

Neuro One Instructions for use



Neuro – The Cochlear Implant System

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MEDICAL

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Introduction

You have just received your Neuro One sound processor, commercialised by Oticon Medical. This manual is intended for the patient, the caregiver and the audiologist by providing important information and instructions on how to use the Neuro One 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

This manual for the Neuro One sound processor explains how to use the device as well as the precautions for use to be observed. If the information provided in this manual and in the packaging of the Neuro One sound processor is incomplete or illegible, please contact the manufacturer or your local distributor.

Indications

The Neuro One sound processor is designed for adults and children of all ages, diagnosed with unilateral and bilateral severe to profound sensorineural hearing loss (and hearing aid use does not provide adequate amplification for speech audiometry), fitted with a Neuro Zti cochlear implant.

Contra-indications

The Neuro One sound processor is not appropriate for patients fitted with an implant other than that specified in the indications. The Neuro One sound processor is not appropriate for patients with implants whose auricle is too small and/or too soft to support the device.

Reliability – quality

The cochlear implant system is an active implantable medical device. To ensure your safety, the Neuro One sound processor is designed and manufactured in accordance with the requirements of European Directive 90/385/EEC. The device conforms to standard EN 45502-2-3: 2010, on Active Implantable Medical Devices (AIMD) – cochlear and auditory brainstem implant systems, as well as standards relating to the safety of Medical Devices.

Implant Compatibility

The Neuro One sound processor is only compatible with the Neuro Zti implant.

Note: it is important to always keep the cochlear implant patient card with you provided by your implant centre and to show it at the time of any examination or medical treatment.

In the case of a bilateral cochlear implantation (each ear has a cochlear implant system):

patients wearing two cochlear implant systems are strongly advised against using a sound processor programmed for one ear on the opposite ear. The implant is designed to recognise the sound processor which has been specifically configured for it (paired). If the sound processor is changed, the implant will not work. To facilitate the recognition of the left/right sound processor and prevent switching them, different colour foolproof keys (stickers) are provided with the product. The Left/Right stickers need to be stuck on a part of the sound processor which is not in contact with the skin. Finally, in case of a fault with one of the sound processors, contact Oticon Medical or your local distributor for a solution.

Neuro One sound processor

compatible with the implants
opposite:



Neuro Zti Cochlear Implant



How Neuro One Works

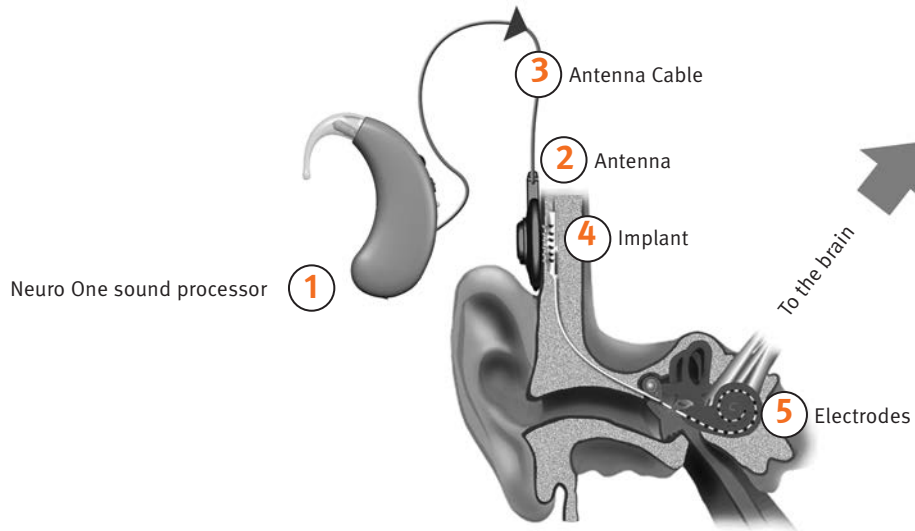
The cochlear implant system consists of an external part and an internal part.

External part

- A Neuro One behind-the-ear hearing device (1) with two microphones.
 - An external antenna (2) connected to the sound processor via an antenna cable (3).
- The sound captured by the microphones is digitally processed by the sound processor. The stimulation signal is then sent to the implant via the antenna through the skin.

