



Hybrid™ User Guide

for Nucleus® 8 System
and Nucleus® 7 System

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.

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Introduction

About this guide

This guide is intended for Cochlear implant recipients and their carers, who use their Cochlear™ Nucleus® 8 system or Cochlear™ Nucleus® 7 system in Hybrid™ mode. The Cochlear Nucleus 8 system consists of the Nucleus 8 Sound Processor (model number CP1110) in Hybrid mode. The Cochlear Nucleus 7 system may consist of the Nucleus 7 Sound Processor (model number CP1000) or Cochlear Nucleus 7 SE Sound Processor (model number CP1001) or Cochlear Nucleus 7 S Sound Processor (model number CP1002) in Hybrid mode.

This guide can also be used as a reference by hearing healthcare professionals.

For more information, refer to the *Nucleus 8 Sound Processor User Guide*, *Nucleus 7 Sound Processor User Guide*, *Nucleus 7 SE Sound Processor User Guide* or *Nucleus 7 S Sound Processor User Guide*.



Note

- Please also refer to your *Important Information for Recipients* document for essential advice that applies to Cochlear implant systems.
- Refer to the Warnings section for warnings relating to the use of the Hybrid system.
- Not all products are available in all countries.

Hybrid system

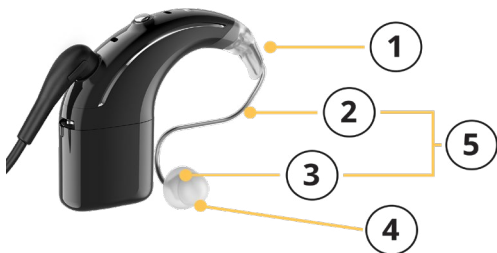
The Nucleus 8, Nucleus 7, Nucleus 7 SE and Nucleus 7 S Hybrid systems include:

- The Cochlear **Hybrid Earhook**—replaces your normal earhook, and connects the Cochlear Hybrid Receiver to your sound processor.
- The Cochlear **Hybrid Receiver**—a cable with a speaker unit that fits in your ear. It has a replaceable wax filter.
- A **dome**—fits over the speaker unit to hold it in place and protect your ear. It is disposable and has a built-in wax filter.



Caution

- Your clinician will select the receiver and dome that you should use. Do not substitute any other parts.
- Your clinician will attach and remove the receiver for you. Do not attempt to do this yourself.



1. Hybrid Earhook
2. Cable
3. Speaker unit (under dome)
4. Dome
5. Hybrid Receiver

Hybrid mode

When using the Nucleus Sound Processor in Hybrid mode, the Hybrid system is worn in the outer ear canal of the respective ear.

In Hybrid mode, your sound processor delivers two types of sound signals:

- The usual electric signals to the cochlear implant
- Extra acoustic signals to the Hybrid system



Sound processors and related accessories contain small parts that alone or in combination may pose a hazard of inhalation, choking or ingestion. Swallowing or inhaling small parts can cause severe or fatal injuries. Use the tamper-resistant locks to keep small parts attached to the processing unit where available, including parts that fit between the processing unit and battery module.

Always supervise children under 3 years of age and others who may be at risk of inhalation, choking or ingestion of small parts when they use the sound processor and related accessories. When not in use, keep small parts, and combinations of small parts, out of reach from children. If small parts are swallowed or inhaled, seek immediate medical attention.

Intended purpose

Cochlear Hybrid Receiver

The Cochlear Hybrid Receiver is intended to be used in combination with other devices as part of a hearing implant system to deliver amplified sound via the ear canal for recipients with residual hearing.

Domes

The Cochlear Hybrid Open Dome, the Cochlear Hybrid Bass Single Dome, the Cochlear Hybrid Bass Double Dome and the Cochlear Hybrid Power Dome are intended to be used as an accessory to the Hybrid Receiver to allow a Hybrid Receiver to fit comfortably and securely within the ear canal. They are also used to assist with delivering sound from the receiver.

