Cochlear™

Nucleus® CR220
Intraoperative Remote Assistant
User Guide

Professional use only

Hear now. And always

Cochlear™

Symbols

Note
Important information or advice. Can save inconvenience.

Warning (harmful)
Potential safety hazards and serious adverse reactions.
Could cause harm to person.

Compatibility

The Cochlear™ Nucleus® CR220 Intraoperative Remote Assistant is compatible with the following implants:

- CI512
- CI513
- CI522
- CI24RE (CA)
- CI24RE (ST)
- CI24RE H
- CI422

It is not compatible with ABI and double array implants

Contents

Introduction

The Cochlear Nucleus CR220 Intraoperative Remote Assistant is a hand-held remote control that enables a clinician to perform impedance and AutoNRT™ tests on a Cochlear implant in the operating theatre.

The intra-operative remote assistant is compatible with the CP810 processor. It does not support bilateral functionality or accessories.

The purpose of this user manual is to guide clinicians through the functions and uses of the CR220 intraoperative remote.

It is strongly advised that you familiarise yourself with the intraoperative remote assistant well in advance of your first scheduled surgery.

The remote assistant is to be used for surgery only.

The sound processor and the remote assistant are not sterilised and should be enclosed in sterile plastic bags during surgery.

About the intraoperative remote

Front view

Not used

Remote assistant display

Not used

Up arrow

Left arrow

Down arrow

Lock or unlock slider

Not used

Home button

OK button

Right arrow

Pin for attaching the remote assistant lanyard

Note: buttons highlighted in orange do not perform any function.

Back view

Personal identification l.

Remote assistant speak

Coil guides for pairing

Hard reset button

Not used

Product information label

USB cable socket

How to navigate through the screens

1. To scroll forward through the screens, press the right arrow button

2. To move back through the screens, press the left arrow button

3. To select an option on a screen, press the 'OK' button

4. To return to the eprevious menu or Home screen, use the 'Home' button

How to hold and operate the remote

Hold the remote assistant in the palm of your hand. Keep it within 2 metres (about six feet) of the sound processor (about six feet) of each other. Operating it at a greater distance may cause increased delay between the sound processor and the remote assistant response time or loss of communication all together.

2 metres or less
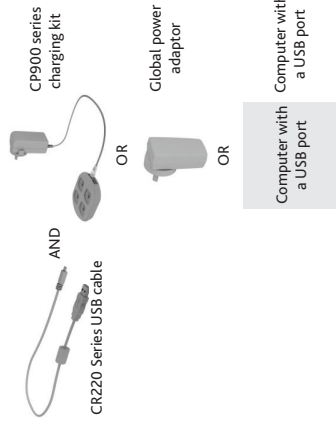
Initial set-up

Charge the remote assistant battery

It is recommended to fully charge the remote assistant battery before using the remote assistant for the first time. It may take approximately 2 to 4 hours to fully charge a completely empty battery. A fully charged battery should provide you with enough battery life to last a full surgery. However, battery life varies depending on amount of usage.

Ensure that you only use battery charging equipment supplied by Cochlear to charge the remote assistant battery.
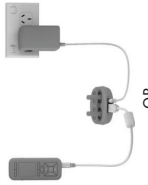
Tools to charge the remote assistant battery

To charge the remote assistant battery, you will need:

CR220 Series USB cable

AND

CP900 series charging kit

OR

Global power adaptor

Computer with a USB port

OR

Computer with a USB port

Three options for charging the remote assistant

1. Charge using the sound processor battery charger

OR

2. Using the global power adaptor

OR

3. Using a computer with a USB port

Charging with a computer

When charging, the indicator light will be steady green

Green indicator light on battery charger

When charging correctly, this screen will appear

When the battery is full, this screen will appear
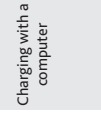
Turning the remote assistant on

To turn the remote assistant on:

1. Press and hold OK button

OK

2. Start up screen will appear

3. surgery warning screen will appear

4. Press OK

OK

5. Home screen will appear

Selecting the language

When using the remote assistant for the first time, it will prompt you to select a language.

1. Selection screen will appear

2. Press up or down arrows to select preferred language

Up

Dn

3. Press OK

OK

Practice mode

Practice mode allows you to familiarise yourself with the remote assistant before you start using it clinically.

 No adjustments or changes to settings are saved or sent to the sound processor while in practice mode.