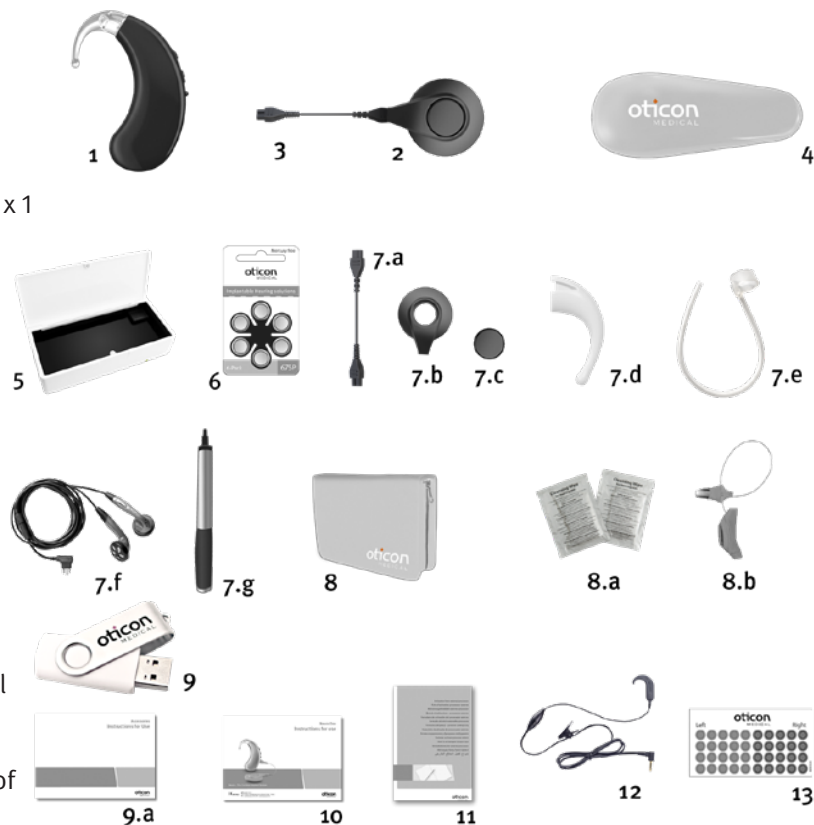
Internal part

The Neuro Zti implant is a small casing (4) placed under the skin. It contains an electronic stimulator which will distribute the sound to the electrodes (5) placed in the cochlea.



Packaging contents

1. Neuro One sound processor x 1
2. Antenna with magnet x 1
3. Antenna Cable x 1
4. Case x 1
5. "Perfect Dry" heating desiccation drying system x 1
6. Zinc-Air battery boxes x 3
- 7. Accessories box x 1 containing:**
 - 7.a Additional antenna cable x 1
 - 7.b Additional antenna x 2
 - 7.c Additional magnet x 2
 - 7.d Additional ear hook x 4
 - 7.e Holding buckle x 1
 - 7.f Microphone earphones x 1
 - 7.g Screwdriver x 1
- 8. Carrier x 1 containing:**
 - 8.a Cleaning wipes x 2
 - 8.b Cover Clip x 1
- N-A 6 Battery blister pack x 1
9. USB memory stick for backing up the settings that also contains the Accessories user manual (9.a) x 1
10. Sound processor User Manual x 1
11. Sound processor registration form (activation of the warranty) x 1
12. Silhouette x 1
13. Identification Stickers Left/Right

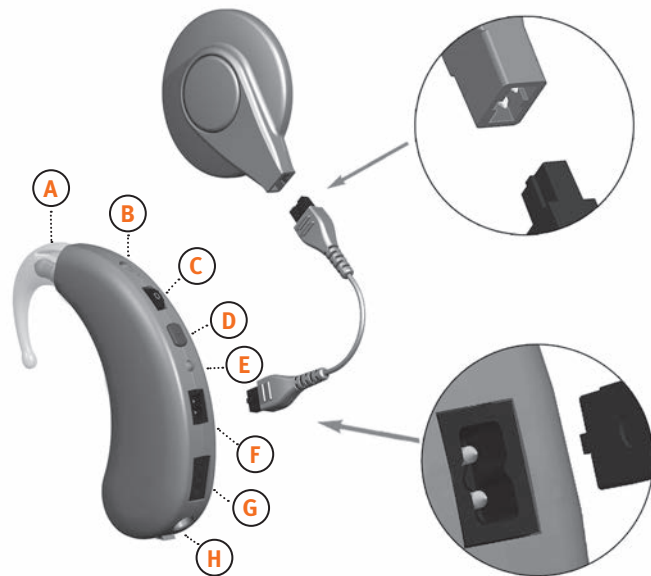


Pictures are not contractually binding

Note: The references are provided in this IFU in the section "References of Neuro One sound processor, spare parts and accessories"

