light: the battery is not charging. Disconnect the battery from the charger and connect it again. If the problem persists, the battery is defective and needs to be replaced.





Note: When you place the rechargeable battery on the charger, the indicator will not light immediately. This takes about five seconds.



Warning: Store in a clean, dry place. Do not immerse in water. Do not cover. Do not use chemicals or water to clean it. Do not try to dismantle, damage or open it. Do not place it on a fire or near a heating area. Dispose of the charger according to local rules. Provision and usage should be carried out under the supervision of a caregiver. Only use the power supply provided by Oticon Medical, which is compatible with the charger. Use the charger in a dry place at temperatures of between 10°C to 45°C.

Using the Neuro 2 sound processor

Check that all the parts of the sound processor are properly connected (antenna cable, magnet, sound processor and battery module).

Switching on/off

To switch on the Neuro 2 sound processor, you can:

- Connect the battery to the sound processor. Neuro 2 will automatically turn on.
- If the battery is already connected, you can switch on the sound processor by pressing the upper part of the push button until visual indication.



Note: In general, your sound processor starts up in the general listening programme (P1). However, it can be configured differently by your clinician.

The sound processor automatically powers off after 30 minutes of disconnection with the implant.

To switch off the sound processor, you can:

- Remove the battery from the sound processor.
- Press the lower part of the push button until visual indication. Note that this power off function is only active if the antenna is not connected to the implant to avoid switching off by mistake during use.

Placing and removing the sound processor behind the ear

To wear the sound processor behind your ear:

- Place the sound processor behind your ear
- With your hand, place the antenna over the implant

To remove the sound processor from your ear:

- Remove the antenna from your head
- Remove the sound processor from your ear

For users with a Digisonic® SP implant on one ear and a Neuro Zti implant on the other ear:

If the sound processors are switched around, the implants will not work. To identify the appropriate sound processor, use one of the following methods:

- Check the sound processor marking
- Check the antenna marking
- Check the light indications of the sound processor to identify the correct side (refer to the “Visual and Auditory indications” section).

For users with a Neuro Zti implant on both ears: The Neuro Zti implants are designed to recognise the sound processor which has been specifically configured for it (paired). If the sound processors are switched around, the implants will not work. To identify the appropriate side of your Neuro 2 sound processor, check the light indications of the sound processor (refer to the “Visual and Auditory indications” section).



Note: When the antenna is removed from the implant, the stimulation stops.



Important: If you are using cochlear implant systems on both ears, you are strongly advised against using a sound processor programmed for one ear on the opposite ear.





Important: If you experience skin redness or irritation while wearing the sound processor on the ear, you can improve wearing comfort by changing the hook size or wearing the sound processor on the contralateral ear (longer antenna cable needed). If the problem continues, remove the sound processor and contact your implant centre.

Identifying right and left devices (bilateral implantation)

Make sure you use and place the sound processor on the ear for which it is programmed. If you switch the devices around, they may not work.

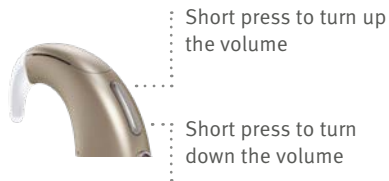
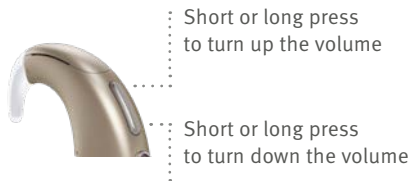
While the processor is not worn, you can identify which ear it belongs to: Press and hold the upper part of the push button and observe the light colour.

	Continuous green light for the left ear
	Continuous orange light for the right ear

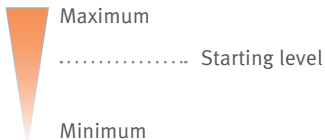
Volume control

The Neuro 2 sound processor lets you control the volume. This volume control can be enabled and disabled by your clinician.

