Nucleus® 7 Hybrid™ Mode

Professionals Guide

CP1000

Hear now. And always

Cochlear®

This guide is intended for Cochlear implant and hearing care professionals who have undergone formal training on how to fit the Cochlear™ Nucleus® 7 Sound Processor (model number: CP1000) in Hybrid™ mode, using Cochlear Custom Sound® software Version 5.0 (or above).

It provides guidance on Hybrid mode candidate evaluation, and the steps involved in selecting, fitting and maintaining the Hybrid mode components.

NOTES

Refer to the following documents for further information:

- the *Custom Sound® Software User Guide* or the online help
- the *Nucleus 7 Sound Processor User Guide*
- the *Nucleus 7 Hybrid User Guide*
- the *Important Information* document for essential advice that applies to Cochlear implant systems.

Symbols used in this guide

	NOTE Important information or advice.
	TIP Time saving hint.
	CAUTION (no harm) Special care to be taken to ensure safety and effectiveness. Could cause damage to equipment.
	WARNING (harmful) Potential safety hazards and serious adverse reactions. Could cause harm to person.

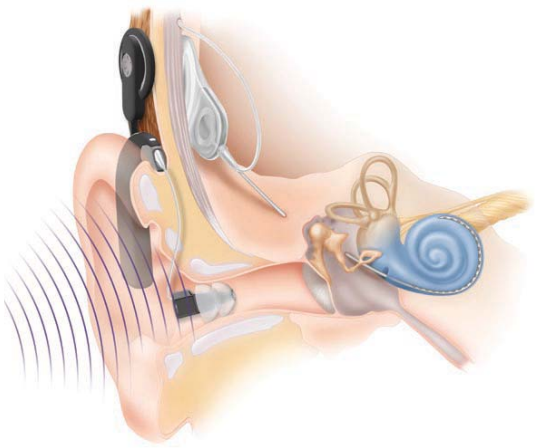
Contents

Introduction

Nucleus Hybrid mode is suitable for most recipients who have aidable post-operative residual hearing.

In Hybrid mode, the Nucleus 7 Sound Processor delivers synchronised signals:

- acoustic signals via the ear canal
- electric signals to the implant.



Hybrid mode is enabled by:

1. Attaching a Hybrid receiver to a Nucleus 7 Sound Processor, and
2. Programming it in the Custom Sound software.

Your role as a clinician

1. **Check Cochlear implant compatibility:** Hybrid mode, as part of the Nucleus system, is compatible with a range of Cochlear implants. Contact Cochlear for the latest information on compatible implants.
2. **Check candidacy:** Perform audiometric testing and counselling to determine if the recipient is a candidate for Nucleus Hybrid mode (see *Candidacy* on page 4).
3. **Fit the Hybrid system to the recipient:** Select the correct Hybrid receiver and dome to fit the recipient's ears (see *Fit the Hybrid system* on page 6).
4. **Assemble the Hybrid system:** Install the Hybrid receiver and dome and show the recipient how to wear the system (see *Assemble the Hybrid system* on page 8).
5. **Program the Hybrid system:** Add a Hybrid MAP using the Custom Sound software (see *Program Hybrid mode* on page 14).
6. **Counsel the recipient** on using and caring for their Hybrid system (see *Care and maintenance* on page 16).

The Nucleus 7 Hybrid system

The Nucleus 7 Hybrid system comprises:

- a Cochlear **Hybrid Earhook**, that replaces the normal earhook
- a Cochlear **Hybrid Receiver**, comprising a cable that plugs into the Hybrid earhook, and a speaker unit that is worn in the ear. The speaker unit has a replaceable wax filter
- a **disposable dome**, with a built-in wax filter.

NOTE
If you prefer, recipients can use a custom earmould instead of a dome for the 60 and 85 Hybrid receiver sizes.

For details on using and caring for the Hybrid system, see the *Nucleus 7 Hybrid User Guide*.