Sound processor Description

- A. Microphone 1
- B. Microphone 2
- C. Setting selector wheel with on-off switch
 - 0: Stop
 - 1: Position 1
 - 2: Position 2
 - 3: Position 3
- D. Programme button: choice of programmes (press once to select the following programme P1-> P2-> P3-> P4-> P1 etc.) – checking that the system works (press for longer)
- E. Orange indicator light
- F. Antenna socket: connection of the antenna cable
- G. Auxiliary socket: connection of external accessories (FM systems, microphone earphones, etc.)
- H. Connection socket for the settings



The sound processor is identified visually by its marking and serial number.

The serial number of your Neuro One sound processor is indicated on the inside of the battery compartment: "Pxxx" (for example P1495/P = sound processor generation / xxx = serial number).

It is recommended that you write down and keep this number, as you may need it in the future.

Note: All parts indicated above are applied parts.

Using the Neuro One sound processor

1. Connecting the components

Both ends of the antenna cable are identical to avoid any confusion for the user. It is to be used according to the following recommendations:

- Connect the antenna to the antenna cable.
- Connect the antenna cable to the sound processor via the antenna socket.

The ends of the antenna cable and of the Neuro One sound processor antenna are equipped with a foolproof key. The connection of the antenna cable to the sound processor, as well as the antenna cable to the antenna, must ensure that the foolproof key is facing in the right direction with respect to the socket and the cable (see paragraph "Sound processor description").

Important: the antenna cable connectors are designed to be used occasionally (change of faulty cable, etc.). To prolong this accessory's service life, we recommend that you store your Neuro One sound processor in its case without disconnecting the antenna cable.

2. Optimising hold

Magnet

The antenna is held on the skin opposite the implant by means of a magnet.

You can adjust the distance between the skin and the magnet at any time by tightening or unscrewing the magnet.

To screw or unscrew the magnet, here are some instructions you can follow:

- Hold the antenna by grasping the magnet cap by its top and bottom, as shown in photo 1 below.
- To tighten the magnet, turn it in the opposite direction indicated by the arrows under the magnet cap (photo 2).

Photo 1

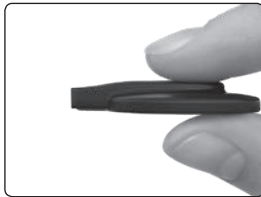


Photo 2



The underside of the magnet indicates the magnetic force:

top part of the magnet



bottom part of the magnet



If the magnet force is insufficient, the antenna may not be held on the skin properly. It is then recommended to change the magnet force (higher force).

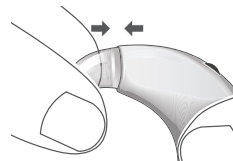
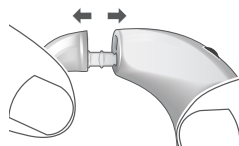
If it is too strong, an irritation or skin redness may occur. A lower force (delivered in the box) may be advised.

If the magnet does not seem suitable, contact your implant centre which will advise you on the suitable force that you can order from your local distributor or the Oticon Medical after-sales service.

Ear hook

The sound processor is provided with an ear hook to ensure that it is held on the ear. So that it can be adapted to each patient, a different length of ear hook is provided in the box. The ear hook can be changed as follows:

- Remove the used ear hook.
- Clip on a new ear hook until you hear a "click".



Holding buckle

For an optimal fit of the sound processor on the ear (notably for paediatric use or active/sport activities), we recommend that you use the silicon holding buckle provided in the Neuro One accessories box.

It is recommended that you refer to the "Accessories Instructions for use" to see how to fit this.

Note: The sound processor may also be held by using an open ear tip made by a hearing-aid specialist.



3. Powering the sound processor

Type of batteries that can be used

Your Neuro One sound processor works using 2 non-rechargeable 675 Zinc-Air batteries. It is important to 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 risks affecting the proper operation of the Neuro One (reduced battery life, sound processor power supply fault).

