PROPOSED PACKAGE INSERT

DEVICE DESCRIPTION

The Nucleus® 24 auditory brainstem implant (ABI) system is designed to provide useful hearing to individuals with Neurofibromatosis Type 2, who become deaf following surgery to remove bilateral auditory nerve tumors. The ABI system includes both surgically implanted and externally worn components. Externally worn components include the SPrint™ (body-worn) speech processor and a microphone/headset. Together, the external components transform acoustical signals in the environment into an electrical code. This coded information is then transmitted from the system's headset to a surgically implanted receiver/stimulator, where it is decoded and delivered to a multichannel electrode array. The system's 21-electrode array is surgically placed on the surface of the cochlear nucleus, which is the first auditory center within the brainstem. Electrical stimulation of the cochlear nucleus results in the signal's transmission to the brain, where it is interpreted as sound.

INDICATIONS

The Nucleus 24® ABI is intended to restore useful hearing via electrical stimulation of the cochlear nucleus. This device is indicated for individuals 12 years of age or older, who have been diagnosed with Neurofibromatosis Type 2 (NF2). Implantation may occur during first- or second-side tumor removal or in patients with previously removed acoustic tumors bilaterally. Because the surgical tumor excision and electrode placement eliminates residual hearing, preoperative audiological criteria are not relevant. Prospective implant recipients and their families should have appropriate expectations, regarding the potential benefits of an auditory brainstem implant, and should be highly motivated to participate in the rehabilitation process.

WARNINGS

Gamma Knife Radiation

Prospective implant recipients who have undergone gamma knife radiation should be considered with extreme caution, due to possible injury to the cochlear nucleus.

Medical Treatments Generating Induced Currents

Some medical treatments generate induced currents that may cause tissue damage or permanent damage to the brainstem implant. Warnings for specific treatments are given below.

- **Electrosurgery:** Electrosurgical instruments are capable of inducing radio frequency currents that could flow through the electrode array. **Monopolar**

electrosurgical instruments must **not** be used on the head or neck of ABI patients as induced currents could cause damage to neural tissues or permanent damage to the implant. **Bipolar** electrosurgical instruments may be used on the head and neck of patients; however, the cautery electrodes must not contact the implant and should be kept more than 1 cm (~1/2 in.) from the ground electrodes.

- **Diathermy or Neurostimulation:** Do not use diathermy or neurostimulation directly over the ABI. High currents induced into the electrode lead can cause tissue damage to the brainstem or permanent damage to the implant.

- **Electroconvulsive Therapy:** Do not use electroconvulsive therapy on an ABI patient under any circumstances. Electroconvulsive therapy may cause tissue damage to the brainstem or damage to the implant.

Ionizing Radiation Therapy

Do not use this therapy directly over the ABI because it may cause damage to the implant.

Magnetic Resonance Imaging (MRI)

Magnetic Resonance Imaging (MRI) is contraindicated except under the circumstances described below. Do not allow patients with a Nucleus 24 ABI to be in the room where an MRI scanner is located except under the following special circumstances.

The Nucleus 24 ABI has a removable magnet and specific design characteristics to enable it to withstand MRI up to 1.5 Tesla, but not higher. If the ABI's magnet is in place, it must be removed surgically before the patient undergoes an MRI procedure.

The patient must take off the speech processor and headset before entering a room where an MRI scanner is located.

If the implant's magnet is still in place, tissue damage may occur if the recipient is exposed to MRI. Once the magnet is surgically removed, the metal in the auditory brainstem implant will affect the quality of the MRI. Image shadowing may extend as far as 6 cm from the implant, thereby, resulting in loss of diagnostic information in the vicinity of the implant.

All Nucleus ABI devices have removable magnets. However, if the physician is unsure that the patient has a Nucleus 24 ABI, an x-ray may be used to check the radiopaque lettering on the device. There are three platinum letters printed on the receiver/stimulator portion of each Nucleus auditory brainstem implant. If the middle letter is a "G", the implant is a Nucleus 24 ABI. Once the magnet has been removed, MRI can be performed.

If you require additional information about removal of the magnet, please contact Cochlear.

Long-term Effects of Electrical Stimulation

Most patients can benefit from electrical stimulation levels that are considered safe, based upon both theoretical and animal experimental data. For some patients, the levels needed to produce the loudest sounds exceed these levels. The long-term effects of such stimulation in humans are unknown.

Ingestion of Small Parts

Parents and caregivers should be counseled that the external implant system contains small parts, which may be hazardous if swallowed.

Head Trauma

A blow to the head in the area of the receiver/stimulator may damage the implant and result in its failure.

PRECAUTIONS

Use of Another Person's Speech Processor

ABI recipients should never use another person's speech processor. The information programmed into the processor is customized for individual use and it is not suitable for another person. Use of another person's speech processor may cause uncomfortably loud or distorted sounds, or unanticipated nonauditory side effects.

Theft and Metal Detection Systems

Devices such as airport metal detectors and commercial theft detection systems produce strong electromagnetic fields. Some ABI recipients may hear distorted sounds when passing through or near one of these devices. To avoid this, turn off the speech processor when in the vicinity of one of these devices. The materials used in the ABI may also activate metal detection systems. For this reason, recipients should carry the Auditory Brainstem Implant Patient Identification Card with them at all times.

Electrostatic Discharge

A discharge of static electricity can damage the components of the ABI system or corrupt the program in the speech processor. Static electricity may be generated, for example, when putting on or removing clothes over the head or when getting out of a vehicle. ABI recipients should touch something conductive, such as a metal door handle before the ABI system contacts any object or person. Prior to engaging in activities that create extreme

electrostatic discharge, such as playing on plastic slides, the speech processor and headset should be removed.

Clinicians should use an anti-static shield on the computer monitor when programming an ABI recipient.

Mobile Telephones

Some types of digital mobile telephones may interfere with the operation of the speech processor or headset. Recipients may hear distorted sounds within 1-4 meters (3-12 feet) of a digital mobile telephone in use.

Bilateral Implantation

The efficacy of bilateral implantation with the ABI has not been studied.

ADVERSE EVENTS

Safety data are based on a total of 90 patients implanted with the Nucleus® 22 ABI device during the clinical investigation. Twenty-six patients experienced a total of 28 medical or device-related complications. Twenty-two of the 28 complications were medical/surgical in nature and the remaining six were device related. Twenty-six of the 28 complications resolved without surgical or extensive medical intervention.

Medical/Surgical Complications

Sixteen of the 90 (17.8%) ABI recipients were not able to perceive sound with the ABI. This was either due to migration of the electrode array during the postoperative period (9 patients), or to misplacement of the electrode array at the time of surgery (7 patients). Two additional patients experienced postoperative flap complications and, in both cases, surgical explantation of the ABI was required. Four patients experienced minor complications that resolved with noninvasive medical treatment (1 patient), reprogramming of the speech processor (2 patients), or spontaneously without intervention (1 patient). The first of these four patients experienced a build-up of fluid beneath the skin flap, the second reported dizziness, blurred vision and tinnitus during the perioperative period, the third reported lightheadedness and dizziness during periods of ABI use, and the fourth patient experienced headaches when using the device.

Device-related Complications

No device failures or other serious device malfunctions occurred during this study. Two patients experienced a mild skin reaction to the ABI's retainer disk. One case was resolved by temporarily reducing the patient's daily use time, and the second by providing the patient with an alternative method of adhesion. During the study period, two patients reported transient changes in the ABI's sound quality. These resolved over time in one

case, and with device reprogramming in the second. Device reprogramming resolved one additional patient's report of pain, caused by activation of two specific electrode channels. A final patient reported hearing a transient popping sound that, subsequently, resolved without treatment.

In addition to the adverse events experienced during the clinical study, the following potential adverse events could occur:

- Individuals are exposed to the normal risks associated with surgery and general anesthesia. In addition, this procedure may result in infection or bleeding, numbness or stiffness around the ear, injury to or stimulation of the facial nerve, taste disturbance, dizziness, increased tinnitus, neck pain and leakage of cerebral spinal fluid. Leakage of cerebral spinal fluid may result in meningitis.

- Risks include those generally associated with a craniotomy operation, in addition to those associated with the implantation of the ABI electrode and receiver/stimulator. Potential recipients should understand that circumstances encountered during surgery may preclude placement of the ABI, and also that the tumor removal surgery results in a total loss of hearing on the operated side.

- The ABI results in a palpable lump under the skin behind the ear. The presence of a foreign body may cause irritation, inflammation or breakdown of the skin and in some cases, extrusion of the device.

- Postoperatively, the electrode array may migrate partially or completely away from the cochlear nucleus, resulting in decreased hearing, a complete loss of sound perception, and/or increased nonauditory sensations. In addition, if the electrode array is misplaced at the time of surgery, the recipient will not receive functional benefit from the device. Such complications may require additional medical treatment, surgery, and/or removal of the ABI.

- Electrical stimulation may result in increased tinnitus, facial nerve stimulation, dizziness or pain. In addition, electrical currents generated by the ABI may spread and stimulate other adjacent brainstem structures. This may produce a variety of nonauditory sensations or movements, such as a tickling sensation in the back of the throat, visual field disturbances, and sensations and/or movements in a limb. In rare cases, electrical stimulation may cause other neurological sequellae that may be severe.

- The long-term effects of electrode insertion and chronic electrical stimulation are unknown. Such effects may preclude replacement of the electrode array, or may lead to eventual deterioration of nerve cells in the central auditory nervous system.

- Failure of component parts (both external and internal) could result in the perception of uncomfortably loud sounds, the complete absence of sound, or in unwanted nonauditory sensations. Failure of various parts of the implanted device could require

its removal and/or replacement, or could result in a reduced number of useable electrodes.

CLINICAL STUDY RESULTS

Clinical Results – Nucleus® Auditory Brainstem Implant System

The effectiveness of the auditory brainstem device, programmed to implement the SPEAK speech processing strategy, was assessed in 60 recipients of the Nucleus 22 ABI system, following three-to-six months of device use. Effectiveness was measured using a standard battery of recorded audiological tests, including measures of environmental sound identification, closed- and open-set speech perception, and lipreading enhancement. The environmental sounds and speech perception tests were administered to subjects in quiet, at 70 dB SPL. For each of these sound-alone tests, individual subject results were compared to chance performance levels, using a binomial statistical model. Lipreading enhancement was assessed using medially placed vowels, consonants and CUNY sentence materials. Using the binomial statistic, each subject's performance in the vision-alone condition was compared to his or her performance when lipreading was supplemented with sound from the ABI. As a final measure of effectiveness, 44 of the 60 (73%) subjects completed and returned postoperative questionnaires, regarding device-related benefits.

Effective Auditory Stimulation

- Eighty-two percent of the implanted subjects were able to perceive sound and use the device postoperatively.

Identification of Environmental Sounds:

- Eighty-two percent of the subjects scored significantly above chance on a recorded, closed-set test of environmental sound identification.
- Using the ABI, subjects recognized 53.9% of common environmental sounds, on average, and 65% of the sample recognized 50% or more of the sounds.