Press the push button to adjust the volume up or down:



If programme control is disabled



If programme control is enabled

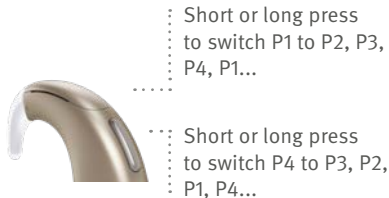


Note: The volume can only be changed when the sound processor is connected to the implant.

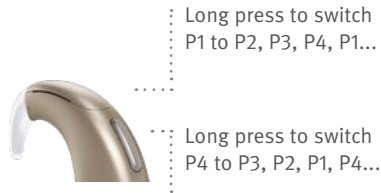
Programme control

The Neuro 2 sound processor can be configured with up to four different programmes (P1, P2, P3, P4). The clinician can define these programmes according to your preferences and conditions of use (normal surroundings, noisy surroundings, telecoil, etc.). This programme selection can also be enabled or disabled by your clinician.

Press the push button to change the programme:



If volume control is disabled



If volume control is enabled



Note: Programmes can only be changed when the sound processor is connected to the implant.

Muting or unmuting

If you need silence for a shorter period of time while wearing the sound processor, you can use the mute function.

The mute function can be enabled and disabled by your clinician.

- To mute the sound processor, press the upper or lower part of the push button for minimum two seconds.
- To unmute the sound processor, press the upper or lower part of the push button briefly.



Important: Do not use the mute function as an off switch, as the sound processor still uses the battery in this mode. The mute function can only be activated when the sound processor is connected to the implant.

Assistive Listening Devices

Assistive listening devices are used to minimize the problems of listening when at a distance from a source of sound and/or in background noise.


Telecoil

The Neuro 2 sound processor has an integrated telecoil, which:

- Enables enhanced listening in places equipped with an induction loop system (e.g: theatre, cinema, lifts)
- Enables the use of connectivity devices equipped with an induction loop system

A telecoil programme can be configured by your clinician.



Note: When a teleloop transmitter is available, it is indicated by this symbol  (or similar)



Visual and auditory indications

The sound processor is equipped with an indicator light and provides auditory indications.




The indicator light has three colours, each of them indicating a different status:

● Green: Ready for use

● Orange: Careful



● Red: Warning – Immediate action from the operator is needed.

Power on/off

	Long orange light followed by a long green light	Correct functioning: The sound processor is booting (orange). The green light indicates the sound processor is ready.
	Long orange light, followed by three short orange lights, followed by a long green light	A problem has occurred. If the problem persists, contact your local Oticon Medical customer service or Oticon Medical distributor.
	Long red light	The sound processor is powering off. If this is unintentional, replace the batteries.



Microphones check

When the sound processor is powered on and not connected to the implant, check the functioning of the microphones before placing the sound processor by simply talking to it.

	Green light following your speech	The microphones are working fine.
	Orange light following your speech	There is a problem with one of the two microphones. Clean the microphone openings. If the problem persists, contact your implant centre, your local Oticon Medical customer service or Oticon Medical distributor.

Implant connection/disconnection check

When the antenna is connected to the implant:






	Green light + One beep	Connection with the implant has been established.
	Repeated long red lights	The sound processor doesn't match the implant on the chosen side. Ensure the sound processor is placed on the correct ear.

When the antenna is disconnected from the implant:

	Red light	The connection with the implant has been lost.
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Programme and mute indications

While the antenna is connected on the implant, you can change programmes or mute the sound:




	One green light + One beep	Programme 1 selected
	Two green lights + Two beeps	Programme 2 selected
	Three green lights + Three beeps	Programme 3 selected
	Four green lights + Four beeps	Programme 4 selected
	Green light followed by orange light	Sound is muted

Your clinician can enable and disable the programme and mute visual indications.

Your clinician can configure the visual programme and mute indications to be repeated continuously.