For restocking on batteries, you can directly contact your local distributor or the Oticon Medical after-sales service.

Battery life

The battery life is variable depending on the patient, setting, acoustic environment and use of the device on a daily basis.

User instructions for batteries

It is recommended that you keep the batteries in a dry place away from temperature variations and observe the expiry date indicated on the packaging. The two batteries used for powering the Neuro One must be the same type and be changed at the same time. It is important to remove the batteries when your sound processor is switched off for a prolonged period (for example overnight).

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

Important: The batteries are small components which could be a hazard if swallowed. Keep the batteries out of the reach of children.

Private alarm

The Neuro One sound processor indicates the end of the battery life by consecutive audible beeps (private alarm) that cannot be heard by those around you. Your clinician must first configure this functionality at the time of an adjustment, so that you may benefit from this private alarm. Two consecutive series of three beeps notify you of the low battery life 30 minutes before the end of the batteries' life. The following six beeps indicate the end of the batteries' life and the cut-off of the sound processor. On hearing the first two series of audible beeps or if the sound stops or has deteriorated, it is highly recommended that you change the two batteries. These discharged batteries could spill corrosive liquid that may damage your sound processor.

Battery compartment

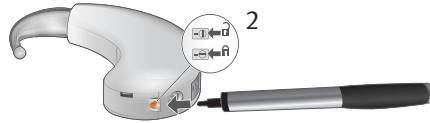
The Neuro One sound processor is equipped with a battery compartment locking system, to keep the battery compartment closed while wearing or if the sound processor is dropped. This closure system is optional and may be activated or deactivated at any time using the specific screwdriver provided.

- To lock the battery compartment: make sure that the compartment is correctly closed. Use the screwdriver provided in the box to turn the screw to the locked position (illustration below).
- To unlock the battery compartment: Use the screwdriver to turn the screw to the unlocked position. You can now freely open and close the battery compartment.

Inserting/changing batteries:

1. Switch off the sound processor (selector wheel on "0")
2. Deactivate the lock, if required.
3. Remove the used batteries and place the two new batteries (remove the protective film) in the compartment observing the polarity indicated on the compartment (the batteries can only be inserted on one side). Reactivate the lock, if required.

You can then switch on your sound processor (turn the selector wheel towards the top to the appropriate position).



The lock is not necessary to keep the compartment closed, but comes as an additional feature. This feature does not replace adult supervision. If the sound processor falls down, verify that the battery compartment is still locked. If necessary, reactivate the lock. Regularly clean the battery compartment so as to prevent the deposit of any substance.

4. Switching on/off

Turn the selector wheel towards the top to switch on the sound processor.

Select the programme using the push button (P1, P2, P3, P4).

Set the position of the selector wheel so as to optimise your listening comfort dependent on the acoustic environment (according to the configuration defined with the clinician).

To stop the device, turn the selector wheel to the bottom so that it is in the “0” position, at which point a click can be felt. In case the device is stopped for prolonged periods (for example during the night), we recommend observing the following procedure:

- Switch off the device.
- Open the battery compartment and remove both batteries.
- Place your Neuro One in the desiccation drying system and follow the steps in the related instructions or in the “Accessories user manual”, and close it until using the sound processor again.

This operation enables the moisture accumulated during use of the device to be absorbed, the battery contacts to be dried and therefore prevents possible malfunction of the sound processor.

Warning: This sound processor is equipped with an automatic restart device in case of malfunction. This leads to momentary power loss.

5. Programme button

The Neuro One sound processor enables four different programmes to be saved (P1, P2, P3, P4). The person responsible for the settings can define these programmes according to your preferences and conditions of use (normal surroundings, noisy surroundings, use of FM system, Telecoil, etc.).

Each quick press on the programme button enables the following programme to be accessed. The programmes follow one another in the order P1, P2, P3, P4, P1 etc. The orange indicator light indicates the programme selected. It flashes once for P1, twice for P2 and so on.

In the case where the clinician does not activate all the programmes, the sound processor will only select the programmes activated (for example, if only P1 and P2 are set, repeatedly pressing on the button will enable you to move from P1 to P2, and then to P1, etc.).

This function may be locked on request during an adjustment session, according to your preferences or needs, so as to simplify the use of your device, or prevent a child from changing the programme.