Lipreading Enhancement:

- Eighty-five percent of the subjects demonstrated statistically significant improvements in open-set sentence understanding, when using the ABI in conjunction with lipreading.
- The average sentence recognition score improved from 31.2% for lipreading alone, to 53.5%, when subjects combined auditory information from the ABI with lipreading.

Open-set Sentence Recognition:

- Using sound alone, 12% of study participants scored greater than 10%, on a difficult open-set test of sentence understanding.

Questionnaire Results:

- Sixty-one percent of the subjects who received the device following removal of their second-side tumor, reported using the ABI on a daily basis for ten or more hours.

- Eighty percent of the respondents reported receiving benefit from the auditory brainstem implant and 84% indicated that the decision to get the ABI was the right one.

- Seventy-three percent of the respondents would recommend an ABI to others.

MAGNETIC RESONANCE IMAGING (MRI) TESTING

The Nucleus 24 ABI System, with the magnet removed, has been tested with an MRI machine having a 1.5 Tesla static field, a 64 MHz RF pulsed field, and pulsed gradient fields up to 20 Tesla/sec with the following results:

- Pulsed gradient fields up to 20 Tesla/sec and with worst-case electrode position do not produce any stimulus output from the ABI.
- There was no observable temperature rise (<0.1°C), in the vicinity of the implant during worst-case imaging of the head.
- There can be image distortion. With worst-case scan parameters, there was a darkening of the image in an area around the implant, extending approximately 2 cm medially and 6 cm inferiorly. The area of darkening was largest in axial scans.

The MRI static field exerts a small force on the implant. The maximum force is less than the normal weight of the implant. This may be perceptible during the MRI procedure, but is not harmful.

INDIVIDUALIZATION OF TREATMENT

Patient Selection Criteria

1) Diagnosis of Neurofibromatosis Type 2;
2) First-side or second-side acoustic tumor removal required (or previous bilateral tumor removal);
3) 12 years of age or older;
4) Psychologically and motivationally suitable.

Clinical Considerations

In order to place the electrode array on the surface of the cochlear nucleus, the surgeon must be able to visualize specific anatomical landmarks. Because many NF2 patients have large tumors that compress the brainstem and distort the underlying anatomy, it may be difficult or impossible for the surgeon to correctly place the array. For this reason, patients with large, longstanding tumors may not benefit from the ABI device, postoperatively. In this series of patients, 16 of the 90 recipients (17.8%) were unable to use the ABI system, postimplantation, due to misplacement or migration of the electrode array.

Patients who receive the ABI at the time that their first tumor is removed, and who have useable hearing in the contralateral ear, are unlikely to use the ABI device on a regular basis. Most often, these recipients assume full-time use of the device, following the surgical removal of their second-side tumor.

PATIENT COUNSELING

Preoperative Counseling

Prospective ABI candidates should be counseled regarding the potential benefits, warnings, precautions and adverse effects associated with auditory brainstem implantation, using the information in this document.

STORAGE, HANDLING, AND STERILIZATION

Store ABI implants at temperatures between –20 and +50 degrees Centigrade. Implants are not subject to aging, however, the certificate of sterilization is valid for 24 months. The "use by" date is stamped on the outside package. If it has expired, return the device to Cochlear.

Handle the implant packages with care. Severe impact that damages the outer storage package may rupture the inner sterile package.

Auditory brainstem implants are supplied sterile in gas-permeable packaging. The titanium plugs are supplied separately in sterile gas-permeable packaging, for use when the magnet is removed. These are single use items. The sterilizing gas, ethylene oxide, turns the indicator bar in the inner package blue. Before opening the sterile package, inspect it carefully. If the sterile package is broken or the indicator bar is not blue, return the device to Cochlear.

INFORMATION FOR USE AND RECOMMENDED TRAINING

Physicians should have extensive experience in acoustic tumor removal surgery. They should be thoroughly familiar the anatomy of the 4th ventricle and the ABI surgical

procedure, and should have experience in cochlear implantation. It is essential that ABI surgeons work with an experienced team of audiological, neurosurgical, neurological, and electrophysiological professionals. The implanting physician and ABI team should attend training sponsored by Cochlear. In addition, a surgical consultant, designated by Cochlear, who is experienced in the procedure, must support each physician's first ABI surgery.

Caution: Federal law restricts this device to sale, distribution and use by or on the order of a physician.

For more information contact:

Cochlear Corporation
61 Inverness Drive East, Suite 200
Englewood, CO 80112
USA

Tel: 1 303 790 9010
Fax: 1 303 792 9025

Cochlear

User Manual Addendum

for the SP*rint*™ speech processor and accessories

For recipients of the Nucleus ABI24M auditory brainstem implant

Nucleus® 24 Auditory Brainstem Implant System

About this document

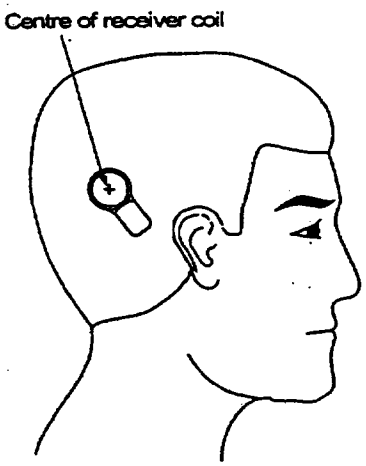
The SPrint speech processor used in conjunction with the Nucleus ABI24M auditory brainstem implant is identical to that used with the Nucleus CI24M cochlear implant. The "User Manual for the SPrint Speech Processor and Accessories" (N02223F ISS1 MAY97) assumes that users have a Nucleus cochlear implant. The following addendum reflects the minor differences in terminology and revised instructions where necessary assuming the user has an auditory brainstem implant.

ADDENDUM NOTES:

p.5,6,51,52,59,61,62,63,64,65,66 : References to cochlear implant
On all occasions when the word "cochlear implant" is mentioned, please replace with the word "auditory brainstem implant".

p.20 : Wearing the Headset
Before 1st paragraph please insert the following text:

If the internal magnet of your auditory brainstem implant has been removed, the transmitter coil must be held in position either by use of a lightly **elasticated headband** or with an adhesive **magnet retainer disk** (available from Cochlear). Your clinic should advise you if your device does not have a magnet. In this case the transmitter coil must be placed towards the rear of the bump formed by the implant. Correct positioning may be assisted by turning on the speech processor and moving the coil over the implant until a tone is heard. The diagram below shows the optimum position for the transmitter coil, directly above the centre of the implant's corresponding receiver coil.



If magnet retainer disks are being used an area of skin must be exposed on the scalp directly over the receiver coil. A circular patch of hair (approx. 15mm in diameter) should be trimmed away, a few millimetres above the centre position for the transmitter coil. The exposed skin should be wiped clean with a cloth moistened with 70% isopropyl alcohol - available from most chemists. When the skin is dry the backing of the retainer disk should be peeled off and the disk pressed firmly to the scalp. When attached the transmitter coil will not sit directly over the retainer disk hence you should position the coil so that it rests just below the magnetic pad and therefore in the centre of the receiver coil. Retainer disks should be renewed every 1-3 days as required. Keep the exposed skin clean and dry, trimming away excess hair as required.

p.58 : Sounds are uncomfortably loud

After the above section please add the following text:

I feel unwell when using my ABI

If you feel dizzy or unwell and these feelings are connected with periods of use of your auditory brainstem implant please discontinue use and contact your implanting centre immediately.

p.61 : Warnings

Please replace the entire section on "Warnings" (p.61-63) with the following text:

Warnings

Electrosurgery

Electrosurgical instruments are capable of inducing radio frequency currents that could flow through the electrode array.

Monopolar electrosurgical instruments must **not** be used on the head or neck of a brainstem implant patient as induced currents could cause damage to brainstem tissues or permanent damage to the implant.

Bipolar electrosurgical instruments may be used if the cautery electrodes are kept more than 10 cm (4 inches) from the extracochlear electrodes.

Diathermy or Neurostimulation

(Neurostimulation applies to implants with extracochlear electrodes.) Diathermy must never be applied over the receiver/stimulator or electrode lead of the brainstem implant. High currents induced into the electrode lead can cause tissue damage to the brainstem or permanent damage to the implant.

Electroconvulsive Therapy

Electroconvulsive therapy must never be used on a brainstem implant patient. Electroconvulsive therapy may cause tissue damage to the brainstem or damage to the implant.

Ionizing Radiation Therapy

Do not use such therapy directly over the brainstem implant since it may be damaged.

Magnetic Resonance Imaging (MRI)

The brainstem implant is designed to be MRI compatible. The implant has a removable magnet and specific characteristics designed to enable it to withstand magnetic resonance imaging up to 1.5 Tesla. If the magnet is still in place, tissue damage may occur if the recipient is exposed to MRI. In this case MRI is contraindicated. Do not allow a brainstem implant recipient without the magnet removed to be in a room where an MRI scanner is located. Once the magnet has been removed, MRI can be performed.

If you require information about removal of the magnet please consult the Surgeon's Guide or contact Cochlear.

Electrical Stimulation

Most patients can benefit from electrical stimulation levels that are considered safe, based upon both theoretical and animal experimental data. For some patients, the levels needed to produce the loudest sounds exceed these levels. The long-term effects of such stimulation in humans are unknown.

Ingestion of Small Parts

The external implant system contains small parts which may be hazardous if swallowed.

Head Trauma

A blow to the head in the area of the receiver/stimulator may damage the internal device and result in its failure.

p.64 : Precautions

Please replace the entire section on "Precautions" (p.64-66) with the following text:

Precautions

If you experience a significant change in performance or if the sound becomes uncomfortable, or if you feel dizzy or unwell, turn off your speech processor and contact your implant centre.

Use the Auditory Brainstem Implant system only with the approved devices and accessories listed in this manual.

The speech processor and other parts of the system contain complex electronic parts. These parts are durable but must be treated with care. The speech processor must not be opened by anyone other than Cochlear's qualified service personnel or the warranty will be invalidated.

Each speech processor is programmed specifically for each individual. Do not wear another person's speech processor or lend yours to another user. Use of another person's speech processor could result in the perception of an uncomfortably loud or distorted sound sensation or a painful non-auditory side effect, or even disturbance to heart function.

Do not expose the speech processor to temperatures greater than 50°C (122°F) or less than 5°C (41°F).

The speech processor sound quality may be intermittently distorted when you are within approximately 1.6km (1 mile) of a radio or television transmission tower. The effect is temporary and will not damage the speech processor.

Theft and Metal Detection Systems

Devices such as airport metal detectors and commercial theft detection systems produce strong electromagnetic fields. Passing through or near one of these fields may result in a distorted sound sensation for some brainstem implant recipients. This can be avoided by turning off the speech processor when in the vicinity of

one of these devices. The materials used in the brainstem implant may also activate metal detection systems. For this reason, it is recommended that recipients carry the Auditory Brainstem Implant Patient Identification Card with them at all times.

