Cochlear®
Hear now. And always

Nucleus® SmartNav

Version 2.0

User Guide

For Professionals

Symbols used in this document

	**Note:** Important information or advice.
	**Tip:** Time saving hint.
	**Warning (harmful):** Potential safety hazards and serious adverse reactions. Could cause harm to person.

Contents

Introduction

Nucleus® SmartNav is designed to be used with the CP1150S Surgical Processor by surgeons and clinical partners to provide a suite of intraoperative measurements related to the placement and function of the electrodes in the cochlea.

To start using Nucleus SmartNav:

1. Follow the link provided by Cochlear™ to download and install Nucleus SmartNav to a compatible iPad®. See *System requirements* on page 9 for more information.
2. Run Nucleus SmartNav.
3. Follow the instructions on the screen to log in and set up the app with a surgical processor.
4. Start using the app

Note: Please see the *Nucleus SmartNav Technical Description* for more technical details on device and application setup, networking and security.

Intended purpose

Nucleus SmartNav is intended to be used in combination with other devices to provide intraoperative measurements that aid in monitoring the insertion, placement and functioning of the electrodes during a cochlear implant surgical procedure, and for use in subsequent fitting or programming of a sound processing unit.

Warning: Nucleus SmartNav and the surgical processor is to be used for surgery only, and should only be used while the recipient is under general anaesthetic. Some diagnostic measurements may cause discomfort in conscious patients.

Indications

Nucleus SmartNav is indicated for use with a compatible Cochlear processing unit or sound processor. Compatible devices are:

- CP1150S Surgical Processor

Nucleus SmartNav is compatible with the following Cochlear Nucleus implants:

- CI600 Series Implants[1]: CI612, CI622, CI624, CI632
- CI500 Series Implants[2]: CI512, CI522, CI532
- CI24RE Series Implants: CI422, CI24RE (CA)

Contraindications

Nucleus SmartNav is not indicated for use with implants other than those listed in *Indications* on page 7.

Warning: Do not attempt stimulation of unsupported implants with Nucleus SmartNav or the surgical processor.

Intended patient population

Nucleus SmartNav is intended for patients implanted with a compatible Cochlear Nucleus implant. There are no restrictions for the intended patient population of the Nucleus SmartNav in terms of age, weight, health or other condition.

Benefits

The clinical benefit of Nucleus SmartNav is to potentially reduce the need for intraoperative imaging and/or revision surgery by confirming placement and function of electrodes during a cochlear implant surgical procedure. Such intraoperative confirmation may reduce the patient's exposure to radiographic imaging and the overall time required for the surgical procedure whilst providing intraoperative feedback on electrode performance that could alleviate the need for subsequent surgeries.

[1] For Canada only: CI632P are also indicated implants within the CI600 series.

[2] For Canada only: CI512P and CI532P are also indicated implants within the CI500 series.

Intended users

Nucleus SmartNav is intended for use by trained professionals experienced in cochlear implantation, including surgeons performing the surgery as well as hearing professionals (e.g. audiologists) and healthcare professionals assisting in the surgical procedure. ESRT and Advanced NRT are optional features and are intended for use by hearing professionals (e.g. audiologists) only.

Special training or qualifications

There is no special training required to use Nucleus SmartNav. Surgeons and hearing professionals using Nucleus SmartNav receive instructions for use and have access to Demo mode in the app. Surgeons and hearing professionals can request in-surgery support from a Cochlear representative when first using Nucleus SmartNav.

Use environment

Nucleus SmartNav is intended to be used in the operating theatre during surgery. None of the parts need to be sterilised since they are intended to stay outside the sterile field. Parts that have to be brought to the sterile field, like the surgical processor, will be covered by a sterile bag in the same way as it is done in a standard cochlear implant procedure (e.g. for intraoperative NRT® recordings).

System requirements

Nucleus SmartNav requires:

- the latest version of iPadOS®. At the time of publication, the latest version is 16.4.