Cochlear Hybrid Ear Lock

The Cochlear Hybrid Ear Lock is intended to be used as an accessory to the Hybrid Receiver to assist with securing the Hybrid Receiver within the ear canal.

Cochlear Hybrid Earhook with Removal Tool

The Cochlear Hybrid Earhook with Removal Tool is intended to be used to assist with wearing the sound processor as part of a hearing implant system.

Indications

Cochlear Hybrid Receiver

The Cochlear Hybrid Receiver is indicated for use with the Nucleus 8 Processing Unit, Nucleus 7 Processing Unit, Nucleus 7 SE Processing Unit, and Nucleus 7 S Processing Unit.

The sound processor in Hybrid mode, regardless of associated implant, is indicated for recipients with residual hearing at frequencies between 125 Hz and 2 kHz.

Cochlear Hybrid Domes and Earhook

The Cochlear Hybrid Earhook with Removal Tool, Cochlear Hybrid Open Dome, Cochlear Hybrid Bass Single Dome, Cochlear Hybrid Bass Double Dome, Cochlear Hybrid Power Dome are indicated for use with the Cochlear Hybrid Receiver.

Cochlear Hybrid Earhook with Removal Tool refers to both the Cochlear Hybrid Earhook with Removal Tool for the Nucleus 8 Processing Unit, and the Cochlear Hybrid Earhook with Removal Tool for the Nucleus 7 Processing Unit, Nucleus 7 SE Processing Unit, Nucleus 7 S Processing Unit.

Cochlear Hybrid Ear Lock

The Cochlear Hybrid Ear Lock is indicated for use with the Cochlear Hybrid Receiver, size 60 and 85.

Contraindications

Cochlear Hybrid Receiver

The Cochlear Hybrid Receiver is not indicated for use with processing units other than those listed in the *Indications*.

The sound processor in Hybrid mode is not indicated for recipients who have no residual hearing at frequencies between 125 Hz and 2 kHz.

Cochlear Hybrid Domes and Earhook

The Cochlear Hybrid Earhook with Removal Tool, the Cochlear Hybrid Open Dome, the Cochlear Hybrid Bass Single Dome, the Cochlear Hybrid Bass Double Dome and the Cochlear Hybrid Power Dome are not indicated for use with devices other than those listed in the *Indications*.

Cochlear Hybrid Ear Lock

The Cochlear Hybrid Ear Lock is not indicated for use with devices other than those listed in the *Indications*.

Intended patient population

There are no restrictions for the intended patient population of the sound processor and accessories in terms of age, weight, health or other condition.

Benefits

The sound processor and accessories operate in conjunction with a compatible Cochlear Nucleus implant system.

Potential benefits of receiving a Cochlear Nucleus implant system include:

- Better understanding of speech in quiet.
- Better understanding of speech in noise.
- Increased satisfaction based on hearing capabilities.

Intended users

Intended users of the sound processor and accessories are:

- Recipients of a compatible Cochlear Nucleus implant.
- Carers of recipients, who carry out recipient functions as needed. Carers may include parents of paediatric recipients who are less than 12 years old, and nurses or other carers of otherwise dependant recipients.
- Audiologists/clinicians.

Use your Hybrid system

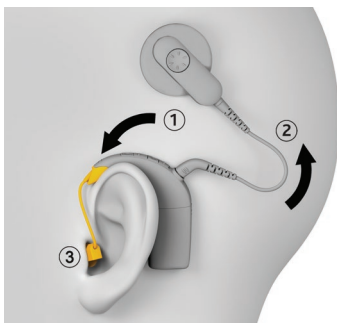
Wear your Hybrid system



Caution

- Recipients or carers should not fit the Hybrid system to the sound processor, or remove it. This should only be done by your clinician.
- Keep the Hybrid receiver away from the coil magnet.
- Do not twist the receiver cable.