Electrostatic Discharge

A discharge of static electricity can damage the electrical parts of the brainstem implant system or corrupt the program in the speech processor. If static electricity is present (e.g. when putting on or removing clothes over the head or getting out of a vehicle), implant recipients should touch something conductive (e.g. metal door handle) before the implant system contacts any object or person. Prior to engaging in activities that create extreme electrostatic discharge, such as children playing on plastic slides, the speech processor and headset should be removed. Clinicians should use an anti-static shield on the computer monitor when programming a brainstem implant recipient.

Mobile Telephones

Some types of digital mobile telephones (e.g. GSM) may interfere with the operation of the external equipment. As a result, brainstem implant recipients may perceive a distorted sound sensation when in close proximity, 1–4 meters (3–12 feet) to a digital mobile telephone in use.

Air Travel

Some airlines request that passengers turn off electrical equipment, such as laptop computers during take-off and landing or whenever the seat belt sign is illuminated. Your speech processor is a computer and therefore it should be turned off when such a request is made. You should notify airline personnel of your hearing impairment so they can alert you to safety measures.

p.71 : Specimen Declaration of Conformity (Active Implantable Medical Device)
Replace the whole Specimen Declaration of Conformity with the following text:

SPECIMEN DECLARATION OF CONFORMITY
(Active Implantable Medical Device)

Manufacturer
Cochlear AG
Margarethenstrasse 47
CH-4053 Basel
Switzerland

Plant
Cochlear Limited
14 Mars Road
Lane Cove NSW 2066
Australia

We hereby declare that the following products:

NUCLEUS® AUDITORY BRAINSTEM IMPLANT SYSTEM

Implant model:	ABI24M
Speech processor models:	SPrint, ESPrit
Diag. & Programming System:	CPS, PPS
Software:	DPS7, WinDPS, NRT and accessories

conform with the essential safety requirements listed in Annex I of the EC Directive on Active Implantable Medical Devices (90/385/EEC).

This declaration is supported by:

EC Design-Examination Certificate according to EC Directive 90/385/EEC Annex 2, Article 4; issued by Notified Body 0197 on 27.11.1996 and EC Design-Examination Certificate according to EC Directive 90/385/EEC Annex 2, Article 4; issued by Notified Body 0197 on .....(TBA)

Approval for a Full Quality Assurance System according to EC Directive 90/385/EEC Annex 2, Article 3; issued by Notified Body 0197 on 30.04.1996

Certificate for a Quality Management System according to DIN ISO 9001/DIN EN 46001 issued by Notified Body 0197 on 30.054.1996.

Basel, April 1999

Dr. M Lehnhardt
Chief Executive Officer
Cochlear AG

CE 0197

END OF ADDENDUM NOTES

N02486F ISS1

User Manual

for the **SP*rint***™ speech processor and accessories

Nucleus® 24 Cochlear Implant System

Cochlear

User Manual

for the SP*rint*™ speech processor and accessories

Part Number: N02210F Issue 2
May 1998.

Contents

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Introduction

The Nucleus® 24 cochlear implant system consists of three parts:

- The CI24M cochlear implant
- The SPrint™ speech processor
- The HS8 headset

Together these three parts convert sounds from the environment into coded electrical information that is interpreted by your brain as sound.

This manual is intended for use by adult and adolescent cochlear implant users. It may also assist caregivers, teachers and other adults involved with children who use the implant.

This manual contains:

- Instructions on fitting, using and caring for the speech processor, headset and accessories
- Troubleshooting procedures
- Basic technical information
- Warnings and precautions

Using the Accessories

Caring for the System

Warnings and Precautions

General Information

Quick Reference Guide

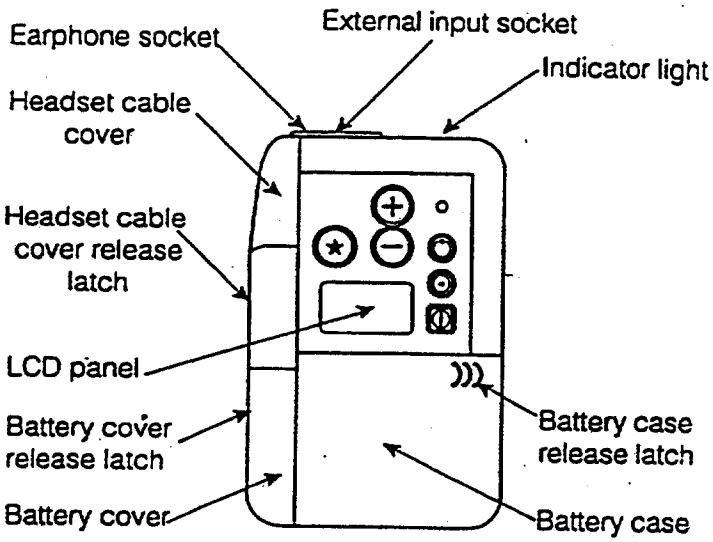
Inside the back cover of this manual is a Quick Reference Card that you may tear out and carry with you. For further information, contact your implant center or your clinician for expert advice.

This manual does not describe the operation of the cochlear implant. Please contact your implant surgeon or implant center for more information.

Understanding the Cochlear Implant System

The SPrint™ Speech Processor

The speech processor is a small computer worn on your body and connected to the headset by cables. It receives sounds from a microphone in the headset, converts them to electrical signals and sends the signal back to the headset.



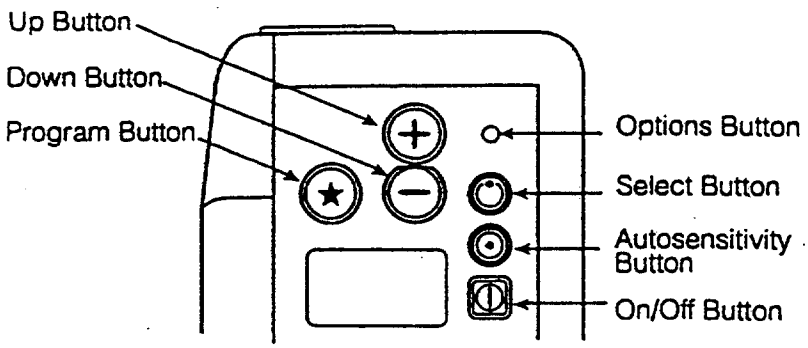
Front view of the SPrint speech processor

Features

The speech processor incorporates the following features, designed to optimise its performance and ease of use:

- Up to 4 different listening programs customized for different conditions
- A volume control in addition to the microphone sensitivity control
- An autosensitivity control
- A liquid crystal display (LCD) panel to display control settings and symbols
- An external input socket, enabling the speech processor to accept signals directly from external devices
- A red indicator light at the top of the speech processor, which indicates that the batteries are working and your microphone is picking up sounds
- Detachable battery cases; a standard two-battery case and a smaller one-battery case as an alternative
- An optional button lock, which disables some buttons to prevent users from accidentally changing the speech processor settings
- An optional personal alarm, which provides users with signals that indicate when settings have been changed or the battery level is low
- An optional public alarm, for use with children, which provides signals that are audible to bystanders

Control Buttons



Controls on the speech processor

The speech processor is controlled by a set of push buttons, and an LCD panel displays information for the user.

- The On/Off button ( ) turns the speech processor on and off. The speech processor uses power whenever it is on, even if you are not using it.
- The Program button ( ) selects one of the programs your clinician has created for you.
- The Select button ( ) provides access to the button lock and the microphone sensitivity and the volume controls (provided your clinician has enabled the volume control for the current program).
- The Options button ( ) provides access to the alarm features of the speech processor.
- The Up ( ) and Down ( ) buttons adjust the microphone sensitivity and the volume, and turn the button lock and alarm features on or off.
- The Autosensitivity button ( ) turns the autosensitivity feature on and off.

LCD Panel

When the speech processor is turned on, the LCD panel displays:

- The active program
- Symbols and settings for the active listening control, either the microphone sensitivity or the volume
- Symbols to indicate active features and diagnostics

Indicator Light

The indicator light activity depends on the battery level.

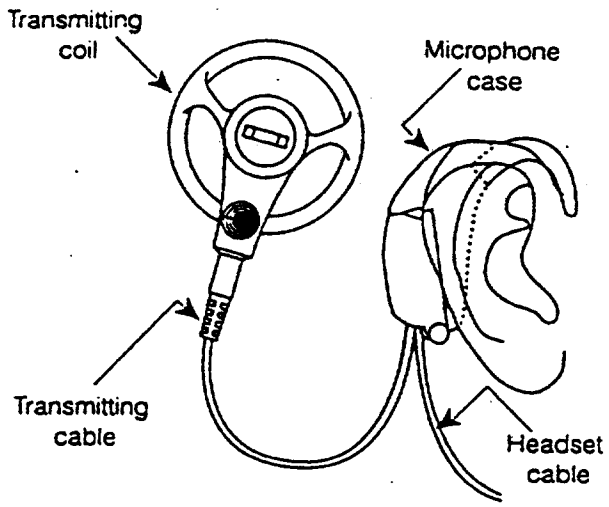
- When the battery level is normal, the indicator light varies in brightness in response to the level of sound you receive
- When the battery level is low, the indicator light blinks slowly
- When the batteries are dead, the indicator light turns off

HS8 Headset

The headset consists of:

- A transmitting coil worn over the implant
- A microphone case worn behind the ear
- A short transmitting cable to connect the transmitting coil to the microphone
- A long headset cable to connect the microphone to the speech processor

The transmitting coil is held securely in place by magnetic attraction between a magnet in the coil and a magnet in the implanted unit. The magnet in the coil may be adjusted for comfort.



The HS8 headset

High Energy NiCad Charger

The High Energy NiCad Charger recharges the nickel cadmium (NiCd) batteries supplied for use with the speech processor.

The charger includes the following features:

- A charge time of six hours (overnight)
- Protection against overcharging
- Charging of one or two NiCd batteries on separate charging and timing circuits. You may insert a battery into the second slot at any time to recharge it independently of the first
- Lights that indicate when batteries are properly inserted and when charging is complete

Accessories

Cochlear provides a range of accessories designed to enhance the usefulness of the speech processor.

The following accessories are available:

- Pouches in various sizes and styles
- Lapel microphone and lapel clips
- Microphone lock (mic lock)
- Microphone sleeve
- Dry pack
- Telephone adaptor
- TV/Hi-Fi cable
- Personal audio cable
- Monitor earphones
- Signal check
- Telecoil

Some accessories may not be available in all regions. Please contact the Cochlear office or distributor in your region for more information.

Using the System

At the initial programming session, your clinician will help you set up your speech processor and headset using the following procedure:

1. Insert batteries into the speech processor.
2. Assemble the headset and connect it to the speech processor.
3. Fit the speech processor and headset so they are comfortable to wear.
4. Turn on the speech processor and select the appropriate program.
5. Adjust the microphone sensitivity.
6. Adjust the volume (if your clinician has enabled it).

These procedures are described in detail on the following pages.