  Nucleus SmartNav is continuously updated to remain compatible with the latest version of iPadOS. The latest version of iPadOS is available at: http://www.apple.com/ipados

  As new versions of iPadOS are released by Apple, Nucleus SmartNav will discontinue compatibility with previous versions of iPadOS.
- an iPad that supports that latest version of iPadOS (if your iPad does not support that latest version of iPadOS, you need to upgrade the iPad)
- an iPad with a screen size of at least 9.7 inches
- a network connection access to Bluetooth®.

It is not designed for use with other Apple devices.

The device requires a passcode or biometric authentication be set before Nucleus SmartNav can be used.

Using the software on a network

Nucleus SmartNav requires internet access to complete the operations:

- Logging into Nucleus SmartNav
- Setting up a surgical processor

For intraoperative use, once you are logged in access to the internet is not required.

Internet access is required to complete operations for the optional features:

- Creation of upcoming surgical sessions
- Registration of implants
- Transfer of session data
- Send troubleshooting data

When offline, optional features transition to a pending state until internet access is restored.

Nucleus SmartNav data security

Device security is a shared responsibility between device manufacturers and health care facilities. Nucleus SmartNav includes a number of built-in features that can help protect the confidentiality and integrity of information such as:

- User names and passwords to control access to Nucleus SmartNav.
- Secure audit logging of interaction and access.
- Requires a passcode or biometric authentication be set on the device before the Nucleus SmartNav can be used.

To help reduce the risk of unauthorised access to Nucleus SmartNav it is best practice to implement an IT security policy within the healthcare facility that considers the following items:

- iPadOS operating systems including the latest security updates from Apple.
- A password policy that requires strong passwords, pins or security codes that are changed regularly and are applied to devices where Nucleus SmartNav is installed.
- Keep all passwords, pins and security codes protected.
- Enable device encryption and encrypt transmitted data.
- Locking and managing access to the device and the surgical processor when unattended.

Setup

Run Nucleus SmartNav

1. Select the Nucleus SmartNav icon to start the app.
2. Follow the instructions on the screen to log in and set up the app.

Note: You will need to log in to the app using your Cochlear Professional Account.

Log in to Nucleus SmartNav

Note: The login process requires the device to have an active internet connection.

To get started, log in via the app using your Cochlear Professional Account, or create a new account.

If you already have a Cochlear Professional Account, you need to ensure your account is associated with your clinic. Log in to myCochlear Professional portal and review your account and if required, add your clinic to your account.

If you don't already have an account, you will need to create one.

Note: New accounts can take up to 72 hours to become active before you can log in and start using the app. Accounts must be related to an organisation. Individual accounts cannot be used with Nucleus SmartNav.

Visit https://mycochlear.com/ to create or update your account.

We recommend that you read our Privacy Notice https://www.cochlear.com/privacy to understand what data is collected and how it is used.

Tip: You will also be required to periodically log in with your Professional Account when starting the app.

Once you have logged in, select an organisation or one of the centres that your Cochlear Professional Account is associated with.

Demo mode

Explore Nucleus SmartNav in Demo mode to familiarise yourself with the application and its interfaces.

Set up the surgical processor

Before you begin using the surgical processor, you will need to set up and pair the surgical processor with the device.

Note: The set up process requires the device to have an active internet connection.

Tip: Ensure that Bluetooth is active on the device.

To set up the processor:

1. Press **Setup new processor**.
2. Nucleus SmartNav searches for a surgical processor to pair with the device.

   Switch the surgical processor on by double tapping the front cover. The LED will indicate that the surgical processor is active.

   If the surgical processor is not found:

   - Ensure that your processor is fully charged, then switch on your surgical processor in pairing mode by double tapping the front cover, a green LED indicator will flash before beginning to blink orange.

   It may take up to 30 seconds for the surgical processor to connect.
3. Check that the serial number displayed in the app matches the serial number on the processor.
4. Double tap the surgical processor when prompted to initiate the verification.

   Your professional identifiers will be sent to Cochlear for verification.

Note: It may take up to 30 seconds to complete the verification and set up.