1. Hold the coil in one hand and place the sound processor on your ear with the other.
2. Place the coil on your head.



3. Place your dome in your ear as instructed by your clinician.

Remove the Hybrid system

When removing your coil and sound processor, remove your dome from your ear as instructed by your clinician.

Care for your Hybrid system



Note

Your Nucleus 8, Nucleus 7, Nucleus 7 SE or Nucleus 7 S Hybrid system is not compatible with any parts that can be used with Freedom, CP800 Series or CP900 Series Sound Processors (for example, domes, earmoulds, receivers or earhook).



Caution

- Handle and store the Hybrid system very carefully.
- Do not drop the Hybrid system.
- Do not use cleaning agents or alcohol to clean your Hybrid system.

The Nucleus 8, Nucleus 7, Nucleus 7 SE or Nucleus 7 S Hybrid system provides the benefit of two wax filters:

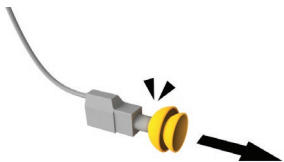
1. An in-built wax filter in the disposable dome.
2. A replaceable wax filter fitted in the receiver's speaker unit.

Every day

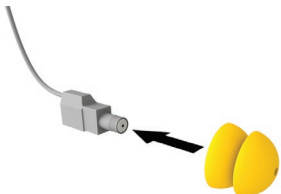
- Check all parts and any Hybrid accessories you use for dirt or moisture. Wipe the accessories with a soft dry cloth.
- Check the dome and its filter. Change the dome whenever its filter is clogged with wax, or whenever the dome is dirty, discoloured or losing shape.
- When changing the dome, also check the wax filter in the speaker unit. Change the speaker unit filter whenever it is clogged with wax or if the sound from the speaker unit does not sound normal.

Change the dome

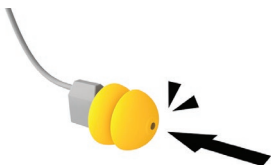
1. Pull the dome off, using your fingernails if necessary, and discard.



2. Push the new dome directly onto the speaker unit.



3. Click it securely into place.



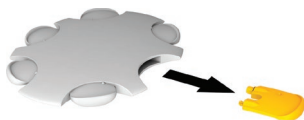
Change the speaker unit wax filter



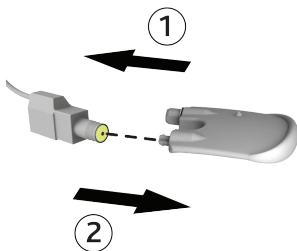
Caution

- Wax filters must **always** be used with the Hybrid system and replaced regularly.
- Keep the Hybrid receiver away from the coil magnet.

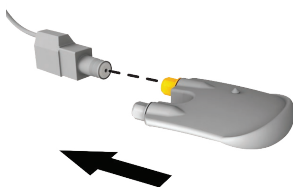
1. Remove a new ProWax tool from its shell. One point on the tool has a removal tool and the other point has the new filter.



2. Insert the removal tool into the existing wax filter and gently move the filter from side to side and remove it from the speaker unit.



3. Push the new filter into the speaker unit.



4. Dispose of the tool and used wax filter.

Troubleshoot

Check the Hybrid system

Problem	Resolution
You do not hear sound through the Hybrid system	<ol style="list-style-type: none">1. Change the sound processor batteries.2. Check your dome. If there is wax buildup, change the dome. See <i>Care for your Hybrid system</i> on page 10.3. Check your speaker unit wax filter. If there is wax buildup, change the filter. See <i>Care for your Hybrid system</i> on page 10.4. Check that the receiver is properly connected to your sound processor.5. If the problem continues, contact your clinician.
You experience discomfort when using the Hybrid system	<ol style="list-style-type: none">1. Check that your dome is properly fitted to the speaker unit.2. If the problem continues, contact your clinician.