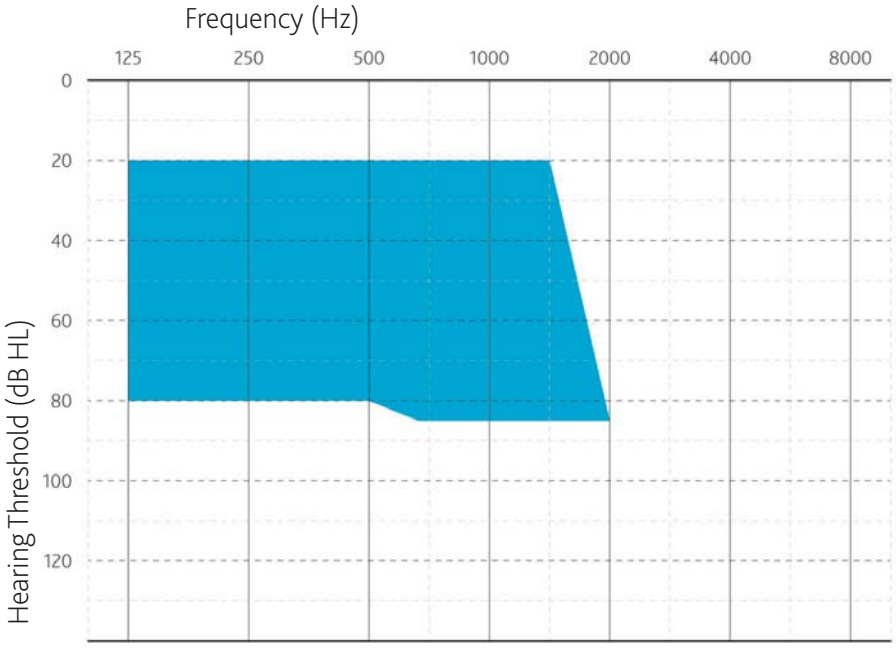
Candidacy

Nucleus Hybrid mode is suitable for recipients who satisfy audiometric and hearing performance criteria post-operatively, and have appropriate expectations regarding outcomes.

New CI recipients: Post-operative evaluation

Perform unaided post-operative audiometric testing of each ear at regular intervals, to monitor residual hearing levels over time. This should include air and bone conduction thresholds and tympanometry as indicated, to detect the presence of any temporary or permanent conductive component.

The current fitting range for the Hybrid receiver is shown below. Post-operative air conduction thresholds within the shaded area can be amplified by Nucleus Hybrid mode.



If repeat post-operative audiometric testing shows rapid progression of hearing loss in the implanted ear, together with a significant reduction in speech perception scores and sound quality, the recipient may prefer to use their sound processor without Hybrid mode.

Existing users: upgrading from older processors

Existing CI recipients, or those using Hybrid mode on older sound processors, can be converted to the Nucleus 7 system with Hybrid mode.

To do this, you need to fit them with a Nucleus 7 Sound Processor and Cochlear Hybrid receiver and dome, and reprogram their system with Custom Sound software Version 5.0 (or above).

See *Convert existing CI only or Hybrid mode recipients* on page 15.

Fit the Hybrid system

The Hybrid system has a flexible, modular design to fit ears of all shapes and sizes as they grow and change – while managing sweat, earwax and the challenges of daily use. To fit the Hybrid system, you need to specify:

- Left or right side
- Speaker unit (60, 85 or 100)
- Receiver cable length (1, 2, 3 or 4)
- Dome type and size (6, 8 or 10 mm).

NOTE
See the Custom Sound software's user guide or online help for more details.

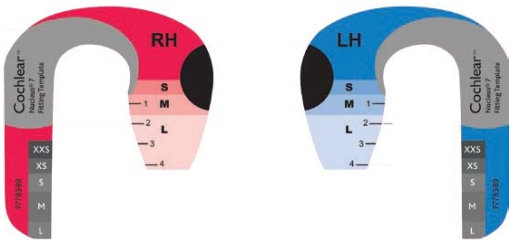
Fit the Hybrid receiver

1. Prescribe a MAP with a recent audiogram entered in the Custom Sound software.
2. The Custom Sound software will suggest a **speaker unit** (60, 85 or 100).

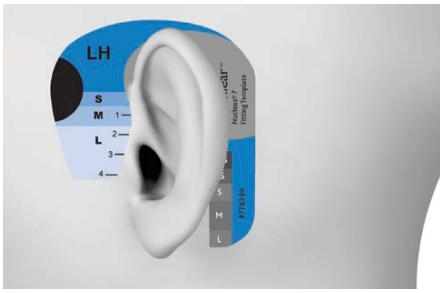
   NOTE
   You can use a different speaker unit than suggested depending on the amplification needed, or if it provides a better physical fit.

3. Use the double-sided Nucleus 7 Fitting Template in the Hybrid Fitting Kit to determine the **receiver cable length**.

   Use the blue side for the left ear, or the red side for the right ear.

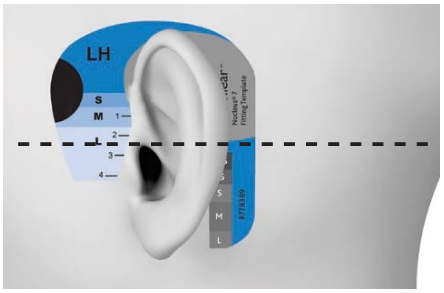


4. Fit the template so it sits on the ear like a behind-the-ear (BTE) sound processor.



5. Look into the ear, with your eye level with the ear canal.

6. Choose the **cable length** closest to an imaginary line across the top of the ear canal. If the line is between two lengths, pick the longer length.