Fitting the Speech Processor

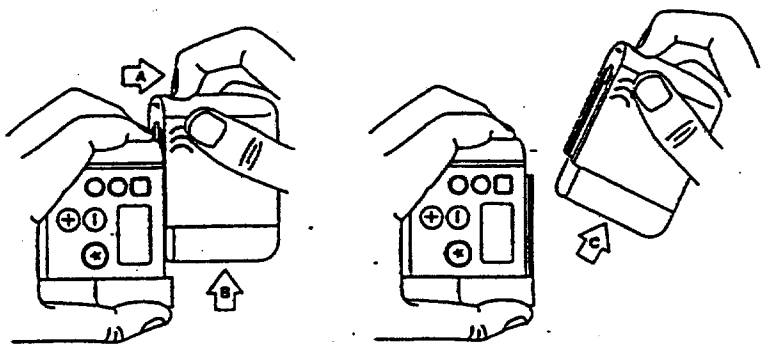
Changing the Battery Case

The speech processor comes fitted with a two-battery case. Cochlear also supplies an alternative one-battery case.

With the one-battery case, the speech processor is smaller but you will need to replace the battery more frequently.

To replace the battery case:

1. Grasp the body of the speech processor in your left hand.
2. Grasp the battery case with your right hand and put your right index finger in the battery case release latch.
3. Slide the release latch (A) and then slide the battery case (B) to separate it from the speech processor (C).



Removing the battery case

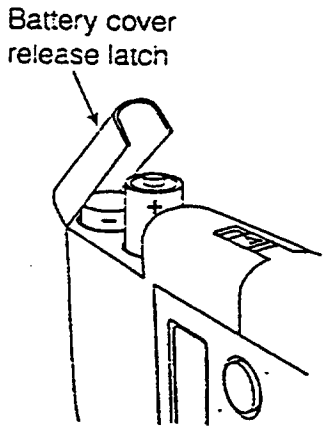
4. Slide the replacement battery case along the runner at the base of the speech processor until it clicks into position.

Inserting the Batteries

Before inserting NiCd batteries into the speech processor, ensure they are fully charged (see 'Recharging NiCd Batteries').

To insert batteries into the speech processor:

1. Put your thumbnail in the battery cover release latch. Slide the latch and pull the battery cover back. Do not attempt to remove the cover completely.



2. Slide in the new batteries in the orientation shown in the diagram on the back of the battery case.
3. Push the battery cover back into place.

Wearing the Speech Processor

You may choose to wear your speech processor in various ways:

- Attached to your belt or waistband using the belt clip on the back of the speech processor
- In one of the pouches supplied by Cochlear
- In a shirt or blouse pocket
- In a cloth pocket attached to the inside of your clothing

Removing the Belt Clip

To remove the belt clip on the back of the speech processor, remove the battery case and slide the clip off the back of the speech processor.

Using the Pouches

Three pouches are available:

- Pouches for the one-battery case and the two-battery case are designed to be worn on a belt or inside a pocket
- A pouch with a harness so it can be worn on a child's back or chest

To fit the pouch, turn off the speech processor and remove the belt clip. Open the pouch flap and gently pull the pouch over the speech processor battery case. Slide the pouch on until you can see all the control buttons through the large opening on the front of the pouch.

To remove the pouch, open the pouch flap and push the speech processor up from the bottom until you can grip it easily. Slide off the pouch.

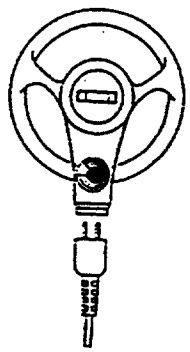
Fitting the Headset

Assembling the Headset

When assembling the headset, do not pull on the headset or transmitting cables – grasp only the connectors. If you have trouble assembling the headset, ask your clinician to help you.

Connecting the Transmitting Coil

Plug the two-pin connector on the transmitting cable into the socket in the transmitting coil.



Attaching the connector to the transmitting coil

Connecting the Microphone Cables

1. Hold the microphone case with one hand and put your thumbnail in the slot on the microphone cover. Remove the microphone cover by pulling it away from the microphone case.

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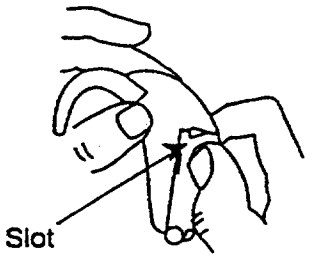
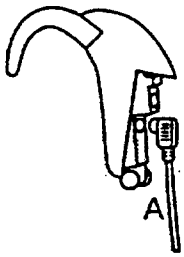
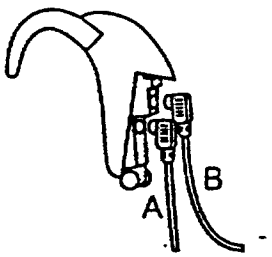


2. Plug the orange connector on the headset cable (A) into the orange socket at the bottom of the microphone case.



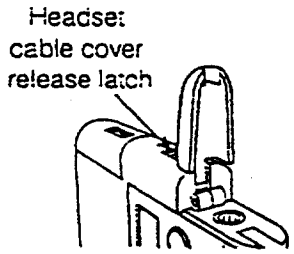
3. Plug the other connector on the transmitting cable (B) into the socket at the top of the microphone case.



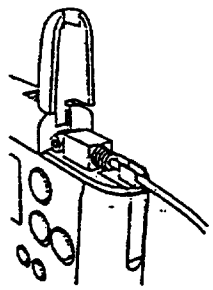
4. Slide the cover hinge over the cables and then over the plastic lip at the bottom of the microphone case. Do not force the hinge over the lip. Ensure the cables extend from the bottom of the microphone case.
5. Close the microphone cover.

Connecting the Headset to the Speech Processor

1. Turn off the speech processor.
2. Hold the speech processor with one hand and put your thumbnail in the headset cable cover release latch. Slide the latch and pull the headset cable cover back.



3. Plug the large end of the headset cable into the socket and lay the cable in the groove just above the socket.



4. Hold the cable in the groove while you click the cover closed. Ensure that the cable comes through the hole at the top of the case.

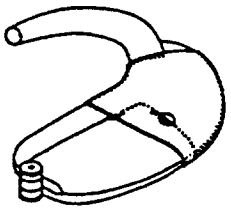
When removing or fitting your cochlear implant system you may wish to disconnect the headset from the speech processor. To do this, unplug the headset cable from the speech processor. Leave the headset cable plugged into the microphone.

Wearing the Headset

Hook the microphone earhook over your ear and place the transmitting coil over the implant.

Locking the Microphone Cover

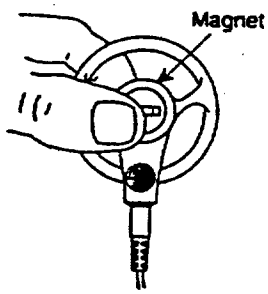
Cochlear supplies a sleeve that slides over the microphone cover to prevent young children tampering with the microphone cover.



To use the sleeve:

1. Unscrew the earhook from the microphone.
2. Slide the sleeve over the end of the microphone.
3. Screw the earhook back into place.

Adjusting the Magnet



Your clinician should adjust the magnet in the transmitting coil to a comfortable strength.

To hold the transmitting coil more firmly against your head, turn the magnet in the coil clockwise. To hold the coil less firmly against your head, turn the magnet counter-clockwise. If the magnetic force is too weak, the coil may fall off. If the magnetic

force is too strong, it may cause discomfort or skin irritation.

Cochlear supplies the transmitting coil with a standard strength magnet but a number of alternative strength magnets are available. Consult your clinician before choosing a magnet of a different strength. To remove the magnet, turn it counter-clockwise. Insert the replacement magnet and turn it clockwise to a stable and comfortable position.

To keep the required magnetic force to a minimum, you may occasionally need to trim or shave your hair in the area over the implant to about 6 mm (1/4 in) or less. The patch of trimmed hair can be concealed by the rest of your hair. Ask your clinician to teach you how to do this or contact your implant center for advice.

Alternative Parts

Cochlear supplies the headset with a standard 11 cm (4 in) transmitting cable, but 8 cm (3 in), 20 cm (8 in) and 28 cm (11 in) transmitting cables are also available. The 20 cm and 28 cm cables enable the microphone case to be worn over the ear on the side opposite to the implant.

Cochlear supplies the headset with a 100 cm (39 in) headset cable for adults; 60 cm (24 in) headset cable for children, but 80 cm (31 in) cables and 45 cm (18 in) are also available.

You may wish to carry a spare headset and transmitting cable with you.

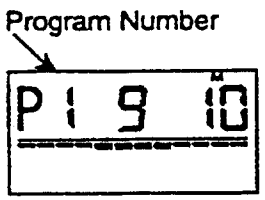
A small earhook and a large earhook are supplied with the headset.

Turning on the Speech Processor

Press the On/Off ( ) button to turn on the speech processor. The speech processor takes about a second to perform its start-up checks. The LCD panel then displays the program number and the listening control settings.

Press the On/Off button again to turn off the speech processor.

Selecting a Program



The speech processor can store up to four speech processing programs at any one time, enabling your clinician to develop programs for different listening environments.

The speech processor labels the programs from P1 to P4 and displays the current program number on the LCD panel.

To change to the next program in the sequence, press the Program button (⊙) . If a program is not installed, the speech processor skips to the next available program. The speech processor retains the current program setting until you press the Program button again, even if you turn off the speech processor.

Adjusting the Listening Controls

The speech processor features both a microphone sensitivity and a volume control.

- The microphone sensitivity controls the softest level of sound picked up by the microphone.

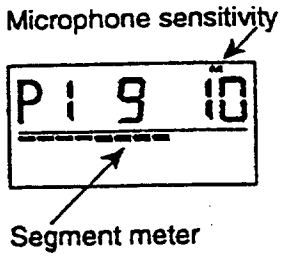
  Reduce the sensitivity to filter out background noise. Increase the sensitivity in quiet environments to hear very soft sounds.

- The volume controls your perception of loudness.

  Reduce the volume if loud sounds are uncomfortably loud. Increase the volume if speech, including your own voice, is too soft.

Your clinician may choose to disable your volume control. If both the microphone sensitivity and the volume controls are available, press the Select (⭘) button to alternate between them. The LCD panel displays the active control.

Adjusting the Microphone Sensitivity



If you use the microphone sensitivity control, the speech processor displays a small 'M' at the top of the LCD panel. Underneath, the LCD panel displays the microphone sensitivity as a number between 0 and 20. For normal conversation, you would typically set the sensitivity to approximately 8.

The speech processor also displays the signal level picked up by the microphone in a 12-segment meter. The meter fluctuates according to the level of sound received.

To adjust microphone sensitivity:
Press the Select (⭘) button until the 'M' symbol appears on the LCD panel.

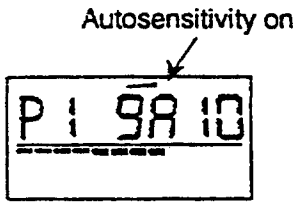
- To increase the sensitivity, press the Up (⊕) button
- To decrease the sensitivity, press the Down (⊖) button

If you need to set the microphone sensitivity consistently higher than ten, consult your clinician.

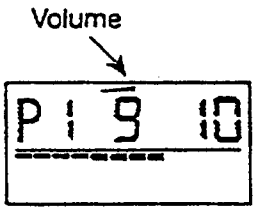
The microphone sensitivity setting is saved with the current program. If you select another program, the microphone sensitivity will change to the setting saved with that program.