Volume indications

While the antenna is connected to the implant:

	One short green light + One beep	Volume is adjusted (up or down)
	One short orange light + Three beeps	Minimum or maximum volume reached
	Green light + Two beeps	Starting volume level reached

Your clinician can enable and disable the volume visual and auditory indications.

Battery low indication

	Continuous short orange lights + Two beeps at moderate intervals	Low battery warning. Change the battery.
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Your clinician can enable and disable the low battery visual and auditory indications.

Battery run out indication

	Four consecutive beeps	The battery has run out. Change the battery.
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Achieving a secure and comfortable sound processor fit

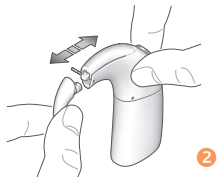
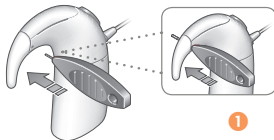
Several options can enhance your comfort as well as the hold of the sound processor on the ear. You can also use these options if you experience redness, skin irritation or general discomfort.

Hook

The sound processor comes with a hook to ensure that it is held on the ear. Different hook sizes (small, large) are available to fit your ear.

The hook can be changed as follows:

- Take the pin tool (provided in the packaging), and push the pin to release the hook (1). The pin will stay attached to the shell.
- Remove the used hook and replace with a new one (2).
- Push the pin back into place using the back end of the pin tool (3).

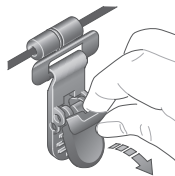
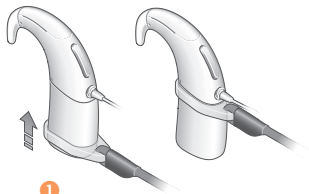


Safety Line

The safety line is used to prevent the loss of the sound processor if it falls off your ear.

The cords of the safety line are easily removable from the clip so the accessory can be safely used for children.

- The cords detach from the clip for safety reasons and allow different cord lengths to be attached.
- Place the elastic ring around the lower part of the sound processor (1).
- Attach the clip to your clothes (2).
- If you only have one sound processor, you can remove the secondary cord by simply pulling it out.



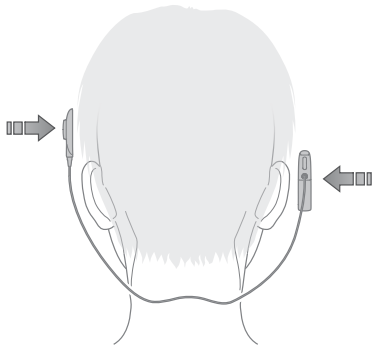
Note: The Safety Line is an applied part. It is an optional accessory, please check the Oticon Medical order form for availability and ordering.

Alternative wearing option for the sound processor

For unilateral patients, you can wear the sound processor on the opposite ear.

To do this, you need to equip your sound processor with a long antenna cable.

- Disconnect the antenna from the antenna cable
- Disconnect the antenna cable from the sound processor
- Connect the longer antenna cable to the antenna
- Connect the longer antenna cable to the sound processor
- Place the sound processor on the opposite ear
- Place the antenna over the implant



Note: Several antenna cables lengths are available. Check availability in the order form and contact your local Oticon Medical customer service or Oticon Medical distributor.

Care and maintenance



Warning: Do not perform servicing and maintenance while the sound processor is in use.

Cleaning

We recommend regular cleaning of your sound processor and its components:

- Hold the Neuro 2 sound processor over a soft/dry surface to avoid any damage if it is dropped.
- Clean the sound processor and its antenna with a soft, dry cloth.
- Carefully brush away any dust, dirt or dead skin from the microphone openings with a soft brush.



Important: Do not use any corrosive or abrasive substance to clean your sound processor.

Audiological cleaning wipes can be used to dissolve earwax and remove perspiration.