Fit a dome

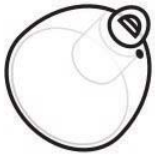
Select the dome type based on the recipient's degree of hearing loss. All domes come in 6, 8 or 10 mm sizes:

Cochlear Hybrid **Open Dome**

Open Domes have a more open fit in the ear canal, and suit recipients with mild to moderate hearing loss.

Cochlear Hybrid **Bass Double Dome**

Bass Double Domes suit recipients with moderate hearing loss. They have a double vent.



Cochlear Hybrid **Bass Single Dome**

Bass Single Domes suit recipients with moderate hearing loss. They have a single vent.

Cochlear Hybrid **Power Dome**

Power Domes fit more snugly, and provide better headroom before feedback, suiting recipients with severe hearing loss.

NOTE
If you prefer, recipients can use a custom earmould instead of a dome for the 60 and 85 Hybrid receiver sizes.

1. The Custom Sound software suggests a **dome type** based on the recipient's audiogram.

   NOTE
   You can use a different dome than suggested if you prefer. While you should fit as open a dome as possible, you also need to prevent feedback (too open) or occlusion (too closed).
2. Select a **dome size** and fit the dome onto the speaker unit and try it in the recipient's ear canal.
3. If the dome does not fit the ear, remove it and discard, then try a different size dome.

Assemble the Hybrid system

Follow the steps below to convert a Nucleus 7 Sound Processor to Hybrid mode by attaching a Hybrid receiver.

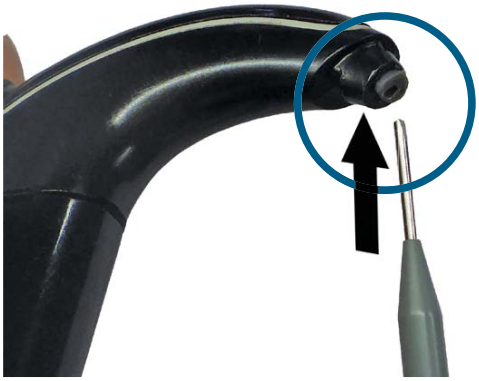
Attach the Hybrid receiver

NOTE
This procedure is intended to be performed by clincians only.

1. Pull up on the normal earhook to remove it.

2. Insert the Cochlear EAC200 Series Screwdriver into the hole in the processing unit plug.

   NOTE
   Keep the plug in case the recipient later wants to use their sound processor without the Hybrid system.



3. Use the screwdriver to carefully remove the plug.

4. Click the Cochlear Hybrid Earhook into place.

5. Align the Cochlear Hybrid Receiver plug with the end of the earhook and carefully slide the plug into the processor.

6. Push carefully until it clicks into place.

   Pull gently on the cable to check that it's securely in place.

7. Push the dome onto the speaker unit until it clicks securely in place.

   Pull gently on the dome to check that it's securely in place.

Wear the Hybrid system

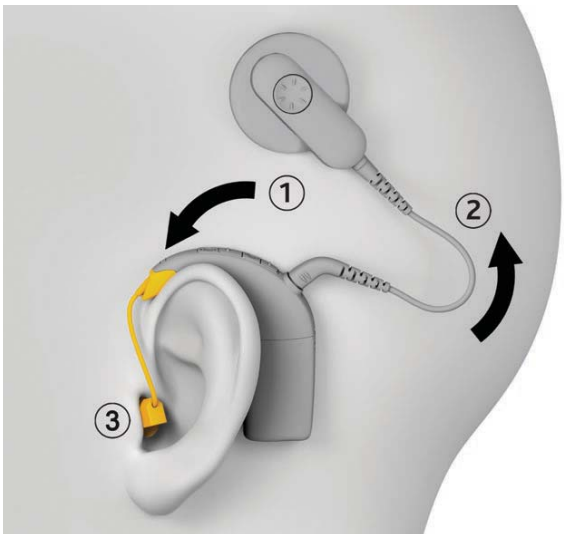
WARNING
The Hybrid system contains small parts. Make carers aware of the risk of choking.

CAUTION
Do not allow the coil magnet to come into contact with the Hybrid receiver as this may impact the Hybrid system's functionality.

NOTE
Always handle the sound processor and Hybrid system with care. Never drop them or twist the cables.

Show the recipient (or carer) the correct method for putting on and removing their Hybrid system:

1. Hold the coil in one hand and place the sound processor on their ear with the other.
2. Place the coil on their head.
3. Show them how to place the dome in their ear.
4. Show them how to remove the dome from their ear when removing their coil and sound processor.



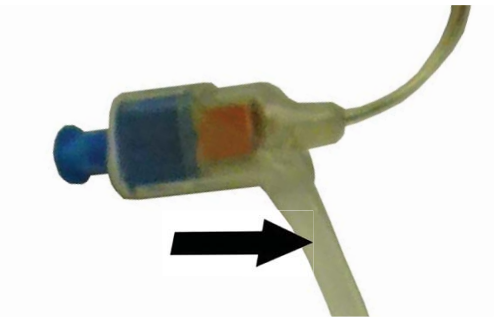
NOTES
- Instruct the recipient (or carer) how to care for their Hybrid system, including changing domes and wax filters. Refer to the *Nucleus 7 Hybrid User Guide*.
- The Hybrid system cannot be attached to the sound processor when using the Aqua+ accessory.