If there is no sound processor paired to the remote assistant:

1. Prompt screen appears
2. Press right arrow
3. Press OK
4. Select 'Start' and press OK
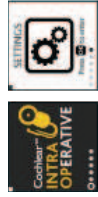5. Screen appears
6. Press OK

If you wish to enter practice mode while a sound processor is paired:

1. Press & hold OK
2. Menu appears
3. Select 'Practice Mode' and press OK
4. Menu appears
5. Select 'Start' and press OK
6. Screen appears
7. Press OK

When using practice mode, a small white or black square will appear in the top left corner of the screen.

To cancel practice mode:

1. Press & hold OK button
2. Menu appears
3. Select 'Exit Practice Mode' and press OK

Pairing the remote assistant

Pairing allows the remote assistant to communicate with the processor.

Before you start, ensure that both the processor and the remote assistant are switched on.

If there is no sound processor currently paired with the remote assistant, the following screen will prompt you to pair a sound processor:

If there is already a sound processor paired, you can re-pair with a different sound processor at any time using the following instructions.

To pair the remote assitant with a sound processor:

1. Hold the processor coil on the coil guides at the back of the remote assistant

2. 'Pair processor' prompt screen will display

3. Press OK and wait during initialisation

OK

When pairing is complete, the 'Processor Paired' screen will appear, followed by the 'Home' screen
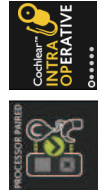
Setting remote assistant beeps

You can adjust the remote assistant beeps from the Settings screen.

1. From the 'Home' screen, use the right arrow key to scroll to the Settings menu

Rt Rt Rt Rt Rt Rt Rt

SETTINGS

2. Press OK

OK

3. Use up and down arrows to select 'Soft', 'Loud' or 'Off'

Up

Dn

4. Press OK

OK

Turning the remote assistant off

To turn the remote assistant off:

1. Press and hold the OK button until the menu screen displays.

2. Select Switch Off from the menu selection to turn the remote assistant off.

OK

SWITCH OFF
Cancel
Switch Off
Reset Settings
CANCEL

Up
Dn

The remote assistant automatically goes into standby mode if it has been inactive for an extended period. Press any button to 'wake' the remote assistant from standby mode.

Day before surgery

Checking the remote assistant battery status

To check the remote assistant battery status, watch for the battery level indicator screen when the remote assitant is switched on.

You can also view the battery status by locking the keypad (see p.21).

Checking the processor status

To check the status of the processor and processor battery:

1. Press the OK button quickly from Home screen. The status screen will display

OK

STATUS
PRESS

OK

If the remote assistant receives an error from the processor, or the processor battery is low, a visual alert will display .

STATUS
Press OK

Recharge batteries and resolve processor errors

Recharge batteries if they are not fully charged. Refer to pages 9-10 for instructions to recharge the batteries.

If the remote assistant displays any processor errors, refer to pages 31-33 to resolve the errors.
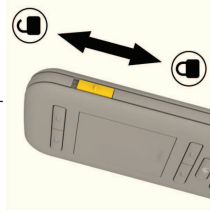
Immediately before surgery

Repeat battery and processor checks

We recommend repeating the battery and processor checks again on the day of the surgery. (See pages 19-20)
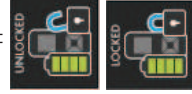
Locking & unlocking the remote assistant keypad

The remote assistant keypad can be locked to prevent pressing keys accidentally.

1. Slide the lock/unlock slider down to lock or up to unlock

2. The 'Locked' or 'Unlocked' screen will appear

The 'Locked' and 'Unlocked' screens also display the remote assistant battery status.

The remote assistant cannot be turned off while the keypad is locked.

Place the remote assistant in a sterile bag

Before entering the operating theatre, place the remote assistant in a sterile bag and seal the bag.

Remote assistant in a sterile plastic bag
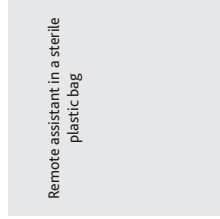
Do not sterilise the remote assistant.

During surgery

During surgery, the intraoperative remote assistant can be used to perform impedance and AutoNRT tests. When performing intraoperative tests, ensure the processor is placed over the implant to get accurate measurements.

Impedance test

The impedance test indicates the electrical status of the intra-cochlear electrodes. It loops continuously through the 22 electrodes, displaying which electrode is being tested, and the status of all electrodes already tested.