Using Autosensitivity

When autosensitivity is turned on, the microphone sensitivity will decrease automatically in a noisy environment. To activate autosensitivity press the autosensitivity button (⊙). When autosensitivity is on, the speech processor displays the letter 'A' on the LCD panel.



Adjusting the Volume



If you use the volume control, the speech processor displays a small triangle at the top of the LCD panel. Underneath, the LCD panel displays the volume as a number between 0 and 10.

To adjust the volume:

1. Press the Select (⊙) button until the volume symbol appears on the LCD panel.
2. Adjust the volume to a comfortable listening level.
3. To increase the volume, press the Up (⊕) button.
4. To decrease the volume, press the Down (⊖) button.

If you are adjusting the volume setting often, or if adjusting the volume causes you discomfort, consult your clinician as your programs may need adjustment.

The volume setting is saved with the current program. If you select another program, the volume will change to the setting saved with that program.

Changing Speech Processor Settings

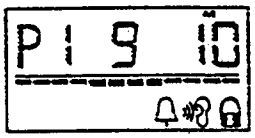
The speech processor has three features that your clinician may enable during programming. They are:

Button Lock
The button lock disables the buttons on the speech processor including the On/Off button ( ). Use the button lock to prevent young children from tampering with the controls.

Personal Alarm
The personal alarm informs users when certain speech processor functions are used.

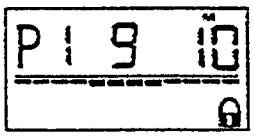
Public Alarm
The public alarm informs bystanders when certain speech processor functions are used. It may help parents and teachers assist a young child in using their speech processor, especially a child who does not reliably report dead batteries.

The LCD panel normally displays a symbol for each feature that you have enabled. For example, the diagram shows the LCD display when you have enabled all three features.

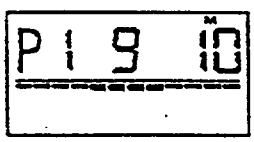


Button Lock

To lock the buttons, press and hold down the Select Button ( ) for several seconds until the button lock symbol ( ) appears on the LCD panel and you hear a long beep.



When the buttons are locked, the On/Off button ( ) has no effect. To turn off the speech processor, you need to unlock the buttons first. To unlock the buttons, press and hold down the Select button ( ) until the button lock symbol ( ) disappears from the LCD panel and you hear a long beep.



Personal Alarm

The personal alarm has five types of signal:

Lock or Reset (1 beep)
Each time the buttons are locked or unlocked, or a reset operation is performed, the speech processor emits one long beep.

Program Button (pings)
Each time the Program button is pressed, the speech processor emits a series of pings corresponding to the program number, that is, 1 ping = P1, 2 pings = P2, etc.

Other Buttons (1 ping)
The speech processor emits a single ping each time you press the Up, Down, Options, Autosensitivity or Select buttons.

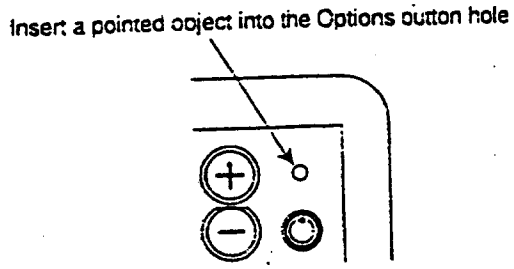
Low Battery Power (4 pings)
The speech processor emits four short pings every minute when the batteries are nearly dead.

Invalid Button Press (1 ping)
If you press a button inappropriately, the speech processor emits a lower-pitched ping. The settings remain unchanged.

Public Alarm

The public alarm has five signals that work the same way as the corresponding signals for the personal alarm.

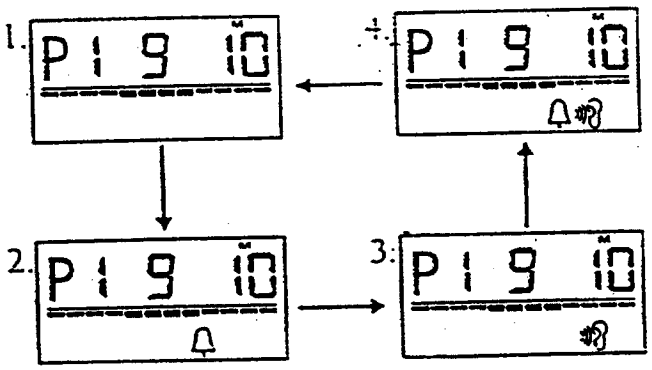
To access the personal and/or public alarm insert a pointed object, such as a pen tip, into the Options button hole.



Press down repeatedly to cycle through the following options as shown in the diagram below:

1. Public and personal alarms off
2. Public alarm on (🔔)
3. Personal alarm on (📳)
4. Public and personal alarms on (🔔📳)

Stop pressing the Options button when the LCD panel displays the symbol(s) corresponding to the desired feature.



Press the Options button repeatedly to find your preferred option

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Resetting the Speech Processor

To return the speech processor to the settings programmed by your clinician:

1. Turn off the speech processor.
2. Hold down the Program button (⊙) while turning the speech processor back on.

The speech processor emits a long beep (if either the public or personal alarm is enabled) and returns to its default settings.

Replacing and Recharging Batteries

The speech processor is powered by one or two AA batteries. Cochlear recommends using only high energy rechargeable nickel cadmium (NiCd) batteries or high quality disposable alkaline batteries.

Caution:
Carry spare batteries in a closed plastic bag. Otherwise the batteries may short circuit on loose metal objects and burn you.

Using NiCd Batteries

Cochlear recommends using NiCd batteries rated at least 1000 mAh. Batteries rated at less than 1000 mAh may not provide satisfactory longevity.

For optimal use of NiCd batteries:

- Do not mix fully charged batteries with partly charged batteries
- Replace the batteries only when the LCD panel displays the low battery symbol, see 'Checking the Battery Condition'

NiCd batteries have a fairly high self-discharge rate. Over several weeks, a fully charged battery will slowly discharge, even if it is not used. With your speech processor, Cochlear supplies two NiCd batteries, which may have discharged by the time you receive them. Recharge the batteries before using them in your speech processor.

When used correctly, NiCd batteries last for approximately 300 charge/discharge cycles. When their longevity starts to decrease, dispose of the NiCd batteries appropriately.

Using Alkaline Batteries

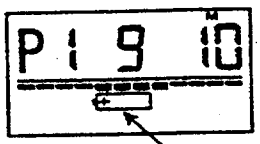
For best use of alkaline batteries:

- Do not recharge disposable alkaline batteries
- Do not mix new and partially used batteries

Checking the Battery Condition

When the batteries get low, the red indicator light on the top of the speech processor blinks and the LCD panel flashes the low battery symbol. If the personal or public alarms are on, the speech processor emits four 'pings' every minute until the batteries are dead.

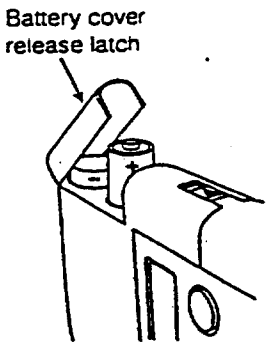
When the batteries are dead, the speech processor stops operating. The red indicator light goes out and the LCD panel displays only the low battery symbol.



Replacing the Batteries

To replace the batteries:

1. Turn off the speech processor.
2. Put your thumbnail in the battery cover release latch. Slide the latch and pull the battery cover back. Do not attempt to remove the cover completely.



3. Remove the old batteries.
   If the batteries are rechargeable, recharge them in the battery charger. If they are disposable, dispose of them appropriately.
4. Slide in the new batteries.
   - In the two-battery case, insert the upper battery (nearest the display panel) with the

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positive (+) terminal pointing to the open end. Insert the lower battery with the negative (–) terminal pointing to the open end.

- In the one-battery case, insert the battery with the positive (+) terminal pointing to the open end.

5. Push the battery cover back into place with your thumb.

Do not leave dead batteries in the speech processor as they may leak corrosive fluids and seriously damage the speech processor.

Recharging NiCd Batteries

Cochlear supplies a High Energy NiCad Charger to recharge high energy AA size NiCd batteries.

> **Caution:**
> Do not recharge carbon, zinc, alkaline (including rechargeable alkaline) or lithium batteries in the High Energy NiCad Charger.

Setting the Adaptor Configuration

The battery charger has an AC adaptor suitable for a wall outlet (AC power supply).

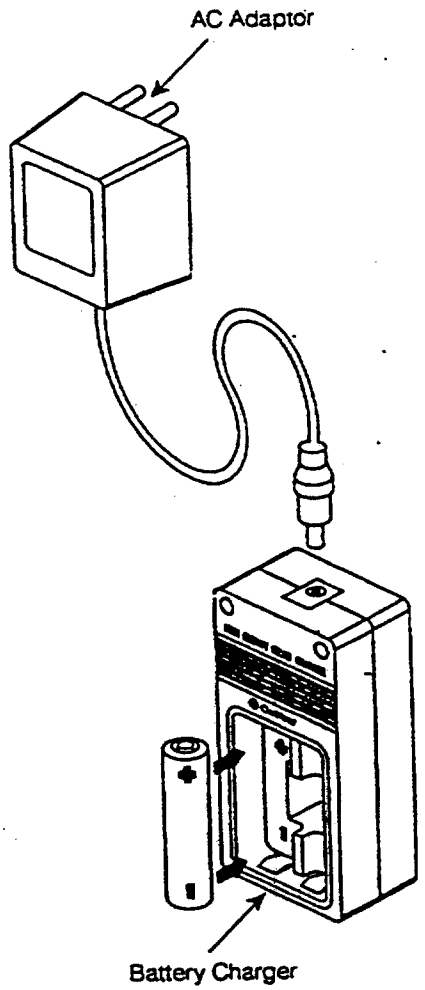
If you have a universal adaptor:

1. Set the adaptor to 6V DC output.
2. Choose the correct adaptor plug.
3. Set the polarity as shown on the charger's label (that is, negative inside, positive outside).

Caution:
Ensure you set the adaptor output correctly or it may damage the charger.

Charging a NiCd Battery

1. Connect the adaptor to the charger. Plug the adaptor into an AC outlet and turn on the power.
2. Insert the battery so that the polarity of the battery matches the polarity of the charger slot, positive (+) to positive, negative (–) to negative.



The indicator light above the slot turns red when you insert the battery with the correct polarity. If you insert the battery incorrectly, the indicator light may flicker but it will not stay on and the battery will not charge. However, you will not damage the battery or the charger.

3. After approximately six hours, the indicator light turns green, indicating the battery is fully charged. Remove the battery from the slot when ready to use.

   If you leave the battery in the charger, it is kept fully charged by trickle charging. It will not be damaged or overcharged.