Problem	Resolution
You hear intermittent or distorted sound, or sound is too soft	<ol style="list-style-type: none"> 1. Check that your dome is properly fitted to the speaker unit. 2. Check that the receiver is properly connected to your sound processor. 3. Check your dome. If there is wax buildup, change the dome. See <i>Care for your Hybrid system</i> on page 10. 4. Check your speaker unit wax filter. If there is wax buildup, change the filter. See <i>Care for your Hybrid system</i> on page 10. 5. Your receiver cable may be too long or too short. If in doubt, contact your clinician. 6. Your dome may be the wrong type or the wrong size. If in doubt, contact your clinician. 7. If the problem continues, contact your clinician.
Sound is too loud	Remove the sound processor and coil from your head immediately and contact your clinician.

Warnings

For parents and carers

- Sound processors and related accessories contain small parts that alone or in combination may pose a hazard of inhalation, choking or ingestion. Swallowing or inhaling small parts can cause severe or fatal injuries. Use the tamper-resistant locks to keep small parts attached to the processing unit where available, including parts that fit between the processing unit and battery module. Always supervise children under 3 years of age and others who may be at risk of inhalation, choking or ingestion of small parts when they use the sound processor and related accessories. When not in use, keep small parts, and combinations of small parts, out of reach from children. If small parts are swallowed or inhaled, seek immediate medical attention.
- Contact your clinician for advice on choosing the most suitable Hybrid system for children.
- Do not allow children to replace a Hybrid system.
- Keep all parts of the Hybrid system out of reach of children. Removable parts (for example, domes, earlocks and wax management systems) can be lost or may be a choking or suffocation hazard.
- Carers should routinely check for signs of discomfort. See your clinician if you are concerned that the Hybrid system is not working at a comfortable sound level.
- No modification of this equipment is allowed. Warranty will be void if modified.

Hybrid system

- Refit and replace domes regularly to ensure optimal fitting and retention. Consult your clinician for advice on Hybrid system misfits or signs of discomfort.
- Remove your sound processor if there is any discomfort or pain (for example, sound level is uncomfortably loud) and inform your clinician.

If the dome is not securely attached to your Hybrid system, it could fall off in your ear canal. If this happens, see your medical practitioner.



The Nucleus 8 Sound Processor, Nucleus 7 Sound Processor, Nucleus 7 SE Sound Processor and Nucleus 7 S Sound Processor, remote and related accessories (such as the Wireless Programming Pod) in Hybrid mode, are MR Unsafe.

Full MRI safety information is available at www.cochlear.com/warnings or by calling your regional Cochlear office (contact numbers available at the end of this document).

Other information

Materials

- Hybrid Earhook is made from polyamide (PA) and liquid silicone rubber (LSR).
- Receiver cable outer sheathing is made from polyamide.
- Hybrid Ear Lock is made of Polyether block amide copolymer (PEBA).
- Domes are made of silicone.

Operating characteristics

Measurements according to IEC 60118-0:2015.

Nominal data. Tolerances, where applicable, according to IEC 60118-7:2005.

Nucleus 7 Hybrid receiver - speaker unit					60	85	100	units
Frequency Range		< 200 – 2200			Hz			
OSPL90	Peak				105	112	119	dB SPL
Reference Test Gain					25	30	38	dB
Full-On Gain	Peak				31	43	52	dB
Total	250 Hz @ 70dB SPL				1.4	0.7	0.5	%
Harmonic	400 Hz @ 70dB SPL				1.3	0.8	0.6	%
Distortion	625 Hz @ 65dB SPL				0.9	0.5	0.7	%
ETLS * (vertical field)					0	0	1	dB
Equivalent Input Noise (EIN)					23	23	22	dB SPL

Nucleus 8 Hybrid receiver - speaker unit					60	85	100	units
Frequency Range		< 200 – 2200			Hz			
OSPL90	Peak	105	111	117	dB SPL			
Reference Test Gain		27	32	40	dB			
Full-On Gain	Peak	37	50	59	dB			
Total	250 Hz @ 70dB SPL	1.6	0.6	0.6	%			
Harmonic	400 Hz @ 70dB SPL	1.5	0.6	0.6	%			
Distortion	625 Hz @ 65dB SPL	1.2	0.6	0.7	%			
ETLS * (vertical field)		1	1	1	dB			
Equivalent Input Noise (EIN)		25	24	24	dB SPL			