Desiccation drying system

We recommend that you dry your sound processor on a daily basis, especially when you do not wear it for a prolonged period (for example during the night):

- Remove the Li-Ion rechargeable battery to charge it while the device is drying or
- Remove the Zinc Air batteries (they should be stored in a cool and dry place away from direct sunlight and heat). Leave the Zinc Air battery cartridge open. The antenna, magnet and antenna cable shall remain connected to the sound processor.
- Place the Neuro 2 sound processor in the desiccation drying system.

- You can also use the desiccation drying system for an ear mould.
Please refer to the desiccation drying system instructions for use to find out more about the drying cycle duration and how to power the desiccation box.



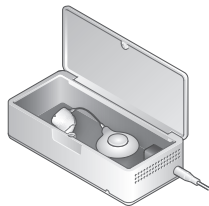
Note: During especially humid conditions (summer, work in professional kitchens etc.), you can optimise drying by adding a drying pellet to the desiccation drying system.



Important: Only use desiccation drying system for drying your sound processor and your retention devices. Use and store your desiccation drying system in a clean, dry place. Do not use in water. Do not cover. Do not use chemicals to clean it. Never open the electronic part of desiccation drying system. Do not place your sound processor in an oven or other warmed up placed to dry.



Warning: Do not place the battery modules in the desiccation drying system.



Storage

Protective case

The sound processor must always be protected from dust, humidity, mechanical vibrations and impact. On a day-to-day basis, you can use the protective case to store the sound processor, spare batteries etc. when you are not using it.

Remember to always remove the Zinc Air batteries before storing the sound processor. It is not necessary to disconnect the antenna and antenna cable from the sound processor.

It is recommended that all external equipment is stored away from direct sunlight and heat.



Important: Always switch off the sound processor before storage to preserve battery power.



Carrying pouch

This small pouch is designed to carry an extra spare battery module or Zinc Air batteries for your sound processor.



USB memory = stick

When adjustments are needed or if you need a new device, the starting point is the settings of your current sound processor. To make sure your settings are easy to access, they are stored on the USB memory stick. The USB stick must be used only by hearing care professionals.



Important: Always take the USB memory stick with you when visiting your implant centre.



Note: The Instructions for use of your sound processor is saved in the USB memory stick.

Troubleshooting

Please refer to the “Visual and auditory indications” paragraph to verify correct start-up, microphone functioning, left/right sound processor selection and implant connection.

If you experience issues while using your Neuro 2 sound processor, you can try to identify and solve the problem following the steps described below.

Each time you are using a spare part, spare antenna or extra antenna cable, make sure you order another one as a backup.

If the problem persists, contact your local Oticon Medical customer service or Oticon Medical distributor.

The sound processor doesn't start or no light is seen during start-up (using Zinc Air batteries)

- Check the Zinc Air battery expiry date (see date on the battery package). If the expiration date is passed, change to new Zinc Air batteries.
- There may be a problem with the battery cartridge. If you have one, connect a compatible rechargeable Li-Ion battery module and check if the sound processor starts. If starting is successful with the Li-Ion battery, this means the Zinc Air battery cartridge is defective and should be replaced. Contact your local Oticon Medical customer service or Oticon Medical distributor.

The sound processor doesn't start or no light is seen during start-up (using rechargeable Li-Ion batteries)

- Check that the rechargeable battery is fully charged. If charging fails, change to a new rechargeable battery module (Li-Ion rechargeable batteries have a limited lifetime). Use Zinc Air batteries as backup if you don't have a functional rechargeable battery.
- There may be a problem with the rechargeable battery (expired). Change the battery module to a Zinc Air battery module and check if the sound processor starts. If starting is successful with Zinc Air batteries, this means the Li-Ion rechargeable battery is worn out and should be replaced. Contact your local Oticon Medical customer service or your local distributor to get a new one.