Wear the ear lock

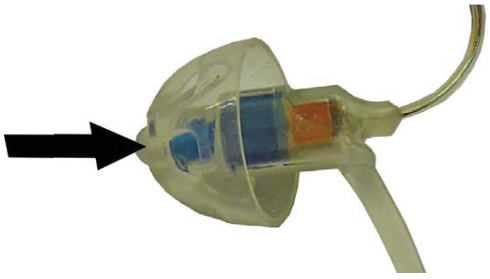
If the recipient has a large ear opening (concha), the Hybrid system may not stay in place. You can use the Cochlear Hybrid Ear Lock to stabilise the speaker unit in the ear.

1. Align the ear lock with the speaker unit as shown.

2. Push the ear lock onto the speaker unit, making sure the speaker unit's tip is exposed.



3. Place the dome over the speaker unit's tip.

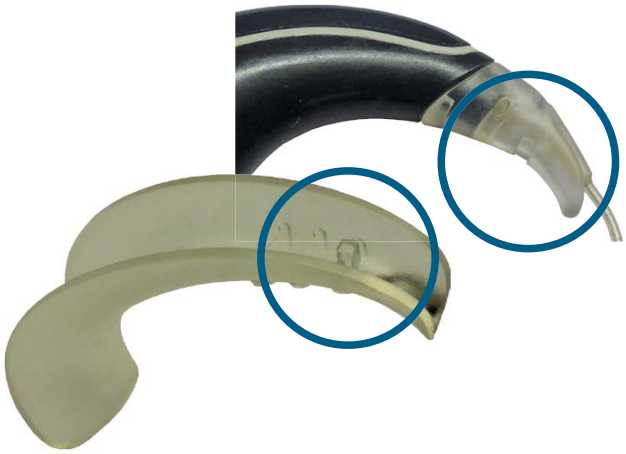


4. Trim the ear lock if it is too long.

Remove the Hybrid receiver

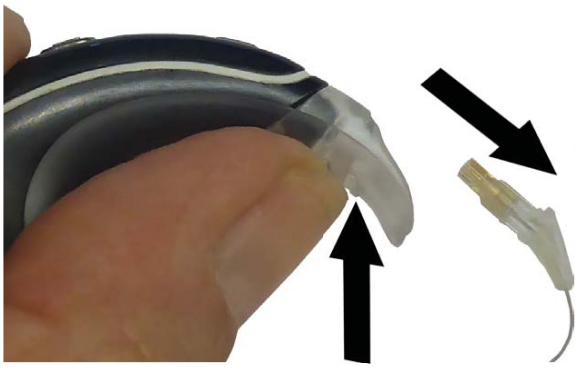
NOTE
This procedure is intended to be performed by clinicians only.

1. Fit the Cochlear Hybrid Removal Tool up under the processor, with the tool's raised tab in the notch under the earhook.



2. Firmly press up on the removal tool to push the tab into the notch on the earhook.

   Grip the Hybrid receiver near the earhook and gently pull it out.



Program Hybrid mode

NOTE
The Nucleus 7 Sound Processor can only be programmed in Hybrid mode with Custom Sound software Version 5.0 (or above). For more information, see the Custom Sound software user guide or online help.

About setting frequency boundaries

An overlapping MAP

A minimally overlapping MAP is automatically generated by the Custom Sound software. The low frequency information is presented via acoustic stimulation only. High frequency information is presented via modified frequency-to-electrode allocation tables. The boundaries of where acoustic stimulation stops and electrical stimulation begin are determined by the recipient's residual hearing.

About Hybrid mode prescription options

Overview of Hybrid mode prescription choices

The Custom Sound software provides three prescriptive methods for programming the Hybrid receiver. The fitting formulas are based on adult recipients and are provided to give you a starting point for making fine tuning adjustments to the frequency-gain characteristics of the system's acoustic output. There is no one fitting method that is universally accepted. It is possible to use preferred prescription targets to manually match the acoustic gain and power output.

The options for Hybrid mode are:

- **CHP:** Cochlear Hybrid Prescription. By default, CHP with WDRC (Wide Dynamic Range Compression) is selected. It can be used with or without compression in Hybrid mode.
- **NAL-RP:** National Acoustic Laboratory. Revision for profound losses prescriptions that equalise prescribed gain to make each frequency band of speech of equal loudness to maximize speech intelligibility.
- **DSL:** Desired Sensation Level Prescriptions. Tries to preserve loudness among speech frequencies.