Environmental conditions

Condition	Minimum	Maximum
Storage and transport temperature	-10° C (+14° F)	+55° C (+131° F)
Storage and transport humidity	0% RH	90% RH
Operating temperature (sound processor)	+5° C (+41° F)	+40° C (+104° F)
Operating relative humidity	0% RH	90% RH
Operating pressure	700 hPa	1060 hPa

Product components

Hybrid receiver - speaker unit	Cable sizes
60	1, 2, 3, 4
85	1, 2, 3, 4
100	1, 2, 3, 4

Labelling symbols

The following symbols may appear on your sound processor or accessories and/or packaging:



Refer to instruction manual



Consult instructions for use



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/European Union



Authorised representative in Switzerland



Unique Device Identifier



Medical Device



Catalogue number



Serial number



Batch code



Date of manufacture



Temperature limits



CE registration mark with notified body number



CE registration mark



Radio compliance certification for Australia and New Zealand

Rx Only

By prescription

Caution: US law restricts this device to sale by, or on the order of, a physician



Recyclable material



Dispose of electrical components in accordance with your local regulations



Dispose of batteries separately from normal waste and according to your local regulations



Type B applied part

IP54

Ingress Protection Rating

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

Electromagnetic compatibility (EMC)



Warning

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 in.) to any part of your sound processor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Interference may occur in the vicinity of equipment marked with the following symbol:



Environmental protection

Your sound processor contains electronic components subject to the Directive 2012/19/EU on waste electrical and electronic equipment.

Help protect the environment by not disposing of your sound processor or batteries with your unsorted household waste. Please recycle or dispose of your sound processor according to your local regulations for electronics.

Summary of Safety and Clinical Performance

A summary of the safety and clinical performance of your devices can be found at:

<https://ec.europa.eu/tools/eudamed>

Refer to Intended purpose on page 5 for the full list and names of your devices.

Serious incidents

Whilst serious incidents in relation to medical devices are rare, it is acknowledged that incidents may happen. As an organisation, Cochlear recognises the potential for harm and will respond to any reported serious incident.

What is a serious incident?

A 'serious incident' means any event that directly or indirectly has caused or could have caused an unexpected or unwanted event including any of the following:

- The death of a patient, user or other person
- The temporary or permanent serious deterioration of a patient's, user's or other person's state of health
- A serious public health threat.

Reporting a serious incident

There is no definitive list of events/incidents that constitute a serious incident, however all serious incidents should be reported to:

- Your local Cochlear office
www.cochlear.com/intl/contact/global-offices

People within the European Union should also report all serious incidents to:

- Your National Competent Authority
https://health.ec.europa.eu/medical-devices-sector/new-regulations/contacts_en

People within Australia should also report all serious incidents to:

- Therapeutic Goods Administration
<https://www.tga.gov.au>

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+A2:2020, Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance.

Trademark legal notice

ACE, Advance Off-Stylet, AOS, Ardium, AutoNRT, Autosensitivity, Baha, Baha SoftWear, BCDrive, Beam, Bring Back the Beat, Button, Carina, Cochlear, 科利耳, コクレア, 코클리어, Cochlear SoftWear, Contour, コントウア, Contour Advance, Custom Sound, DermaLock, Freedom, Hear now. And always, Hugfit, Human Design, Hybrid, Kanso, LowPro, MET, MP3000, myCochlear, mySmartSound, NRT, Nucleus, Osia, Outcome Focused Fitting, Off-Stylet, Piezo Power, Profile, Slimline, SmartSound, Softip, SoundArc, SoundBand, True Wireless, the elliptical logo, Vistafix, Whisper, WindShield and Xidium are either trademarks or registered trademarks of the Cochlear group of companies.

Hear now. And always

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P1858256 D1818787-V3 2025-02

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