No sound is received (but sound processor is powered on)

- Check that the microphones are working correctly.
- Make sure the antenna is properly connected to the sound processor.
- Refer to the "Sound processor check" section.
- Make sure you are using the proper antenna type (Zti – Neuro 2 LD or Zti – Neuro 2 SD). If you are using a Zti - Neuro 2 LD antenna, try using the spare antenna.
- Check the antenna and antenna cable are not visually damaged. If so, change the defective part.
- Check that the sound processor is not in a muted mode.
- If the problem continues, contact your implant centre, your local Oticon Medical customer service or Oticon Medical distributor.

Reduced or distorted sound

- Check that the volume is not turned down (if configured with volume control).
- Check that the right programme has been selected for the listening conditions.
- Check that the microphones are working correctly.
- If the problem continues, contact your implant centre, your local Oticon Medical customer service or Oticon Medical distributor.

Red light flashes slowly when placing the antenna on the ear

- The sound processor you are trying to connect is not paired with the implant (wrong ear or wrong person). Check you are correctly matching the sound processor using the left/right light identification function. When placing the correct antenna on the correct ear, the indicator light is green and a short beep indicates matching.

No light, no beep when placing the antenna over the implant

- Clean the antenna cable plug.
- Clean the sound processor and antenna sockets.
- Press the cable plugs firmly in place.
- If this does not work, try connecting with another cable.
- If this does not work, try connecting with another antenna of same type
- If the problem continues, contact your implant centre, your local Oticon Medical customer service or Oticon Medical distributor.

Unexpected short battery life

If you are using Zinc Air batteries

- Change both batteries.
- Check that you are using the right type of batteries (type 675 or PR44) and their expiry date has not been exceeded.
- Check that you are following the care instructions of the batteries.

If you are using rechargeable Li-Ion batteries

- Check that the rechargeable battery has been fully charged/recharged.
- Try connecting another Li-Ion rechargeable battery. If it works, the old rechargeable battery is maybe running out and should be replaced by a new one.

If the problem continues, contact your implant centre, your local Oticon Medical customer service or Oticon Medical distributor.

Problem holding the antenna

- If it is held too tightly, loosen the magnet by turning it maximum half turn by following the marking indicated on the antenna. If it is not enough, you may need a lower magnet force. Contact your implant centre for advice.
- If it is not held tightly enough, you may need a higher magnet force. Contact your implant centre for advice.

How to return a defective accessory or a Neuro 2 sound processor

We advise you to follow the steps online www.oticonmedical.com on the "Service request" section to define how to handle a defective accessory or a Neuro 2 sound processor.



Important: Do not return your Neuro 2 sound processor until you have gone through the troubleshooting procedures and agreed with your implant centre, your local Oticon Medical customer service or Oticon Medical distributor to return it.

Disposal

The sound processor and battery charger are electronic devices. The batteries are chemical devices. Disposal of these parts together with household waste can create a risk for the environment.

Contact your local authorities to determine the proper method of disposal.

Oticon Medical is concerned about the environment, and is a member of the French environmental body “Récylum” for the collection and recycling of our devices. You can return your system to us (or via your distributor) for recycling.

Risks and related instructions for use



Warning: No modification of this equipment is allowed. Any modification will automatically lead to cancellation of the warranty.



Important: We strongly advise you to take out insurance covering loss, theft or irreparable damage. Please contact your implant centre for information.



Warning: The use of the sound processor and its accessories outside the operating and storage conditions could cause a safety risk.



Warning: You may experience side effects during normal use (e.g., overstimulation, abnormal feeling). If the problem persists, remove the sound processor from your ear and contact your implant centre.



Warning: The use of long cables with infants and young children creates a risk of strangulation and choking hazard. Caregivers must supervise patient at anytime.



Warning: The use of small parts with infants and young children creates a risk of suffocation, swallowing and ingestion hazard, these parts include: Magnet, Zinc Air battery, battery modules, hook, hook pin, pin tool. Caregivers must ensure these components are not manipulated by the patient. In case of swallowing, you must contact the nearest medical center.



Warning: In case of injury with a cutting part from the sound processor, you must contact the nearest medical center.