Warning: Do not connect to devices that have had their operating system altered. Only connect to devices that are protected, e.g. password or PIN access control. Consider security when connecting your surgical processor to devices.

Nucleus SmartNav menu

Select the menu icon at top left of the screen to open the Nucleus SmartNav menu.

- **Sessions** - returns to the active session or the application dashboard if no surgical session is currently active.
- **Setup new processor** - go through the process of setting up and pairing a new processor.
- **Demo mode** - enables Nucleus SmartNav demo mode for users to run through all of the key functionality of Nucleus SmartNav through a series of pre-packaged surgical sessions.

Note: The Demo mode option will be hidden when a surgical session is active.

Settings

- **Account details** - view the details of the account being used with Nucleus SmartNav. Here you can also reset the password associated with the account, sign out of the account on the device and update location information.
- **App settings** - view and change settings such as announcements, electrode conditioning and enabling advanced features like Electrical Stapedius Reflex Threshold (ESRT) and Advanced NRT.
- **About** - view information about Nucleus SmartNav and linked surgical processor, and access the application audit log.

Session actions

During a surgical session the following session actions available through the application menu:

- **Electrode Conditioning** - enables electrode conditioning during the placement check and NRT measurements. When selected, Nucleus SmartNav performs electrode conditioning. This produces at least two bursts at a high current level to reduce impedances on the electrode.
- **Announce Angle** - enables audio announcement of angular depth of insertion during insertion diagnostics.
- **New session: current implant** - finalises the current session as discontinued and begins a new session with the same patient and implant information.
- **New session: new implant** - finalises the current session as discontinued and begins a new session with the same patient information but prompts for new implant information.
- **End session** - finalises the current session as discontinued.

Note: Discontinued sessions are shown in the previous session list from the application dashboard.

Sessions

In Nucleus SmartNav you can create, view or edit upcoming sessions and view previous sessions from the dashboard. All sessions are filtered by organisation and are searchable.

Create a new session

To create a new session:

1. Choose an organisation.

   Note: Organisations are linked to the user account and can be changed by selecting the organisation at the top of the Nucleus SmartNav dashboard.

2. Select **Create Session**.
3. If the patient has a Cochlear Account that is linked to the selected clinic, you can search and select a patient to populate the session details. If the patient does not have a Cochlear Account or it does not show up, select **Enter details manually**.
4. Enter or update the patient details.

   Note: It is possible to edit patient details during a session but you cannot edit the details during the finalisation process.

5. Scan the implant data code using the device camera.

   

   or

   Enter the serial number for the implant.

   Tip: The implant data code is located on the right side of the sticker label on your implant packaging.

6. Select a Cochlea anatomy.
7. Enter the Skin Flap Thickness.
8. Enter the Cochlea diameter.

   Note: The cochlea diameter measurement should come from preoperative medical imaging. If selecting 'not measured' Nucleus SmartNav will use the population mean of 9.2 mm.

9. Select a Fitting Clinic associated with the patient.
10. Choose an Operating Surgeon.

    Note: Surgeon accounts are linked to the current selected organisation. If the surgeon does not appear, you can create a new entry by selecting **Add a Surgeon**.

Once the patient and surgery details have been entered, you can:

- Select **Save** to save the session as an unscheduled session in upcoming sessions
- Select **Start Surgery** to begin the session
- Select **Schedule for Later** to save the session in upcoming sessions.

Editing and deleting upcoming sessions

Upcoming sessions can be edited by selecting the edit icon that appears on the right of the session in the upcoming sessions list on the dashboard.

Upcoming sessions can be deleted by sliding the session to the left in the upcoming session list on the dashboard and selecting **Delete**.

Before surgery

Cochlear recommends recharging the surgical processor and the device with the app before every surgery.

Enable advanced features

Advanced features such as ESRT and Advanced NRT will not be displayed in the surgical workflow by default. You must enable these features from **App Settings** in the application menu to make them available during a session.