6. Setting selector wheel

This programmable function is used, according to the mode configured, to adjust your listening to the acoustic environment. Your clinician will set the most appropriate mode for your daily routine, and will indicate the suitable setting for using each of the programmes.

Change the position of the selector wheel in order to find the most comfortable listening position. This function can also be locked during an adjustment session, notably in the case of young children, to prevent any mishandling, or to simplify the use of your device.

7. Indicator light

The orange indicator light is activated during an adjustment session and enables the status of the sound processor to be easily identified, notably for people who are not familiar with the functioning of the device (teachers, educators, etc.).

Start-up test

At start-up, the light illuminates twice, and then extinguishes.

Stimulation indication

The light regularly flashes depending on the stimulation rate of the implant.

This light configuration can be activated upon request by your programming clinician.

Programme selection

Each quick press on the programme button is followed by one or more consecutive flashes of the light, indicating the programme selected (once for P1, twice for P2 etc.).

Detecting Battery discharge

The light flashes for 30 seconds to warn of the low battery life. It flashes again 30 minutes later to indicate the full discharge of the batteries and the cut-off of the sound processor.




This configuration can be deactivated at your request by your clinician.

Detection of any other errors

In case of a significant error that may alter the stimulation, the sound processor restarts (leading to momentary power loss) and then the light flashes quickly and extinguishes. If the problem persists, contact your local distributor or the Oticon Medical after-sales service.

8. List of additional accessories available

For more information about the accessories and their use, refer to the accessories manual available on the USB memory stick provided with the kit.

Cover Clip		This Nylon and Spandex cover protects the sound processor from moisture and perspiration, notably during sporting activities or in case of a damp environment.
Carry case		The case consists of several compartments that can be used to store all of the necessary equipment (batteries, accessories, etc.) for the system during your travels.
Screwdriver		The screwdriver is used to activate or deactivate the locking system of the sound processor's battery compartment.

Assistive Listening Systems

Assistive listening systems are used to improve the understanding of speech in noisy surroundings by reducing the effect of distance between the sound source and the user.

1. Integrated telecoil

The Neuro One sound processor integrates a telecoil which enables enhanced listening in public places with a transmitter (theatres, conference rooms, cinemas, airports, etc.). This telecoil is activated by simply selecting the programme specified beforehand with your implant centre (P1, P2, P3 or P4).

2. Auxiliary Socket

The Neuro One sound processor integrates a direct connection (auxiliary socket) that is compatible with various external hearing aid accessories (FM system, contralateral microphone, etc.), such as those shown below, that are commercially available.



The use of such a system requires an adjustment at your implant centre in order to define a new specific programme. You then just need to connect your system to the auxiliary socket of the Neuro One and select the programme specified by your clinician (P1, P2, P3 or P4). Contact Oticon Medical to know which FM systems are compatible with the Neuro One sound processor. For further information, please contact your clinician.

If an accessory is failing, the sound processor stops stimulating and the indicator light flashes slowly for 1 minute, then the sound processor cuts-off.

Disconnect the auxiliary accessory before starting the sound processor.

Care and user instructions

1. Care

Precautions

The Neuro One sound processor contains high performance electronic components that can be damaged. It must therefore be handled with care and not be exposed to extreme temperatures. Secondly, under certain conditions, the temperature (T°C) of your sound processor may reach 42°C maximum instead of 39°C (temperature when working normally). Therefore, you may experience a warm sensation. In this case, remove the external part from the ear and switch it off.

Important: If the device is dropped, check that it then works normally.

If in doubt, do not try to repair it yourself. The device does not contain any component that can be repaired by the user or the implant centre; any attempt to open the unit will automatically lead to cancellation of the warranty. In case of a problem, contact the Oticon Medical after-sales service which is alone capable of carrying out maintenance on its products.

It is important not to immerse your sound processor in water in order to avoid damaging the electronic components. Therefore, never wear the device in the shower, bath or while swimming. In the event of dropping it in dirty water, switch off the sound processor, remove the batteries, immediately rinse the equipment in clean water and dry for 72 hours.

Make sure to always carefully disconnect the antenna cable by holding the socket with two fingers. You risk damaging the cable by pulling directly above. It is highly recommended to keep one or more additional antenna cables. We recommend that your device is serviced annually, which involves checking that it is working properly as well as checking the calibration of the microphones, so as to optimise its service life.