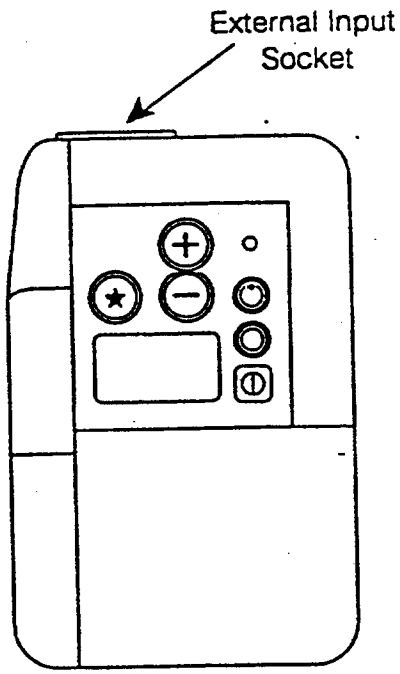
For best use of the battery charger:

1. If a power failure interrupts the charging, remove and reinsert the battery to reactivate the timing circuit.
2. Do not overcharge the batteries, as it will reduce their life. Overcharging may occur if you move the battery while in its charger slot. The charger may restart the charge cycle and overcharge the battery.
3. Use the charger indoors only.

Connecting External Devices to the Speech Processor

The speech processor can accept signals directly from external sources through the external input socket. The socket may be used to connect to:

- Lapel microphone
- Telephone adaptor
- Telecoil
- TV/HiFi cable (model TV1)
- Personal audio cable (model WALK1)
- FM cable



Note:
Connect the personal audio cable only to equipment powered by batteries. To connect the speech processor to AC powered equipment (that is, equipment connected to a wall outlet) use the TV/Hi-Fi cable.

When you connect a lapel microphone or telephone adaptor to the external input socket, the speech processor turns off the headset microphone and processes signals only from the external input socket.

If you connect any other Cochlear device to the external input socket, the speech processor mixes the external signal with environmental sound received from the headset microphone. Adjust the microphone sensitivity to control the level of environmental sound received from the headset microphone.

To prevent damage to the external input socket:

- Keep the rubber flap in place when the socket is not in use
- Teach children not to put anything in the socket

Using the Accessories

Using the Lapel Microphone

The lapel microphone can improve communication in noisy environments. Contact your clinician for the best program settings in these conditions.

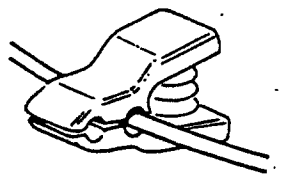
1. Plug the lapel microphone into the speech processor external input socket.
2. Select microphone sensitivity on the speech processor. Adjust the microphone sensitivity to suit the loudness of the speaker and the environmental noise.

When talking to one person, try clipping the microphone to their clothing. When talking in a small group, either pass the microphone from speaker to speaker or place the microphone on the table. If you pass the microphone around, hold it no more than 10 cm (4 in) from the speaker and point it toward the speaker's mouth.

Securing the Headset Cable

You can use the lapel clip to hold the headset cable to your clothes.

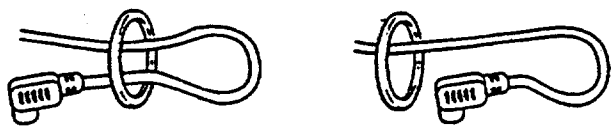
1. Remove the small rubber ring from the lapel clip.
2. Place the cable in the clip as shown and attach the clip to your clothing.



3. Keep the rubber ring (and spare ring) in a safe place for future use.

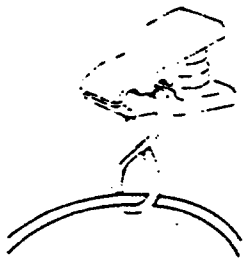
You can attach the headset cable securely in one position.

1. Remove the rubber ring from the lapel clip.
2. Disconnect the headset cable from the microphone.
3. Loop the cable and slide the rubber ring over the loop and plug so that it encircles the cord.

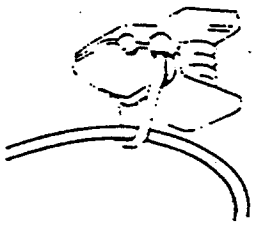


4. Attach the lapel clip to the rubber ring so the ring lies in the slot as shown.

5. Loop the ring a second time over the clip jaws, fitting it into the same slot.



6. Gently pull the cable through the jaws to fit into the same slot.



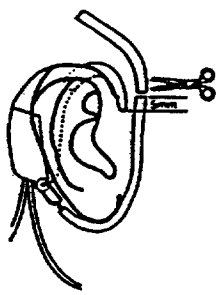
You can move the cable through the clip by opening the jaws and gently pulling the cable through its slot. You can then attach the clip to a convenient place on your clothing. Remove the ring by simply sliding it off over the plug.

Securing the Headset Microphone

The microphone lock (mic lock) is used to anchor the microphone case over the external ear.

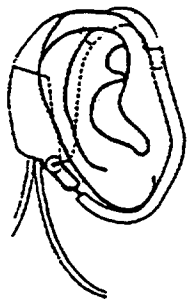
1. With the tubing pointing down, hook the two claws of the mic lock plastic clamp into the holes on each side of microphone case.

2. Hook the microphone case over the ear and pass the tubing under the ear lobe and up to the ear hook.
3. Measure the length of tubing required to fit under the ear lobe allowing for approximately 5 mm (3⁄16 in) of tubing to be fitted over the ear hook itself.
4. Remove the microphone and mic lock from the ear and cut the tubing at the measured point.



5. Slide the cut end of the tubing about 5 mm (3⁄16 in) over the ear hook.

6. Hook the microphone case complete with mic lock over the ear and secure the tubing under the ear lobe. Place the transmitting coil in position over the implant.



Listening on the Telephone

Telephone Adaptor

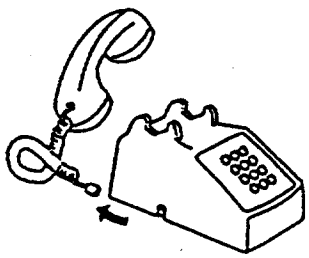
To improve the signal quality while listening on the telephone, you can use an adaptor that connects the speech processor directly to the telephone.

There are two models of telephone adaptor:

- the model TLP-102
- the model TRP-100, if the signal produced by the TLP102 is too loud.

To connect the telephone adaptor:

1. Unplug the handset cord from the telephone base socket.



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2. Plug the short telephone adaptor cord into the socket from which the handset cord has been removed.
3. To make the attachment permanent, remove the adhesive pad from the back of the adaptor unit and mount the unit onto the telephone base as shown. If you wish to use the adaptor with other telephones, however, do not remove the cover from the adhesive.
4. Plug the telephone handset cord into the telephone adaptor socket.
5. Insert the long telephone adaptor cord into the speech processor external input socket. The speech processor turns off the headset microphone.

6. Set the microphone sensitivity so that the other person's voice sounds comfortable. Hold the handset in the usual way to speak into it. Your clinician will tell you the best program settings for using the telephone adaptor.

Note:
The telephone adaptor works only with phones with a modular socket. However, some phones with a modular socket may

not work because the handset is wired up in a non-standard way. Please contact the Cochlear office or distributor in your region for information and assistance.

Use the telephone adaptor only with telephones approved by your local telecommunications authority, and connect it only to Cochlear speech processors. Connecting the adaptor to any other device may contravene local laws. Performance may vary depending on the quality of the telephone.

Using the Telecoil

Using the telecoil with a hearing aid compatible telephone which has been fitted with an induction loop in the handset (in many countries telephones have an induction loop built into the handset).

1. Set the microphone sensitivity button on the SPrint to 0.
2. Plug the telecoil into the external input socket on the SPrint.
3. Place the telecoil on or over the earpiece of the telephone handset.
4. Increase the microphone sensitivity button to the desired level.
5. If a clear signal is not received, reposition the telecoil on the handset to improve the clarity.

Using the telecoil in an induction loop environment.

1. Set the microphone sensitivity button on the SPrint to 0.
2. Plug the telecoil into the external input socket on the SPrint.
3. Attach the telecoil to your clothing using the m-clip, so that it is in a vertical position to pick up the induction field.
4. Increase the microphone sensitivity button to the desired level (you may need to tilt the telecoil slightly to obtain the best sound).

Listening to the TV or Hi-Fi

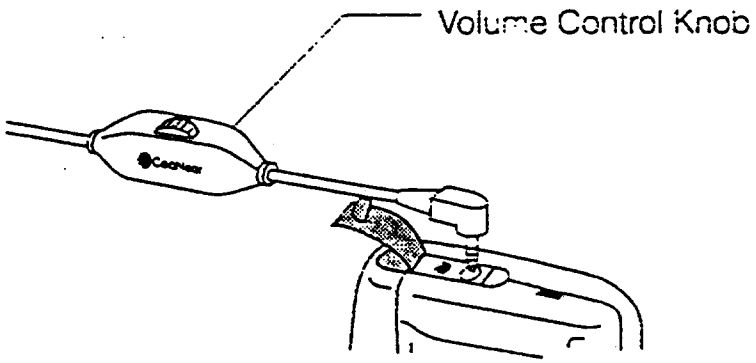
The TV/Hi-Fi cable can be used to connect a TV or stereo to the speech processor.

Caution:
Do not plug your speech processor directly into a TV or stereo without using the TV/Hi-Fi cable. The cable has electrical isolation to protect you from electrical shock.

A 5.5 m (18 ft) cable connects the TV or stereo to the speech processor.

To connect the TV/Hi-Fi cable:

1. Turn off the speech processor and the external audio equipment.
2. Plug the cable connector marked 'Cochlear' into the speech processor external input socket as shown.



Connecting the TV/Hi-Fi Cable

3. Plug the cable connector marked 'TV1' into the output socket on your audio equipment.
4. Turn on the speech processor and select the appropriate program. Contact your clinician for advice on which program settings to use with your audio equipment.
5. Adjust the volume of your audio equipment using the control knob on the TV/Hi-Fi cable, near the speech processor.
   - On position 1 the volume is very low and few sounds are picked up from the audio equipment.
   - On position 5 the maximum volume is picked up from the audio equipment.

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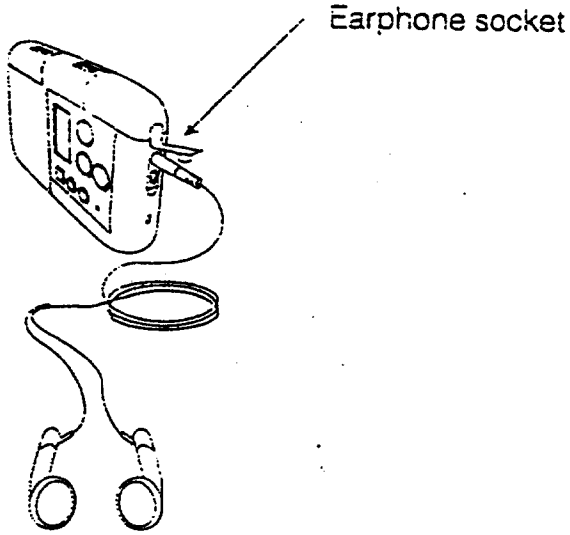
6. The microphone in your headset remains on and you may perceive some environmental sounds. Adjust the microphone sensitivity to alter the balance between the environmental sound and the audio equipment:
   - To hear more environmental sound and less from the audio equipment, press the Up (⊕) button
   - To hear less environmental sound and more from the audio equipment, press the Down (⊖) button

   Note:
   Like other consumer electrical and communication equipment, devices which connect your speech processor to AC powered equipment (equipment connected to a wall outlet), such as the TV/HiFi cable or telephone adaptor should not be used during electrical storms.