Program new Hybrid mode recipients

To program a new Nucleus 7 Sound Processor recipient in Hybrid mode using the Custom Sound software:

1. Create a recipient and input their audiogram.
2. Obtain impedance measurements.
3. Create a Hybrid mode MAP.
4. Fit the MAP to the recipient.
5. Balance electrical and acoustic loudness.
6. Save the MAP(s) and write to the processor.

Convert existing CI only or Hybrid mode recipients

To convert an existing recipient (Freedom Hybrid, CP800 Series or CP900 Series) to a Nucleus 7 Sound Processor in Hybrid mode in the Custom Sound software:

1. Check that an up to date audiogram is entered for the recipient.
2. Open the existing Freedom Hybrid, CP800 Series or CP900 Series MAP.
3. Obtain impedance measurements.
4. Select the MAP to convert:
   - 4a. Select 'Convert'.
   - 4b. Click on the 'Acoustics' button in the 'Set Levels' screen.
   - 4c. Ensure the 'Hybrid MAP' checkbox is selected and click the 'Recalculate' button.
   - 4d. Select the 'Receiver' that is connected to the Nucleus 7 Sound Processor.
5. Fine-tune the MAP.

   All electrical path parameters from the existing MAP are automatically copied to the electrical path parameters of the Nucleus 7 system. However, you should check that the acoustic and electrical path balance provides the best possible listening experience for the recipient. To fine-tune the acoustic path:
   - 5a. Fit the MAP to the recipient.
   - 5b. Balance electrical and acoustic loudness.
6. Save the MAP(s) and write to the processor.

Care and maintenance

This section covers the care and maintenance of the Hybrid system only. Educate recipients about relevant parts such as the wax filter and domes and regularly check they are looking after the system using the advice in this section, and in the user guides.

Refer to the *Nucleus 7 Hybrid User Guide* for care and maintenance procedures.

WARNING
The Hybrid system contains small parts. Make carers aware of the risk of choking. Reinforce that carers must take responsibility for the cleaning, care and maintenance of the Hybrid system.

Recipient care tasks

Care for domes

Domes are disposable. They should be checked daily, and changed whenever they lose shape, look dirty or discoloured, or the dome's in-built wax filter is clogged.

Care for speaker unit wax filters

The speaker unit wax filter must always be in place when wearing the processor in Hybrid mode. The replaceable filter should be checked whenever the dome is being changed, and replaced if it is clogged with wax or if sound quality has changed.

Clinician-only care tasks

There are extra steps you can take to clean and maintain a recipient's Hybrid system when they come to see you:

- Check for correct attachment of the Hybrid receiver.
- Check for correct insertion of the speaker unit.
- Check the fit of the dome is still correct as the ear may change with time and weight fluctuations. Examine the ear with an otoscope to check for any sore spots inside and around the ear.
- Replace the Hybrid receiver if the cable is broken, stretched or twisted.
- Replace the speaker unit wax filter if it looks dirty or clogged with wax.
- Replace domes whenever they lose shape or look dirty or discoloured.

Troubleshoot

This chapter provides troubleshooting procedures for the Hybrid system, only for clinician-oriented tasks.

For product-specific troubleshooting, see:

- the *Nucleus 7 Sound Processor User Guide*
- the *Nucleus 7 Hybrid User Guide*
- the *Custom Sound® Software User Guide* or the online help.

Equipment required

Check regularly that the items listed below are in good repair and well stocked. Have plenty of spare parts – especially receivers, domes, earhooks and wax filters.

- Nucleus 7 Hybrid Fitting Kit
- Cochlear EAC200 Series Stetoclip
- Cleaning set, wax loop, tissues
- Replacement ProWax filters
- Vent cleaner
- Cochlear EAC200 Series Screwdriver.

Troubleshooting procedure

1. Interview the recipient.
2. Take an otoscopic examination and ensure there is no wax blockage in the ear canal.
3. Inspect the sound processor thoroughly.
4. Ensure that thresholds have not changed by repeating pure tone audiometry. Identify any middle ear issues with Otoscopy and Tympanometry.
5. Refer to the following table for suggested solutions.

Observations, possible causes and solutions

PROBLEM	POSSIBLE CAUSE	TEST / RESOLUTION
Recipient can't hear anything through the Hybrid system	Batteries are flat	Check batteries and replace/recharge if necessary.
	Wax is blocking a filter	1. Replace the dome (with its built-in wax filter). 2. Check the wax filter on the speaker unit and replace if necessary. Educate the recipient to do this regularly.
	Hybrid receiver is broken	Replace the Hybrid receiver.
	Sound processor fault	1. Perform a listening test using a Stetoclip. If this shows a problem, send the sound processor for repair. 2. Perform a listening test using a Cochlear Monitor Earphone Adaptor and earphones. If this shows a problem, send the sound processor for repair.
Feedback	The Hybrid receiver cable is not the right length	1. Check the Hybrid receiver cable length. If it is too long, the cable will not sit nicely against the ear and the speaker unit may sit too low in the ear canal. If it is too short, the dome may keep falling out. Adjust so it sits snugly and without tension. See *Shape the Hybrid receiver cable* on page 22. 2. If it is still not correct, change to a different length Hybrid receiver.
	Dome vent is too large	Change to a dome with less venting.
	Dome fit is too loose	Change to a bigger dome.
The sound processor LED lights steady orange	Incorrect Hybrid receiver is connected	Change to the correct Hybrid receiver.