Playing sport

The cochlear implant system allows participation in most sporting activities. However, precautions must be taken. Depending on the sport, this can include wearing a protective helmet, using a system for holding the sound processor, or removing the sound processor.



Warning: Participation in contact sports is not advised as a severe impact may damage your cochlear implant and your sound processor.

For the implanted part, deep-sea diving below a depth of 20m is not advised.

Magnetic fields

The sound processor must be removed when in the proximity of a strong magnetic field.



Warning: The sound processor must be removed before any medical examination is carried out (radiotherapy, MRI, ultrasound, scan). Electronic components in an active implantable medical device may be damaged by therapeutic ionizing radiation, and any damage to the device may not be immediately detectable.

Medical examinations



Warning: The implanted part is sensitive to electric currents. You must contact your implant centre and Oticon Medical before any treatment using electric currents or any exposure to intense radiation (radiotherapy etc.).

Before any MRI exam is carried out, the MRI exam application form (available on: www.oticonmedical.com) must be completed by the radiology department involved, and returned to Oticon Medical. The MRI exam has to be processed with head first.

Always seek medical guidance and/or contact your local Oticon Medical customer service or Oticon Medical distributor before entering a restricted area which could affect the correct functioning of your implant and your sound processor.

Settings

Each sound processor is programmed for personal use by a clinician authorised by Oticon Medical. It must not under any circumstances be lent to another person or exchanged for someone else's sound processor.

The sound processor requires careful adjustments to achieve optimal listening quality. Checking the adjustments is recommended at least once a year.

Electrostatic discharge

Electrostatic discharges are the visible sparks that can arise when there is contact between two people or with an object. They are caused by cold, dry climates. Contact with certain components can promote the appearance of such discharges (clothes made of synthetic material, getting out of the car, plastic toboggans, computers or television screens, carpets, etc.). The Neuro 2 sound processor is designed to provide effective protection against these electrostatic discharge phenomena to prevent any damage to the device or alteration to the listening programme. However, we advise you to take certain precautions to prevent the exposure of the sound processor to such discharges: carefully remove a pullover, take care when getting out of the car, etc. Furthermore, any person that comes into contact with the sound processor must make sure to touch the person wearing the cochlear implant system before touching the device to remove any residual static electricity.

Passing through security gates

Security gates (airports, shopping centres, etc.) produce powerful electromagnetic fields.

Passing through or close to these gates may trigger the detector alarm or disrupt the sound received by the person wearing the implant. It is recommended that you switch off your sound processor and inform the security officers by showing your patient card.

Warm sensation

The temperature (°C) of your sound processor can increase up to 43°C, without exceeding it.

If you sense an elevated temperature of the instrument, remove it from your ear and switch it off. If the problem persists, contact your implant centre, your local Oticon Medical customer service or Oticon Medical distributor.

IP classification

IP68 classification per IEC 60529 standard. Instrument can withstand prolonged immersion in water up to 1 meter. Dust tight when tested under specified conditions. Dust will not interfere with the satisfactory operation of the device.



Warning: The sound processor must never be washed or immersed in water or any liquids. It is important to protect the microphones from dust, dead skin, dirt, sweat and humidity as it can damage your sound processor microphones. Never wear the device in the shower, bath or while swimming.








Important: In the event of dropping the sound processor in any liquid, switch off the sound processor, remove the battery module or Zinc Air batteries, immediately rinse the equipment in clean water and let it dry. You can use the desiccation drying system to speed up the drying.



Warning: If there is any doubt about the functioning of your hearing system, please contact your local Oticon Medical customer service or Oticon Medical distributor to ensure you are not exposed to any safety risks.

Sound processing features

Neuro 2 provides powerful sound processing features that are designed to ensure hearing comfort and speech understanding.