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

Cleaning

Clean the sound processor very carefully on a regular basis using a cotton cloth or, preferably, a stiff bristled brush lightly moistened with alcohol. Make sure to protect the microphones from dust, dirt, sweat and humidity. Cleaning wipes are also provided in this box.

These wipes are saturated with a bactericide and levuricide solution that enables earwax to be effectively dissolved and dust and perspiration residue to be removed. For further information, refer to the "Accessories user manual" provided on the backup media included in this box.



Storage

It is recommended to store the entire external equipment away from direct sunlight and heat. The sound processor must be protected from dust, humidity, mechanical vibrations and impacts. On a day-to-day basis, you can use your case to store the sound processor when you are not using it. You just need to remove the batteries before positioning the device in the mould provided for this. For further information, refer to the "Accessories user manual" provided on the backup media included in this box.



Desiccation system

In case your sound processor is stopped for prolonged periods (for example during the night), we recommend removing both batteries and placing the Neuro One in the desiccation box (Perfect Dry®) provided for absorbing the residual humidity. Refer to the user instructions before use or to the "Accessories user manual" provided on the backup media included in this box. The batteries should be stored in a cool (<math><20^{\circ}\text{C}</math>) and dry place away from direct sunlight and heat.



Recycling

The main objective of Directive 2012/19/EU (WEEE) is the prevention of waste electrical and electronic equipment and in addition, the re-use, recycling and other forms of recovery of such waste, so as to reduce the disposal of waste. The "crossed out dustbin" symbol shown in the "Miscellaneous information" section indicates that the equipment cannot be disposed of with household waste, but is subject to sorted waste collection. The equipment must be delivered to an appropriate collection point for processing.

Concerned about the preservation of our environment, Oticon Medical is a member of the environmental body Réylum (France) for the collection and recycling of our devices. You can send us your system (or via your distributor) so that your hearing system can be recycled.

2. Risks and user instructions

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

Accessories

The use of accessories that are not compatible may cause uncontrollable electromagnetic disturbance, or leakage current towards the patient when an accessory, directly connected to the mains and without any electrical insulation, is connected to the sound processor. It is therefore essential that you only use accessories with the sound processor provided by Oticon Medical or those which are specified as compatible by Oticon Medical.

As the sound processor is **made up of small components** (cables, magnets, batteries, etc.), families with young children must make sure to keep these components out of their reach to avoid any ingestion or inhalation.

Playing sport

- The cochlear implant system allows for participation in most sporting activities. However, precautions must be taken, wearing a protective helmet, a system for holding the sound processor, or the removal of the sound processor may be necessary depending on the sport. A severe impact may damage your cochlear implant system. Therefore, it is not advised to participate in contact sports.
- Deep-sea diving below a depth of 20 m is also not advised.

Medical examinations

- The sound processor must be removed before any medical examination is carried out (radiotherapy, MRI, ultrasound, scan).
- Your implanted receiver contains a removable magnet that 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.).

- Your implanted system is compatible with 1.5 Tesla MRI imaging devices. It is also compatible with 3 Tesla imaging devices but requires removal of the implant magnet prior to the exam. The MRI exam application form (available on www.oticonmedical.com) must be completed by the radiology department involved, and returned to Oticon Medical before any exam is carried out. The MRI exam has to be processed with head first.

Settings

Each sound processor is programmed by a **clinician authorised by Oticon Medical** for personal use and must not under any circumstances be lent to or exchanged with another person.

Electrostatic discharge

Electrostatic discharges are the visible sparks when there is contact between two people or with an object. They are encouraged by cold, dry climates. Contact with certain components can encourage the appearance of such discharges (clothes made of synthetic material, getting out of the car, plastic toboggan, computer or television screens, carpets, etc.). The Neuro One sound processor is designed to provide effective protection against these electrostatic discharge phenomena (compliance with NF EN 60601-1-2: 2007) 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 may come 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 closely 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.

Travelling by plane

As with any electrical equipment, it is essential to switch off your sound processor during take-off and landing.

Tools and Troubleshooting

1. Testing tools

Various functionalities and tools are made available to you in order to check that the Neuro One sound processor and its accessories are working properly:

- Indicator light.
- Private alarm to detect the end of battery life.
- Self Check function to check the integrity of the system.
- Microphone earphones.

It is important to clearly understand the way these tools work in order to best manage your equipment on a day-to-day basis.