PROBLEM	POSSIBLE CAUSE	TEST / RESOLUTION
High distortion	Wax is blocking a filter	1. Replace the dome (with its built-in wax filter). 2. Check the wax filter on the speaker unit and replace if necessary. Educate the recipient to do this regularly.
	Hybrid receiver is broken	Check the Hybrid receiver using a listening test, and replace it if required. If the test is not conclusive, reproduce the 'Total harmonic distortion' measurement described in the Data Sheet supplied with this guide and check against the outlined limits.
Occlusion ('Head in a bucket' sensation)	The dome vent is blocked	Check the vent for obstruction. Replace the dome if necessary.
	Dome vent is too small	Pull the speaker unit slightly out of the ear. If this makes the sound quality improve, change to a dome with a larger vent size.
	Dome fit is too tight	Change to a smaller dome.
Intermittent contact, crackling sound	Wax or moisture	1. Wipe the system dry. 2. Replace the dome (with its built-in wax filter). 3. Check the wax filter on the speaker unit and replace if necessary. Educate the recipient to do this regularly.
	Loose connection point at the earhook	Perform a listening test using a Stetoclip while carefully moving all parts of the Hybrid system in turn. Replace the Hybrid receiver if necessary.
	Sound processor fault	Perform a listening test using a Stetoclip. If this shows a problem, send the sound processor for repair.

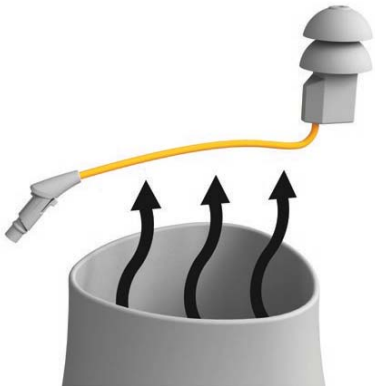
PROBLEM	POSSIBLE CAUSE	TEST / RESOLUTION
Painful fit	Speaker unit is incorrectly inserted into the ear	Insert correctly and re-train the recipient in correct insertion.
	Hybrid system is not properly fitted	1. Check areas of the outer ear where the sound processor sits for sore spots or friction marks. 2. Check the Hybrid receiver cable length. If it is too long, the cable will not sit nicely against the ear and the speaker unit may sit too low in the ear canal. If it is too short, the dome may keep falling out. Adjust so it sits snugly and without tension. See *Shape the Hybrid receiver cable* on page 22.
	Wax buildup in the outer ear canal	Check for sore spots using an otoscope – these are usually caused by wax buildup. Refer the patient to a medical practitioner to have their ear canal cleaned.
Output lower than expected	Microphone cover needs changing	Change microphone cover.
	Loose Hybrid receiver connection	Check the Hybrid receiver connection to the earhook and replace any damaged parts.
	Incorrect program	Perform a listening test. Use Acoustic Test Box or Hearing Instrument Test Box if available and cross check against target curve in the Custom Sound software.
	Hybrid receiver is broken	Check the Hybrid receiver using a listening test, and replace it if required. If the test is not conclusive, reproduce the OSPL90 curve from the Data Sheet and check against the outlined limits.

Shape the Hybrid receiver cable

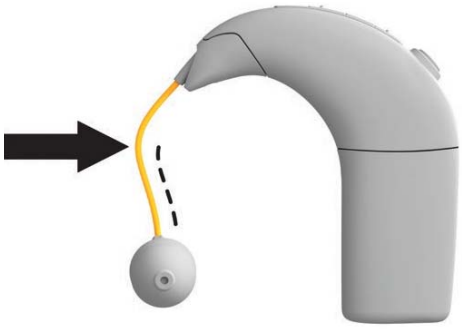
Problem: Hybrid receiver cable is between sizes – too long or too short.

Solution: To improve fitting comfort and retention, the Hybrid receiver cable is heat formable. This allows for variations in ear anatomy and for those recipients whose measurements fall between two lengths.

1. Remove the sound processor from the ear and heat the Hybrid receiver cable with hot air equipment (a few seconds only, 130 °C max).