	Coordinated Adaptive Processing: Automatically delivers the perfect balance between different sound processing technologies to enhance listening and speech understanding, whatever the environment.
	Voice Guard: Helps preserve the natural characteristics of speech and fine details of sound – from soft to loud – making them audible, comfortable and clear.
	Voice Track™: Aims for better speech understanding in noisy environments by reducing the volume of disturbing sounds, while maintaining audibility of important sounds like alarms etc.
	Free Focus: Constantly analyses your environment and detects the voice or voices closest to you. Once found, it automatically zooms in on them and fades out background sounds.
	Special purpose programmes: Allow you to control the sound processing feature that matches your listening needs in specific situations.

Physical and performance characteristics

Sound processor

Sound processor	Maximum dimensions (height): 52.4 mm Weight with Zinc Air batteries: 10.3 g Weight with 120mAh Li-Ion battery: 9.1 g Weight with 200mAh Li-Ion battery: 11.7 g
Power supply	Operating voltage range: from 1.8 VDC to 5 VDC Maximum consumption: 60 mW Maximum transmission power: 35 mW
Power sources	Battery modules: Neuro 2 Zinc Air battery cartridge with 2 disposable 675 Zinc Air batteries (type 675 or PR44) Li-Ion Neuro 2 rechargeable battery module 120 mAh Li-Ion Neuro 2 rechargeable battery module 200mAh
Operating conditions	Operating temperature: 5°C to 40°C Relative humidity: 10 to 90% Atmospheric pressure: 700 hPa to 1060 hPa
Transport conditions	Temperature: -30°C to 60°C Relative humidity: 10 to 90% Atmospheric pressure: 700 hPa to 1060 hPa
Storage conditions	Temperature: -30°C to 60°C Relative humidity: 10 to 90% Atmospheric pressure: 700 hPa to 1060 hPa
Essential performance	Accuracy of the electrical stimulation (<10% at C-level)

Classifications	Protection against electric shocks: Internally powered ME equipment Type B applied part Protection against dust and water: IP68
Standards	European Directive 90/385/EEC EN 45502-2-3 ISO 14708-7

Li-Ion rechargeable batteries

Operating conditions	Temperature: 0°C to 50°C Relative humidity: 10% to 93% (non-condensing)
Transport conditions	Temperature: -25°C to 60°C Relative humidity: 10% to 93% (non-condensing)
Storage conditions	Temperature: 0°C to 40°C Relative humidity: 10% to 60% (non-condensing)
Nominal voltage	3.7 volts
Battery life	Depending on the type of battery connected, the user's physiology, sound processor settings, acoustic environment and use of the device on a daily basis.
















Battery charger















Power supply	100-240V 50-60Hz
Charger power	USB powered / mains adaptor
Operating conditions	Temperature: 10°C to 45°C Relative humidity: 25% to 85% at 40°C (non-condensing)
Storage conditions	Temperature: -20°C to 70°C

Accessories intended to be used with the Neuro 2 sound processor

- Antenna (163895-163908, 156721, 164881, 164933, 160549, 164935, 164940)
- Antenna cable (171291, 171292, 171294, 171295, 171297, 171298)
- Battery cartridge Zn-Air (170645-170654)
- Care kit (173124) containing: carrying pouch, cleaning cloth, hook pin, pin tool
- Charger (181544)
- Desiccation Drying System (178020)
- Hook (182630, 165232)
- Magnet (167767-167774, 161337, 161344-161346, 161406, 161394-161397, 170257-170320)
- Power supply (182242, 182245-182247, 182249-182251)
- Protective case (178055)
- Rechargeable battery (158065-158070, 158072-158077, 153347, 153349, 153179, 153298, 165441, 165443-165445)
- Safety line (173869)
- Tamper tool (185326)
- Disposable batteries intended to be used with the Neuro 2 sound processor:
Zinc Air batteries type 675 (187503)

Symbols

	CE registration mark with notified body number. Indicates compliance with the requirements of the Active Implantable Medical Device Directive 90/385/EEC.
	Warning.
	Consult the operating instructions.
	Serial number.
	Reference.
	Batch code.
	Date of manufacture.
	Manufacturer.
	Affected by dampness – store in a dry place.
	Type B applied part. Device for which the parts applied and connected to the user are not conductive.
	Temperature limits to which the medical device can be exposed.
	Humidity limits to which the medical device can be exposed.
	Atmospheric pressure limits to which the medical device can be exposed.
	Recharging date of the rechargeable battery.
	Loop system installed.