Monitoring a Child's Speech Processor

The monitor earphones enable you to listen to sounds being transmitted from a speech processor to the implant. This may help you:

- Assess whether the balance between the sounds received by the headset microphone and an FM receiver is appropriate
- Identify any microphone distortions



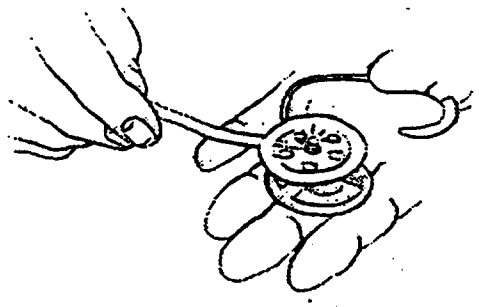
To connect the monitor earphones:

1. Leave the child's speech processor turned on.
2. Align the earphone connector with the earphone socket and insert the connector. Do not use excessive force. The sound you hear is the sound received by the microphone before it is processed by the speech processor.
3. Adjust the microphone sensitivity and volume to the desired levels. If the sounds you hear are distorted, contact your clinician or Cochlear for advice.

Checking a Child's Transmitting Coil

Use the signal check to check whether the child's transmitting coil is sending a signal across the skin to the implant.

1. Turn on the speech processor and select the normal program settings.
2. Hold the transmitting coil in one hand.
3. Place the signal check over the transmitting coil as shown below. It does not matter which side the transmitting coil faces the signal check.



Using the signal check

4. If the system is functioning, the red light in the center of the signal check will illuminate.
5. If the red light does not illuminate, hold the coil in your hand and place the signal check over it.

   If the red light still does not illuminate, perform the following steps until the problem is identified.

6. Change the headset cable. Hold the signal check over the transmitting coil and speak into the microphone.

If the signal check light illuminates with incoming sound, then the original headset cable is faulty.

7. Change the transmitting cable. Hold the signal check over the transmitting coil and speak into the microphone.

   If the signal check light illuminates with incoming sound, then the original transmitting cable is faulty.

8. Plug the lapel microphone into the speech processor external input socket – thereby disconnecting the headset microphone. Align and hold the signal check over the transmitting coil.

   If the signal check light illuminates with incoming sound, then the problem is in the headset microphone and you should contact your implant center.

If, after performing these steps, the signal check light does not illuminate with incoming sound, contact your implant center.

Caring for the System

Storing the Cochlear Implant System

When you are not using your cochlear implant system, store it in the storage case provided. Loosely wrap the headset and cables, tuck them into the pouch in the lid of the storage box and place the speech processor in the box.

For long term storage, remove the batteries from the battery case.

Keeping the Cochlear Implant System Clean

Avoid getting sand or dirt into any part of the system. If you do, shake out as much sand or dirt as possible. If necessary, contact your implant center or Cochlear to arrange repair.

To clean external parts of the system, wipe gently with a cloth slightly dampened with mild detergent. Regular cleaning prevents dirt building up.

Clean the pouch by hand-washing it in cold water and mild detergent. Ensure it is completely dry before use.

Keeping the Cochlear Implant System Dry

If you live in a humid environment, or perspire heavily, excess moisture may get into the speech processor or headset. Use the dry pack supplied with your speech processor to remove excess moisture. Do not wear any external part of your cochlear implant system while bathing or swimming.

To remove excess moisture from the speech processor and headset:

1. Place the speech processor, headset and dry pack into the pouch provided.
2. Roll down the top of the pouch and snap it shut.
3. Leave the pouch overnight. The dry pack will absorb excess moisture in that time.

The effective life of a dry pack depends on the relative humidity of the environment. To re-use the dry pack, follow the instructions included with the dry pack.

You can also buy a suitable dry pack from a pharmacy or electronics store.

> **Caution:**
> Keep the drying chemical material away from young children. Swallowing this material can cause serious internal injuries.

If you drop your speech processor into water, take the following steps to minimize damage:

1. Remove the battery case immediately and do not replace it. Do not open the case of the speech processor.
2. Shake out as much water as you can.
3. If the speech processor was dropped into salt water, soak it in distilled water (or clean tap water) for five minutes. Change the water and repeat twice.
4. Pour rubbing alcohol into a glass container and soak the speech processor in the alcohol for five minutes.
5. Gently shake out any excess.
6. Place the speech processor in a warm place overnight to dry out. Ensure the temperature does not exceed 50°C (122°F).
7. Return the speech processor and battery case to Cochlear or your implant center for repair.

Cochlear cannot guarantee that they will be able to repair any water-damaged part.

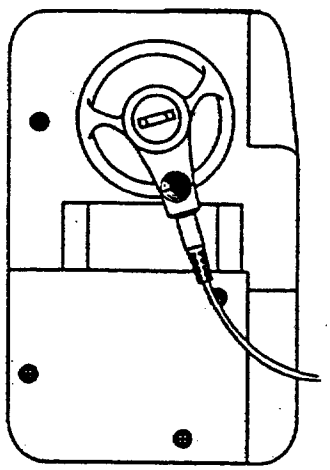
Troubleshooting

Diagnostic Tests

There are some tests that you can perform to identify faults.

Testing RF Transmission

To check that the speech processor is transmitting sounds to the cochlear implant, turn on the speech processor and place the transmitting coil over the back of the speech processor as shown.



The LCD panel displays the RF test coil symbol ((( ))) if your speech processor is transmitting.

Headset Function Check

1. Turn on the speech processor and ensure the coil is directly over the cochlear implant.
2. Set the microphone sensitivity to '10'. Speak into the headset microphone.

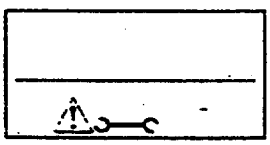
If the segment meter responds to speech, then the headset and its connection to the speech processor are functioning correctly.

3. If the segment meter does not respond to speech, replace the headset cable with a spare and check the segment meter in response to speech.
4. If the segment meter still does not respond to speech, replace the transmitting cable with a spare and check the meter in response to speech.
5. If the segment meter still does not respond to speech, connect the lapel microphone to the speech processor External Input Socket and check the meter in response to speech.

If you still have a problem, contact your implant center.

Symptoms

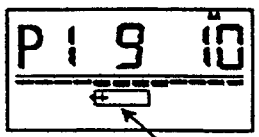
The Read Manual (⚠) and Service Required (⊶) Symbols are Displayed



If the LCD panel displays the Read Manual and Service Required symbols together, the current speech processor program is faulty. Turn the speech processor off and then on again.

If another program is available, the speech processor automatically selects it and continues to work normally. If no other program is available, the speech processor stops working but continues to display the Read Manual and Service Required symbols. Return the speech processor to your clinician for testing.

The LCD Panel Displays the Low Battery (⇐▭) Symbol



If the LCD panel displays the Low Battery symbol:

1. Check that the batteries are inserted correctly.
2. If the Low Battery symbol still appears, replace the batteries.

If you have the personal alarm enabled, it will sound four short pings each minute when the batteries in your speech processor are nearly dead. Replace the batteries immediately.

I don't hear anything
I only hear sounds intermittently

Check the display panel troubleshooting symbols and functioning of the headset as described below:

1. Turn on the speech processor.
2. Ensure the headset is properly connected.
3. Check the headset function. See 'Headset Function Check'.

4. Check the RF transmission. See 'Testing RF Transmission'.

If the RF Test symbol does not appear, inform your implant center that the speech processor failed the transmission test.

Speech sounds unclear to me
Speech sounds too soft /too noisy

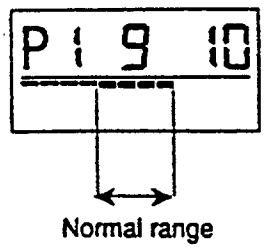
Soft speech and loud background noise are the two main factors that may influence your ability to understand speech in a particular environment.

If background noise is too loud, turn the autosensitivity on.

If this does not help, turn the autosensitivity off and:

1. Check that the headset transmitting coil is in place.
2. Check the segment meter.

- If the meter displays less than five segments, the speaker may be too soft. Check the meter while you speak. If the meter works normally when you speak, and the environment is quiet, turn up the microphone sensitivity. Otherwise, ask the other speaker to talk more loudly.
- If the meter consistently displays more than eight segments, try to locate and remove sources of background noise. Try turning the microphone sensitivity down, so that the segment meter displays between five and eight segments.



3. After adjusting the sensitivity, you may need to adjust the volume, if enabled. If loud sounds are uncomfortably loud, turn down the volume. If speech, including your own voice, is too soft, try turning up the volume.

After trying these solutions, if you still have a problem, you and the speaker may need to move to a quiet room. Sometimes individual room acoustics and background noise cause problems that cannot be resolved.

In addition, other factors not related to the performance of the speech processor may influence your ability to understand speech in a particular situation. For example:

- Interference from tinnitus (head noises)
- Loss of concentration due to illness or fatigue
- Quick changes of topic in conversation
- Difficulty in lipreading the speaker, due to poor position of the speaker or poor lighting

If you find that you still have problems, contact your implant center for assistance.

Sounds are Uncomfortably Loud

Remove your headset, turn off the speech processor and consult your clinician.

Intermittent Buzzing Sounds

You may occasionally perceive intermittent buzzing or distorted speech. Electromagnetic interference (EMI) may temporarily affect the operation of your speech processor and transmitting cables.

Electromagnetic fields of different strengths are produced by almost all types of electronic devices. The headset cables, like antennae, pick up environmental electromagnetic fields. The speech processor attempts to process these signals as environmental sounds. The EMI will be no louder than your programmed comfort levels and will not hurt you or damage your speech processor.

Common sources of EMI include:

- Radio transmission towers
- TV transmission towers
- Shopping center security systems
- Airport security systems
- Some digital mobile telephones

However other electronic devices that are sources of EMI may not be readily visible. If you hear intermittent buzzing or distorted speech, look for electronic equipment that may be a source of EMI and move away from it. If you still hear buzzing or distorted speech, turn off your speech processor, remove your transmitting coil and consult your clinician.

The cochlear implant has been carefully designed to protect users from most sources of EMI. The cochlear implant cannot be affected by EMI and cannot send unprocessed electrical signals to the electrode array.

Battery Charger will not Charge Batteries

If the charge light does not turn on when you insert batteries into the battery charger:

1. Check that the batteries are not already charged.
2. Remove and reinsert the batteries to ensure they are properly connected.

If the charger still does not work, return it to Cochlear for repair. Do not attempt to repair it yourself.

Warnings and Precautions

This section describes the warnings and precautions that apply to your cochlear implant system. Read this section carefully to ensure that you understand the care of your system.