Self Check function

Your sound processor integrates a function that is used to check that it is correctly sending the sound information to the implant and to thus check that the system and its accessories are working properly (antenna and antenna cable).

The test is carried out as follows:

- Position the antenna on the skin, opposite the implant.
- To carry out the test, press and hold the push button for 6 seconds.
- If the test is successful, an audible beep rings and the orange led flashes for 15 seconds.
- If the test reveals a malfunction, the led will illuminate continually and then briefly flash, twice consecutively.
- In case of an anomaly, refer to the chapter "Problems and Solutions".

Microphone earphones

The Neuro One sound processor is equipped with an auxiliary socket that enables one to listen to the audio signals which enter the sound processor. This accessory is used to identify problems on the microphone: microphone entry blocked, faulty microphone.

Warning: The quality of the sound heard with these earphones is not representative of the sound heard by the patient with his sound processor. For further information, refer to the "Accessories user manual" provided on the backup media included in this box.

This test tool is used as follows:

- Switch off the sound processor.
- Carefully connect the earphones to the sound processor's auxiliary socket observing the connection direction.
- Switch on the sound processor on a programme without any auxiliary input activated, to evaluate the sound quality received.
- Once finished using the sound processor, switch it off again before disconnecting the earphones.

Note: There is a risk of audio feedback when the earphones are too close to the microphone. The sound level received by another listener using the earphones is not representative of that heard by the patient. When using the microphone earphones, it is important that the sound processor should be turned to a programme without any auxiliary input activated, this to avoid an overconsumption error on the sound sound processor.



2. Problems and solutions

The Neuro One behind-the-ear sound processor requires numerous adjustments to identify the optimal listening quality. A check of the adjustment at least once a year is recommended to make sure that the implant system is working properly. For young children, parents and educators are specifically advised to supervise the behaviour of the child during use of the sound processor. In case of an abnormal feeling or pain during the routine use of the device, it is recommended to change the hook or remove the sound processor from the ear and contact the implant centre.

The combined use of the various testing tools as well as implementing the instructions presented below can assist in troubleshooting issues with the sound processor. If the problem persists, it is recommended that you contact your implant centre, local distributor or the Oticon Medical after-sales service.

No sound is received

1. Check the status of the sound processor (correct connection of the antenna cable, locking of the battery compartment, position of the selector wheel, programme selected).
2. Change both batteries.
3. Check the quality of the microphone using the microphone earphones.
4. Check that the antenna cable and the antenna are working properly using the integrated Self Check function ("Checking that the system works", "Repair, Tools, Problems and Solutions" section).
5. Change the antenna cable or the antenna.
6. Contact your implant centre, your local distributor or the Oticon Medical after-sales service.

Intermittent sound

1. Check that the position of the selector wheel and the programme selection are suited to the listening conditions.
2. Change both batteries.
3. Check that the care instructions are being observed.
4. Check the condition of the antenna cable and the antenna using the Self Check function.
5. Contact your implant centre, your local distributor or the Oticon Medical after-sales service.

Reduced or distorted sound

1. Check that the position of the selector wheel and the programme selection are suited to the listening conditions.
2. Try another programme.
3. Change the batteries.
4. Check the quality of the microphone using the earphones.
5. Contact your implant centre, your local distributor or the Oticon Medical after-sales service.

Quick flashing indicator light for one minute

1. Change both batteries.

The sound processor restarts and the indicator light flashes quickly then extinguishes

The sound processor detects an error. If the problem remains, contact your local distributor or the Oticon Medical after-sales service.

Insufficient battery life (less than a working day)

1. Change both batteries.
2. Check the type of batteries used (type P675 or PR44).
3. Check that the care instructions are being observed ("Care and user instructions" section).
4. Contact your implant centre, your local distributor or the Oticon Medical after-sales service.

Problem of holding the antenna

The antenna is held on the skin opposite the implant by means of a magnet.

If it is held too tightly:

1. Loosen the magnet by turning it in the direction indicated by the arrows (cf. the "Optimising hold" paragraph, in the "Using the Neuro One" section).
2. Ask for advice from your implant centre for changing the magnet (low force magnet provided in the box).

If it is not held tightly enough:

1. Re-tighten the magnet by turning it in the opposite direction to that indicated by the arrows (cf. "Optimising hold" paragraph, "Using the Neuro One" section).
2. Ask for advice from your implant centre in order to obtain a stronger magnet.