Start a session

1. Select a session for the patient from the upcoming sessions on the dashboard. If you have not scheduled a session for the patient please see *Create a new session* on page 14.
2. Review and update the session details.
3. Select **Start Surgery**.

Connect to the surgical processor

Tip

Ensure that the device's Bluetooth is enabled.

If the surgical processor has gone into sleep mode, it can be awakened at any time by double tapping on the cover.

Connect Nucleus SmartNav and the surgical processor:

1. Double tap the front cover of the surgical processor to turn it on.

   A green light will flash and then an orange light appears when the processor is on.
2. Check that the surgical processor is paired to Nucleus SmartNav device.

   Note: If the surgical processor is not paired to Nucleus SmartNav device you may need to re-execute the surgical processor setup process (See *Set up the surgical processor* on page 12). This can be initiated via the application menu.
3. Check the battery status of the device and the surgical processor.

During surgery

During surgery, the app can be used to measure angular insertion depth (for compatible electrode types) and speed, the electrode placement, the impedance, ESRT and NRT threshold of electrodes inside the cochlea.

When performing intraoperative tests, ensure the surgical processor is placed on the implant to obtain any measurements. If the surgical processor is removed from the implant during measurement, replace the surgical processor and follow the on-screen prompts in the app to resume the intraoperative tests.

Surgical considerations before performing measurements

Extracochlear electrodes

For live diagnostics, the Nucleus SmartNav system needs to be used during electrode insertion. Surgeons will therefore need to ensure that the system is set up prior to commencing electrode insertion. Both of the live diagnostic insertion measurements (angular insertion depth and speed of insertion) require that the extracochlear ground electrodes be in contact with tissue i.e. there is a current path between intra- and extra- cochlear electrodes during insertion.

Surgeons will therefore need to ensure that prior to electrode insertion:

- Extracochlear (ECE1) electrode is placed under the temporalis muscle.
- The skin flap is covering and in contact with the plate electrode (ECE2) of the implant.

Note: Ensure that the tissue/ECE interface is wet and that there is good contact for a stable current path during measurements.

Skin flap and draping

The skin flap thickness and thickness of the draping play an important role in the quality of communication between the surgical processor and the implant. This impacts the connection quality and accuracy of intraoperative measurements for Nucleus SmartNav.

To ensure the best possible connection:

- Keep draping to a minimum to reduce the coil-to-coil distance between the surgical processor and the implant.
- A large skin flap thickness might cause intermittency. It is a best practice to measure the skin flap thickness.
- Securing the processor with Steri-strips or applying pressure to the processor is recommended

Sterile field

Warning: The surgical processor is not sterile. Place the surgical processor in a sterile bag before use in the sterile field.

The device with the app is only to be used outside the sterile field. If your procedures introduce a potential risk of contamination of the device during surgery please take steps to protect the device from contamination.

Device setup

1. Place the surgical processor onto the implant.

   A green light will blink when the processor is communicating with the implant.
2. Device setup checks the connection between the surgical processor and the implant. Follow the on-screen instructions to improve the connection.
   The on-screen instructions describe the connection between the surgical processor and the implant and as a result, which diagnostic tests are available.
3. When setup is complete, proceed to the next step.

For the CI600 Series implants

With the CI600 Series implant, avoid sliding the surgical processor sideways onto the implant. This could cause the surgical processor magnet to misalign with the implant. Always place the surgical processor down onto the implant.

To place the surgical processor onto the implant:

1. Hold the surgical processor slightly above the implant location on the head.
2. Rotate the surgical processor slightly in both directions (clockwise and anti-clockwise).

3. When you feel a strong pull, place the surgical processor on the implant.

Run insertion diagnostics

For compatible electrode types, as you insert, the app displays and announces angular insertion depth, to track the progression of insertion. The app also communicates insertion speed during insertion.

To run live diagnostics during surgery,

1. Press **Start** on the Live Diagnostics screen.
2. Press **Stop** once the insertion is complete to end the measurement.

Angular insertion depth

If performing surgery with a compatible electrode type (Nucleus CI624, CI622, CI522 and CI422 cochlear implants), the app will simultaneously provide visual and audio readout at preset angles as real-time feedback of the electrode location.