1. From the Home screen, press the right arrow

Rt

2. Impedance screen will display

IMPEDANCE
Press OK to measure impedance

3. Press OK to start continuous impedance measurement

OK

IMPEDANCE

4. When you are satisfied with the impedance results, press OK to stop the test

OK

5. 'Stopping' screen will display, followed by results screen

IMPEDANCE
Stopping...

IMPEDANCE

Electrode definitions for impedance test

Not yet tested/skipped

Impedance OK

Open circuit

Currently being measured

Impedance not found

AutoNRT test

Neural Response Telemetry (NRT) measures neural activity within the cochlea in response to electrical stimulation from the implant. An AutoNRT test provides a quick, non-invasive, objective measure of peripheral neural function.

1. Use right arrow to reach AutoNRT screen

Rt

2. AutoNRT screen will display

3. Press OK

OK

4. AutoNRT launch screen will display

5. Press OK

OK

6. AutoNRT will run

7. On successful completion, AutoNRT complete screen will display

8. Number of electrodes successfully measured will also display

Viewing results while AutoNRT is running

While the AutoNRT test is running, you can press the right and left arrow buttons to switch between the following results views: Electrode view, graph view and trace view.

Electrode view   **Graph view**   **Trace view**

Pausing AutoNRT

You can pause the AutoNRT results while the test is running.

1. Press any button to pause the process and display the AutoNRT Paused screen.

2. If you choose to cancel the AutoNRT test prior to successful measurements, the screen displays a cancelled message.

Viewing final AutoNRT results

The results screen displays the most recent tests for the currently detected implant. The results are displayed in the following screens:

Electrode definitions for AutoNRT

Not yet tested/skipped

NRT OK

Open circuit

Currently being measured

Neural response not found

After surgery

Cleaning the remote assistant

To keep the remote assistant clean, wipe it with a soft dry cloth. Do not use alcohol, household cleaners or abrasive materials to clean the remote assistant.

If the remote assistant gets wet:

1. Turn it off
2. Wipe it with a soft dry cloth
3. Leave out to dry for approximately 12 hours.
4. Turn it on again after it is dry. If the remote assistant no longer functions, return it to your Cochlear representative. Cochlear cannot guarantee that it can repair a water-damaged remote assistant.

   Do not use an oven or microwave or any other electrical or heating device to dry the remote assistant.

Uploading results to fitting software

You will need to upload the results from the remote assistant to the cochlear implant fitting software (CustomSound or NFS). Refer to the user guide for your fitting software for full instructions.

Troubleshooting

The remote assistant displays visual alerts when errors occur. Some alerts mean that the testing processes cannot continue (e.g. if the processor coil has moved off the implant). In these cases, the problem will need to be rectified before testing can continue.

Visual alerts

Error	Screen display	Troubleshooting information
Processor error		Text
Incorrect coil type		Text
Coil cable fault		Text
Can't find processor		Text

Error	Screen display	Troubleshooting information
		Text
Incorrect implant		
Coil fault		
Coil off implant		
Processor battery low		
Remote assistant battery low		
Processor battery empt		

Error	Screen display	Troubleshooting information
		Text
Remote assistant battery empty		
Processor and implant error		This alert may display during impedance or AutoNRT testing
Charge processor error		This alert may display during impedance or AutoNRT testing
Charge remote error		This alert may display during impedance or AutoNRT testing
Switch on processor error		This alert may display during impedance or AutoNRT testing

Displaying system details

You can view the remote assistant serial and version numbers from the Settings menu.
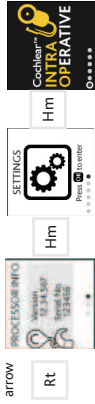
1. From the 'Home' screen, use the right arrow key to scroll to the Settings menu

Rt	Rt	Rt	Rt	Rt	Rt

2. Press OK

OK

3. 'Beeps on remote' menu will display

4. Press right arrow

Rt

5. 'Remote info' screen will display

6. Press right arrow

Rt

7. 'Processor info' screen will display

8 Press Home button to return to settings menu and 'Home' screen

Hm

Hm

Resetting the remote assistant

If the Home button does not work or the remote assistant display freezes, you can reset the remote assistant by inserting a pointed object into the reset socket located on the back of the remote. This will reset the remote to its original settings, including language, pairing information, remote beeps and remote alerts.

General care and precautions

- Only use the intraoperative remote assistant while the recipient is under anaesthetic.