Note: The first time the magnet is unscrewed may prove difficult.

Important: Any equipment sent to your local distributor or the Oticon Medical after-sales service must be accompanied by a detailed description of the symptoms.















Warning: In case of skin redness or irritation during the routine use of the device, it is recommended to change the magnet force.

Miscellaneous Information

1. Technical characteristics

Sound processor	Maximum dimensions: 50.5 x 50 x 10.6 mm Weight (with batteries): 11.4 g
Power supply	Operating range of the device: from 1.8 V to 3.7 V 2 disposable 675 Zinc-Air batteries Maximum consumption: 60 mW Maximum transmission power: 35 mW
Storage and Transport Conditions	Storage and transport temperature: -20°C to 50°C Relative Humidity: 0 to 90% Atmospheric pressure: 700 hPa to 1060 hPa
Conditions of use	Operating temperature: 5°C to 40°C Relative Humidity: 0 to 90% Atmospheric pressure: 700 hPa to 1060 hPa

2. Symbols

	Refer to instruction manual.
	Waste electrical and electronic equipment (WEEE)
	Type B device
	Switching the sound processor on/off
	P675: "675" (European designation) or "PR44" (international designation) Zinc Air batteries +: Battery positioning direction
	Operating instructions
	Temperature limit to which the medical device can be exposed
	Humidity limit to which the medical device can be exposed
	Atmospheric pressure
	Manufacturer
	Date of manufacture
	Reference
	Serial number
	CE registration mark with notified body number. Indicates compliance with the requirements of the Active Implantable Medical Device Directive 90/385/EEC

3. Profile of the person handling the sound processor

The patient is the operator when he:

- Changes the batteries.
- Switches the sound processor on and off.
- Changes the programme.
- Connects and disconnects the antenna cable.


Children under seven years old must carry out these operations under the supervision of an adult.

4. 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 One sound processor. Therefore, these devices should be kept as far away as possible from the Neuro One and its accessories in order to avoid such effects.

Guidelines and manufacturer's declaration – Electromagnetic emissions	
The Neuro One sound processor is intended for use in the electromagnetic environment specified below. The Neuro One 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 One sound processor is intended for use in the electromagnetic environment specified below. The Neuro One 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	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 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 One sound processor is intended for use in the electromagnetic environment specified below. The Neuro One 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 ± 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						

Date of last review: 2018-01

Essential performance:

The Neuro One sound processor should stimulate below the thresholds defined in DigiMap USB within a 10% tolerance.

References of Neuro One sound processor, spare parts and accessories:

- Neuro One sound processor: M80336, M80337, M80338, M80339, M80340, M80341, M80342
- Antenna: M80344, M80346, M80793, M80795, M80343, M80345, M80792, M80794
- Antenna cable: A-SP9-ANL2-BL-6, A-SP9-ANL2-NBR-6, M80790, M80791; A-SP9-ANL2-BL-10, A-SP9-ANL2-NBR-10, M80923, M80924
- Magnet: M80755, M80754, M80753, A-SP9-MG2-BL-3, A-SP9-MG2-BL-4, A-SP9-MG2-BL-5, A-SP9-MG2-BL-6, A-SP9-MG2-BL-8, A-SP9-MG2-BL-10, M80925, M80926, M80927, M80928, M80929, M80930, M80931, M80932, M80761, M80760, M80759, A-SP9-MG2-NBR-3, A-SP9-MG2-NBR-4, A-SP9-MG2-NBR-5, A-SP9-MG2-NBR-6, A-SP9-MG2-NBR-8, M80933, M80934, M80935, M80936, M80937, M80938, M80939, M80940
- Protective case: M80349
- “Perfect Dry” heating desiccation drying system: 178020
- Zinc-Air batteries: 187503, 182397, 182398
- Ear hook: M80352, M80353
- Holding buckle: OA-BUCKL
- Microphone Earphones: M80351
- Neuro One Screwdriver: M80374
- Carrier: M80350
- Cleaning wipes: 4856
- Cover clip: OA-SLE-C-BLK, OA-SLE-C-NBR, OA-SLE-C-SIL, OA-SLE-C, OA-SLE-MIC-BLK, OA-SLE-MIC-NBR, OA-SLE-MIC-SIL
- USB memory stick: 07919
- Silhouette: M80379, M81113
- Identification Stickers Left/Right: M80334

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