	The electrical device must be disposed of in a separated waste collection. Directive for recycling electrical and electronic equipment (waste electrical and electronic equipment (WEEE)).
	P675: “675” (European designation) or “PR44” (international designation) Zinc Air batteries. +: Battery positioning direction.
	Restriction of Hazardous Substances. This restricts the use of six hazardous materials found in electrical and electronic products.
	Keep away from small children to reduce the risk of accidental swallowing, choking and strangulation.
	Not made with natural rubber latex.
	The product is recyclable.
	Avoid heat exposure.
	Do not dismantle.
	Do not dismantle the battery modules.
	Do not expose to fire.
	Do not puncture.
	Dry location use only.
	Federal Communications Commission mark. Declaration of conformity certifying that the electromagnetic interference of the device is compliant with the limits given by the Federal Communications Commission.
	Class II electrical device with double insulation.

Manufacturer's declaration

Medical electrical equipment requires special precautions to be taken for EMC (Electromagnetic Compatibility) and it is necessary to install and start it according to the EMC information provided in the tables below. Portable RF (radio frequency) communication devices, such as mobile telephones, may affect the operation of the Neuro 2 sound processor. Therefore, these devices should be kept as far away as possible from the Neuro 2 and its accessories in order to avoid such effects.

FCC and Industry Canada Compliance Statement

This device complies with part 15 of the FCC rules and contains license-exempt transmitter(s) / receiver(s) that comply with Industry Canada's RSS-310. Operation is subject to the following two conditions:

1. this device must not cause harmful interference, and
2. this device must accept any interference received, including interference that may cause undesired operation.

Caution

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Unique Identifier : Neuro 2

Guidelines and manufacturer's declaration – Electromagnetic emissions

The Neuro 2 sound processor is intended for use in the electromagnetic environment specified below. The Neuro 2 user should ensure that it is used in such an environment.

Emissions tests	Compliance
CISPR 11 RF emissions	Group 1
CISPR 11 RF emissions	Class B
Harmonic emissions IEC 61000-3-2	Not applicable
Voltage fluctuations and flicker emissions IEC 61000-3-3	Not applicable

Guidelines and manufacturer's declaration – Electromagnetic immunity

The Neuro 2 sound processor is intended for use in the electromagnetic environment specified below. The Neuro 2 user should ensure that it is used in such an environment.

Immunity test	Test level IEC 60601	Level of compliance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 2 , ± 4 , ± 6 kV contact ± 2 , ± 4 , ± 6 , ± 8 kV air
Power frequency (50/60 Hertz) magnetic field IEC 61000-4-8	30 A/m (50/60 hertz)	30 A/m (50/60 hertz)



UT is the A.C. mains voltage prior to application of the test level.

Guidelines and manufacturer's declaration – Electromagnetic immunity

The Neuro 2 sound processor is intended for use in the electromagnetic environment specified below. The Neuro 2 user should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Level of compliance
Radiated RF IEC 61000-4-3	± 10 V/m from 80 MHz to 2.7GHz 80% AM at 1kHz	± 10 V/m from 80 MHz to 2.7GHz 80% AM at 1kHz

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 – 390	TETRA 400	Pulse modulation 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM \pm 5 kHz deviation 1 kHz deviation	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0,3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0,3	28
870						
930						

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0,3	28
1845						
1970						
2450	2400 – 2570	Bluetooth, WLAN, 802,11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0,3	28
5240	5100 – 5800	WLAN 802, 11 a/n	Pulse modulation 217 Hz	0,2	0,3	9
5500						
5785						

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