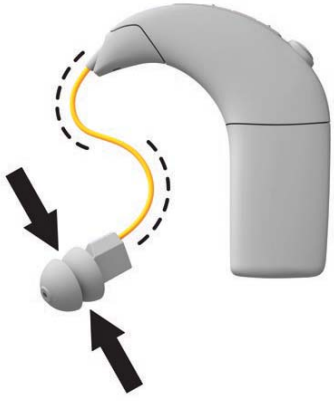


2. To add length, straighten the S curve.



3. To stop the Hybrid receiver cable bowing from the side of the ear, or to increase the insertion depth, adjust the bend into the canal.

4. Hold the Hybrid receiver cable in the desired shape until it is cool. It must be cool before it is tried on the ear again.



Managing occlusion

Occlusion is often described by the patient as:

- sounding like their head is inside a bucket
- sounding like they are speaking into a tunnel
- having a bad perception of their own voice
- feeling like acoustic stimulation is becoming unbearable.

NOTE
An initial feeling of occlusion may occur when the system is first fitted or the program is changed. This usually subsides after a few days of use. Occlusion is less likely to happen with domes.

PROBLEM	POSSIBLE CAUSE	TEST / RESOLUTION
The recipient experiences a 'boomy' sound quality, also known as a 'head in bucket/barrel' effect.	Occlusion is caused by a dome blocking the ear, with sound amplified in the ear canal.	Change to a dome with a larger vent or decrease the low frequency gain for high level sounds.
The recipient experiences an 'echo' effect when speaking.	Occlusion is caused by the frequency gain response of the Hybrid system.	Reduce the gain in the lower frequency channels. Check sound quality adjustments with and without electrical stimulation to ensure the overall sound quality is comfortable.

Service

For any problems with the Hybrid system, refer first to *Troubleshoot* on page 18.

For any problems with the Nucleus 7 Sound Processor, refer first to the support material provided.

If the issue cannot be resolved, replace the Hybrid system or contact your local Cochlear representative. Cochlear will have a replacement delivered to the clinic as soon as possible.

Serviceable components

You can service the Hybrid system yourself as long as you maintain a well-stocked Hybrid Fitting Kit. Check the fit of the Hybrid receiver and replace the dome regularly as a recipient's ear shape will change with time.

If the Hybrid earhook, receiver or dome breaks or is lost or damaged, you can replace it from your existing stock or order it from Cochlear. If an earmould is damaged, fit a dome if possible and order a new or replacement earmould.

The Nucleus 7 Sound Processor is serviceable by Cochlear. Check the recipient's warranty documents or contact your local Cochlear representative to find out more.

Warranties

Refer to the warranty document in the recipient document package or contact your local Cochlear representative for details.

Warnings

- For each individual sound processor, only use the Hybrid receiver type that you have fitted and programmed in the Custom Sound software.
- If the recipient is unable to provide feedback on comfort, counsel carers to monitor volume levels and battery heat and regularly check for any signs of discomfort or pain.
- You should carefully assess the appropriateness of fitting the Nucleus 7 Sound Processor in Hybrid mode to a child or intellectually disabled recipient. The system contains small parts, which can pose a choking hazard.
- When programming the Hybrid system, ask for recipient feedback prior to adjusting levels to ensure comfort. Counsel the recipient on the risks when the volume is pushed too high.
- When programming the Hybrid system, perform due diligence to ensure very loud input levels will not be uncomfortable or damaging to the recipient.

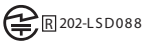
Cautions

- Counsel the recipient and carer to never allow the speaker unit and coil magnet to touch when handling or storing the system or removing domes.
- Counsel the recipient and/or carer to check regularly for any Hybrid system misfit or discomfort.
- Counsel carers to routinely check the Hybrid system by turning on the sound processor and listening closely to the Hybrid system. Where available carers should be advised to use the Cochlear EAC200 Series Stetoclip.
- If you fit earmoulds, only use them with the 60 or 85 size Hybrid receivers. Do not use custom earmoulds for any larger size receivers.

Other information

Labelling symbols

The following symbols may appear on your processor or remote components and/or packaging:

	Refer to instruction manual
	Specific warnings or precautions associated with the device, which are not otherwise found on the label
	Manufacturer
	Compatible sound processors
	Authorised representative in the European Community
	Catalogue number
	Serial number
	Batch code
	Date of manufacture
	Temperature limits
	CE registration mark with notified body number
	Radio compliance certification for Australia and New Zealand
	Radio compliance certification for Japan
	Radio compliance certification for Korea

Rx Only By prescription


Recyclable material


Dispose of electrical components in accordance with your local regulations


Type B applied part

IP44 Ingress Protection Rating

- Protected against access of solid foreign objects greater than or equal to 1.0mm diameter.
- Protected against failure from splashing water.

IP57 Ingress Protection Rating

- Protected against access of solid foreign objects greater than or equal to 1.0mm diameter.
- Protected against failure from dust penetration.
- Protected against failure from temporary immersion in water

Certification and applied standards

The Nucleus 7 Sound Processor fulfils the essential requirements listed in Annex 1 of the EC directive 90/385/EEC on Active Implantable Medical Devices as per the conformity assessment procedure in Annex 2.