- Do not use or store the device in dusty or dirty areas, extreme high or cold temperatures (e.g. Do not store in direct sunlight, behind a window or in a car for extended periods of time)

- Take care when placing the remote assistant in a bag or pocket with other objects as the display may scratch. Commercially available protective films may be used to protect the remote assistant display from scratches.

- Do not use alcohol, household cleaners or abrasive materials to clean the remote assistant.

- Do not use any commercial or household appliance to dry the remote assistant.

- Only use the CR200 Series Global Power Adaptor, the CP900 Series Global Power Adaptor (if using the CP900 Series Battery Charger) or the CR200 Series Global charging kit when charging your remote assistant from mains power.

- Do not bend or compress the display on the remote assistant.

- Do not use excessive force when connecting or disconnecting the USB cable or when using the buttons on the keypad.

- Do not disassemble, deform or immerse in water. If the remote assistant is not working, return it to your clinician. Warranty will be void if opened.

- Do not use the remote assistant if it becomes unusually warm. Inform your Cochlear representative immediately.

- Dispose of electrical components in accordance with your local regulations.

- When charging the remote with a computer, ensure the computer conforms to IEC 60950 standards.

Technical and legal information

Technical information

The remote assistant wireless communication link operates in the 2.4 GHz ISM band using GFSK (Gaussian Frequency Shift Keying) on 10 channels. The link uses a proprietary bi-directional communication protocol and operates over a distance of up to 2m from the CP810 series processor. When interference is present, the wireless communication link switches between the 10 channels to find a channel where the interference least affects the operation of the link. The remote assistant indicates via its display when the processor is not within operating distance, and when the link has been interrupted due to interference.

Specifications

Physical configuration

The remote assistant comprises:

- Custom analogue and digital integrated circuits based on a micro-processor design, with bi-directional wireless communication capabilities.

- Push-buttons/keys and a slider for control of processor features and its own system features.

- A display for indicating system status and activity.

- A speaker for sounding an audible alert.

- In-built coil sensor to check if the processor's coil is receiving sound signals from the processor and for pairing.

- On-board battery charging circuit.

- A temperature sensor for battery safety.

- A micro USB connector for charging the remote assistant and updating the firmware.

Materials

The remote assistant housing, including non-metallic buttons/keys, is made of polycarbonate.

Dimensions

Length	Width	Depth
110 mm	46.1 mm	13.35 mm

Weight

The remote assistant weighs 65 g.

Operating characteristics

Characteristic	Range
Wireless technology	Proprietary Low Power Bidirectional Wireless Link
RF frequency	2.4 GHz
Operating battery voltage	3.7 V
Battery charging voltage	4.2 V
Battery capacity	680 mAh (Internal Lithium-ion battery)
Push-key functions	Remote assistant on and off and remote assistant settings change
Wireless transmission range	Up to 2 m
Display	128 x 128 pixels, colour LCD

Environmental conditions

Condition	Minimum	Maximum
Storage temperature	-40 ºC (-40 ºF)	+50 ºC (+122 ºF)
Storage relative humidity	0% RH	90% RH
Operating temperature	+5 ºC (+41 ºF)	+50 ºC (+122 ºF)
Operating relative humidity	0% RH	90% RH

Certification and applied standards

The CR220 Remote Assistant fulfils the essential requirements listed in Annex 1 of the EC directive 90/385/EEC on Active Implantable Medical Devices as last amended by EC Directive 2007/47/EEC.

CE 0197

Equipment classification

Your remote assistant is internally powered equipment Type B as described in the international standard IEC 60601-1:2005, Medical Electrical Equipment - Part 1: Basic Safety and Essential Performance.

FCC (Federal Communications Commission) and Canadian IC compliance

This device complies with part 15 of the FCC Rules and with RSS-210 of Industry Canada. Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications made to this equipment not expressly approved by Cochlear Limited may void the FCC authorization to operate this equipment.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

FCC ID: WTOR200FF

IC ID: 8039A-R200FF

Labelling symbols

The symbols below are found on your remote assistant components and packaging

	Consult instructions for use
	Storage temperature limits
	Relative humidity limits
	Disposal - do not dispose in fire
	Disposal – dispose of electrical components in accordance with your local regulations
N2792	Certification - Japan
Z1297	Certification - Australia
	Certification - New Zealand
SN	Serial number
	Date of manufacture
	Type B applied part
	This device restricted to sale by or on the order of a physician.
	Recycle
CE0197	CE Registration Mark

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.

Nucleus® cochlear implant systems are covered by one or more international patents.

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