Discuss these warnings and precautions with your physician before undergoing any major medical procedure.

Warnings

Medical Treatments Generating Induced Currents
Some medical treatments generate induced currents that may cause tissue damage or permanent damage to the cochlear implant. Warnings for specific treatments are given below.

- **Electrosurgery:** Electrosurgical instruments are capable of inducing radio frequency currents that could flow through the electrode array. **Monopolar** electrosurgical instruments must **not** be used on the head or neck of a cochlear

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implant patient as induced currents could cause damage to cochlear tissues or permanent damage to the implant. Bipolar electrosurgical instruments may be used on the head and neck of patients, however, the cautery electrodes must not contact the implant and should be kept more than 1 cm (~½ in.) from the extracochlear electrodes.

- **Diathermy or Neurostimulation:** Do not use diathermy or neurostimulation directly over the cochlear implant. High currents induced into the electrode lead can cause tissue damage to the cochlea or permanent damage to the implant.
- **Electroconvulsive Therapy:** Do not use electroconvulsive therapy on a cochlear implant patient under any circumstances. Electroconvulsive therapy may cause tissue damage to the cochlea or damage to the cochlear implant.

Ionizing Radiation Therapy

Do not use this therapy directly over the cochlear implant because it may cause damage to the implant.

Magnetic Resonance Imaging (MRI)

Magnetic Resonance Imaging (MRI) is contraindicated except under the circumstances described below. Do not allow patients with a cochlear implant to be in the room where an MRI scanner is located except under the following special circumstances.

The Nucleus 24 cochlear implant has a removable magnet and specific design characteristics to enable it to withstand MRI up to 1.5 Tesla, but not higher. If the cochlear implant's magnet is in place, it must be removed surgically before the patient undergoes an MRI procedure. The patient must take off the speech processor and headset before entering a room where an MRI scanner is located.

If the implant's magnet is still in place, tissue damage may occur if the recipient is exposed to MRI. Once the magnet is surgically removed, the quality of the MRI will be affected by the metal in the cochlear implant. Image shadowing may extend as far as 6 cm from the implant, thereby, resulting in loss of diagnostic information in the vicinity of the implant.

If the physician is unsure that the patient has a Nucleus 24 cochlear implant with a removable magnet, the physician should use an x-ray to check the radiopaque lettering on the implant. There are three platinum letters printed on each implant. If the middle letter is a "J", "L", or "T", the implant has a removable magnet. Once the magnet has been removed, MRI can be performed. If you require additional information about removal of the magnet, please contact Cochlear.

Loss of Residual Hearing

Insertion of the electrode into the cochlea will result in complete loss of residual hearing in the implanted ear.

Long-term Effects of Electrical Stimulation

Most patients can benefit from electrical stimulation levels that are considered safe, based on animal experimental data. For some patients, the levels needed to produce the loudest sounds exceed these levels. The long-term effects of such stimulation in humans are unknown.

Ingestion of Small Parts

Parents and caregivers should be counseled that the external implant system contains small parts which may be hazardous if swallowed.

Head Trauma

A blow to the head in the area of the cochlear implant may damage the implant and result in its failure.

Precautions

If you experience a significant change in performance or the sound becomes uncomfortable, turn off your speech processor and contact your implant cente.

Use the cochlear implant system only with the approved devices and accessories listed in this manual.

The speech processor and other parts of the system contain complex electronic parts. These parts are durable but must be treated with care. The speech processor must not be opened by anyone other than Cochlear's qualified service personnel or the warranty will be invalidated.

Each speech processor is programmed specifically for each individual. Never wear another person's speech processor or lend yours to another user. Using another person's speech processor may result in uncomfortably loud or distorted sounds.

Do not operate the speech processor at temperatures greater than 50°C (122°F) (or less than 5°C (41°F).

The speech processor sound quality may be intermittently distorted when you are within approximately 1.6 km (1 mile) of a radio or television transmission tower. The effect is temporary and will not damage the speech processor.

Theft and Metal Detection Systems

Devices such as airport metal detectors and commercial theft detection systems produce strong electromagnetic fields.

Some cochlear implant recipients may experience a distorted sound sensation when passing through or near one of these devices. To avoid this, turn off the speech processor when in the vicinity of one of these devices.

The materials used in the cochlear implant also may activate metal detection systems. For this reason, recipients should carry the Cochlear Implant Patient Identification Card with them at all times.

Electrostatic Discharge

A discharge of static electricity can damage the electrical components of the cochlear implant system or corrupt the program in the speech processor.

If static electricity is present (for example, when putting on or removing clothes over the head or getting out of a vehicle), cochlear implant recipients should touch something conductive (for example, a metal door handle) before the cochlear implant system contacts any object or person.

Prior to engaging in activities that create extreme electrostatic discharge, such as children playing on plastic slides, the speech processor and headset should be removed. Clinicians should use an anti-static shield on the computer monitor when programming a cochlear implant recipient.

Mobile Telephones

Some types of digital mobile telephones (for example, GSM) may interfere with the operation of the external equipment. As a result, cochlear implant recipients may perceive a distorted sound sensation when in close proximity (1-4 m/3-12 ft) to a digital mobile telephone in use.

General Information

SPrint™ Speech Processor Specifications

Dimensions:
103 x 67 x 23 mm (4.1 x 2.6 x 0.9 in) with two batteries)

Weight:
114 g (with one battery)
146 g (with two batteries)

External Audio Input:
3.5 mm Audio Input Socket with signal inputs typically in the range of 0.1–30 mV (RMS).
The ring connection provides a current-limited supply (150 µA) for an external input device.

Headset Connection:
Custom 4-pin connector

Power Consumption:
Average 100 mW
One or two 1.5 V AA size high energy NiCd or alkaline batteries

Transmission Frequency:
5.0 MHz

Equipment Classification:
The speech processor is internally powered equipment type B, with an F type applied part.

IP44:
Degrees of protection provided by enclosures for electrical equipment. The relevant standards are IEC 529 and AS 1939-1990.

HS8 Headset

Microphone Dimensions:
38.5 x 17.4 x 7.8 mm (1.5 x 0.7 x 0.3 in)

Transmitting Coil:
35.4 mm (1.4 in.) in diameter

Transmitting Frequency:
5.0 MHz

Battery Charger

Dimensions:
110 x 56 x 40 mm (4.3 x 2.2 x 1.6 in)

Weight:
100 g (without batteries or AC adaptor)

Circuit:
Two independent charge systems for rapid charging of one or two high energy NiCd AA batteries. Each system charges a NiCd battery with a current of 180 mA in six hours. The indicator light shows red when the charge cycle is in progress.

The light changes to green when the cycle is complete and the current has reduced to 20 mA trickle charge.

Current Supply:
6V DC, 500 mA

AC Adaptor

Output Required:
6V DC, 500 mA

> **Caution:**
> Be sure to use an AC adaptor that is compatible with the standard power outlet in your country or you may damage your charger.

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Registration

In accordance with international practice and regulatory legislation, each component of the cochlear implant system is shipped with a registration card. Registering your cochlear implant system secures your warranty rights and enables Cochlear to track all devices.

Also provided is a patient identification card which you should carry at all times.

The implant center and the cochlear implant user are responsible for correctly completing both the registration card and the patient identification card. Please return registration cards to Cochlear within 30 days of receiving the cochlear implant system.

This information is collected and used in accordance with legal requirements concerning data protection.

Quick Reference Guide

for use with the SP*rint*™ speech processor and accessories

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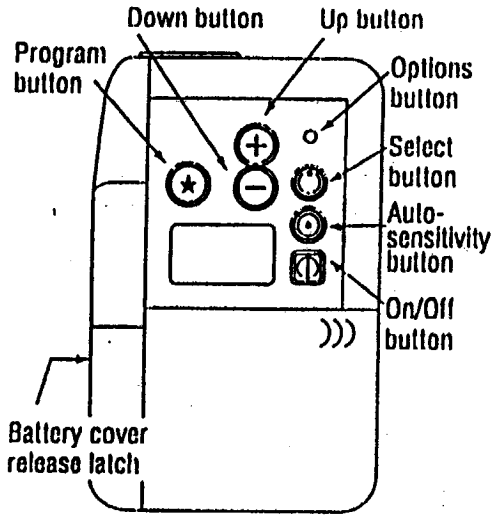
Quick Reference Guide

Tear out this guide and carry it with you for handy reference.

Speech processor controls



To turn speech processor on/off

- Press the On/Off button to turn on or turn off the speech processor.

To select another program

- Press the Program button to select the next available program.

To reset the speech processor

- Turn the speech processor off.
- Hold down the Program button while turning the speech processor back on.

To adjust microphone sensitivity

- Press the Select button until the M symbol appears on the LCD panel.
- Adjust the sensitivity so that it is set approximately to 8.
- Press the Up button to increase the sensitivity.
- Press the Down button to decrease the sensitivity.

To select autosensitivity

- Press the autosensitivity button.

To adjust the volume

- Press the Select button until the volume symbol ( ) appears on the LCD panel.
- Adjust the volume to a comfortable listening level.
- Press the Up button to increase the volume.
- Press the Down button to decrease the volume.

To lock the buttons

- Hold down the Select button for several seconds until the LCD panel displays the button lock symbol ( ) and you hear a long beep.

To set the personal/public alarm

Press the Options button by inserting a pointed object into the options button hole and press down repeatedly until the LCD panel displays the symbol(s) corresponding to the desired feature(s).

The following options are available:

- Public and personal alarms off
- Public alarm on (🔔)
- Personal alarm on (👤)
- Public and personal alarms on (🔔👤)

Setting appropriate levels

Ensure the transmitting coil is placed directly over the implant.

- If the environment is too noisy, turn the autosensitivity on.
- If this is not successful, turn off the

If this makes speech too soft, turn up the volume to compensate.

- If other speakers are too soft, but your voice is at the right level and the environment is quiet, turn up the microphone sensitivity.
- If all speech, including your own, is too soft, increase the volume.
- If loud sounds are uncomfortable, turn down the volume.

If you still have a problem after trying these solutions, you and the speaker may need to move to a quiet room.

Individual room acoustics or noise may cause problems that cannot be resolved.

To replace the batteries

1. Turn off the speech processor. Put your thumb in the battery cover release latch. Slide the slot and
2. Remove the old batteries.
3. Insert the new batteries in the same orientation as the diagram on the back of the battery case
4. Push the battery cover back into place.

Troubleshooting

If the LCD Panel displays the Low Battery symbol (▭):

- Check that the batteries are inserted correctly.
- If the Low Battery symbol still appears, replace the batteries.

If you don't hear anything or only hear sounds intermittently:

- Ensure the speech processor is turned on and the LCD panel is not displaying the Low Battery symbol.
- Ensure the headset and transmitting
- Ensure the coil is placed directly over the cochlear implant.
- Set the microphone sensitivity to '10' and speak into the 11S8 microphone.

If the segment meter responds to speech, then the 11S8 headset and the speech processor are working correctly.

If the meter does not respond to speech, replace the headset cable and transmitting cable, in turn, with a spare and check the meter.

If the meter still does not respond to speech, contact your implant center for further information.

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