CE 0123

The year in which authorisation to affix the CE mark was granted was 2017.

Equipment classification

The sound processor is internally powered equipment Type B applied part as described in the international standard IEC 60601-1:2005/A1:2012, Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance.

Legal statement

The statements made in this guide are believed to be true and correct as of the date of publication. However, specifications are subject to change without notice.

Hear now. And always

Cochlear Ltd (ABN 96 002 618 073) 1 University Avenue, Macquarie University, NSW 2109, Australia
Tel: +61 2 9428 6555 Fax: +61 2 9428 6352
Cochlear Ltd (ABN 96 002 618 073) 14 Mars Road, Lane Cove, NSW 2066, Australia
Tel: +61 2 9428 6555 Fax: +61 2 9428 6352
EC REP **Cochlear Deutschland GmbH & Co. KG** Karl-Wiechert-Allee 76A, 30625 Hannover, Germany
Tel: +49 511 542 770 Fax: +49 511 542 7770
Cochlear Americas 13059 E Peakview Avenue, Centennial, CO 80111, USA
Tel: +1 303 790 9010 Fax: +1 303 792 9025
Cochlear Canada Inc 2500-120 Adelaide Street West, Toronto, ON M5H 1T1, Canada
Tel: +1 416 972 5082 Fax: +1 416 972 5083
Cochlear AG EMEA Headquarters, Peter Merian-Weg 4, 4052 Basel, Switzerland
Tel: +41 61 205 8204 Fax: +41 61 205 8205
Cochlear Europe Ltd 6 Dashwood Lang Road, Bourne Business Park, Addlestone, Surrey KT15 2HJ, United Kingdom
Tel: +44 1932 26 3400 Fax: +44 1932 26 3426
Cochlear Benelux NV Schaliënhoevedreef 20 i, B-2800 Mechelen, Belgium
Tel: +32 15 79 55 11 Fax: +32 15 79 55 70
Cochlear France S.A.S. 135 Route de Saint-Simon, 31035 Toulouse, France
Tel: +33 5 34 63 85 85 (International) or 0805 200 016 (National) Fax: +33 5 34 63 85 80
Cochlear Italia S.r.l. Via Larga 33, 40138 Bologna, Italy
Tel: +39 051 601 53 11 Fax: +39 051 39 20 62
Cochlear Nordic AB Konstruktionsvägen 14, 435 33 Mölnlycke, Sweden
Tel +46 31 335 14 61 Fax +46 31 335 14 60
Cochlear Tıbbi Cihazlar ve Sağlık Hizmetleri Ltd. Şti.
Çubuklu Mah. Boğaziçi Cad., Boğaziçi Plaza No: 6/1, Kavacık, TR-34805 Beykoz-Istanbul, Turkey
Tel: +90 216 538 5900 Fax: +90 216 538 5919
Cochlear (HK) Limited Room 1204, 12/F, CRE Building, No 303 Hennessy Road, Wanchai, Hong Kong SAR
Tel: +852 2530 5773 Fax: +852 2530 5183
Cochlear Korea Ltd 1st floor, Cheongwon Building 33, Teheran-ro 8 gil, Gangnam-gu, Seoul, Korea
Tel: +82 2 533 4450 Fax: +82 2 533 8408
Cochlear Medical Device (Beijing) Co., Ltd
Unit 2208-2212, Tower B, Gemdale Building, 91 Jianguo Road, Chaoyang District, Beijing 100022, P.R. China
Tel: +86 10 5909 7800 Fax: +86 10 5909 7900
Cochlear Medical Device Company India Pvt. Ltd.
Ground Floor, Platina Building, Plot No C-59, G-Block, Bandra Kurla Complex, Bandra (E), Mumbai – 400 051, India
Tel: +91 22 6112 1111 Fax: +91 22 6112 1100
株式会社日本コクレア（**Nihon Cochlear Co Ltd**）〒113-0033 東京都文京区本郷2-3-7 お茶の水元町ビル
Tel: +81 3 3817 0241 Fax: +81 3 3817 0245
Cochlear Middle East FZ-LLC
Dubai Healthcare City, Al Razi Building 64, Block A, Ground Floor, Offices IR1 and IR2, Dubai, United Arab Emirates
Tel: +971 4 818 4400 Fax: +971 4 361 8925
Cochlear Latinoamérica S.A.
International Business Park, Building 3835, Office 403, Panama Pacifico, Panama
Tel: +507 830 6220 Fax: +507 830 6218
Cochlear NZ Limited
Level 4, Takapuna Towers, 19-21 Como St, Takapuna, Auckland 0622, New Zealand
Tel: + 64 9 914 1983 Fax: 0800 886 036

www.cochlear.com

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