Note: Announcement of angle for angular depth of insertion can be enabled or disabled under **App Settings** in the App menu.

Speed of insertion

For all electrode types, the app will concurrently provide real-time measurements for the speed of insertion. Providing visual readout every few seconds until the electrode insertion is completed.

View placement check report

After insertion, placement check indicates if there is a probability of fold.

Note: The placement check and conditioning process can take up to 2 minutes to complete.

After insertion:

- Press **Placement Check** on the Insertion Diagnostics screen to generate a post-insertion report.
- This report can be skipped by pressing **Cancel**.

The post-insertion diagnostics show the following:

Angular Depth (for compatible electrode types)

Placement check – to identify a high probability of a fold and indicates the electrode number where this occurs.

Total Time – to complete insertion.

Average speed – in mm per second.

Time and speed of insertion – a graph representation of the speed of insertion shown in mm per second.

After viewing the results:

- Press **Impedance Check** to continue
- Or press **Retest Placement Check** to rerun the tests.

Run impedance test

The impedance test continuously loops through the electrodes, displaying their electrical status.

To start the test:

- From the Impedance screen, press **Start**.

The screen displays the completion percentage during the measurement process.

To retest:

- After the results are displayed, press **Retest** to run the test again.

Electrode colour codes for impedance test results

- Impedance OK
- Short circuit
- Open circuit

When you are satisfied with the results:

- Press **NRT**
- Or press **ESRT** if Advanced Features is enabled.

Run ESRT

Note: ESRT must be enabled from **App Settings** in the application menu. This is an advanced measurement and users should be trained in the function.

An impedance check must be run before performing ESRT.

Two people are required to measure ESRT:

- the surgeon who observes the stapedius muscle
- the SmartNav user who will present the stimulus

Both parties will need to be able to communicate verbally during the test.

To run ESRT measurements:

1. Configure the ESRT setting.
2. Press **Stimulate**.

   Note: You can change the step size by selecting Step up or Step down and entering a new size. The step down value should be smaller than the Step up value.

3. The surgeon looks for contraction of the stapedius muscle and notifies Nucleus SmartNav user.
4. If there is a response, press the check symbol. If there is no response, press the cross.

   The system will automatically step up or step down the current level for the next stimulation.
5. Continue for remaining electrodes.
6. Press **NRT** when all electrodes have been measured.

Electrical stapedius reflex

The acoustic stapedius reflex is a small movement of the stapedius muscle in the middle ear that is elicited by loud sounds. The ESRT can be tested with an implant recipient and is generally believed to have a correlation with C level. There are two ways to measure ESRT:

Visual inspection ESRT

During surgery, after the electrode has been placed and with the skin flap still open, the implant can be stimulated and the surgeon can look for a stapedius reflex by visual inspection of the stapedius tendon or the middle ear ossicles. Please keep in mind the following tips:

- Make sure the extracochlear electrodes are covered to get a good electrical connection. Test the impedance first. If needed, use saline to improve the electrical contact.
- Do not use a muscle-relaxing agent since this will suppress the ESRT.

Run AutoNRT

To run AutoNRT® measurements:

- From the NRT screen press **Start** to measure AutoNRT.

Note: The test may take up to 7 minutes for automatic measurement.

Switch AutoNRT views (if required):

- While AutoNRT is running, you can press **Profile** and **Trace** tabs to switch between views, if required.

The electrode being measured will be indicated on the screen.

Profile view – shows the neural response profile of the electrode array.

Trace view – shows the last 3 responses for current electrode tested in fading intensity. The brightest being the most recent measurement taken.

View AutoNRT results:

- When the AutoNRT is complete the results will be displayed.

Final AutoNRT results for the most recently detected implant can be viewed in two different ways.

Profile view – shows the neural response profile of the electrode array.

Trace view – in trace view you can select each electrode on the display and show the final neural response result for the selected electrode.

Electrode colour codes for AutoNRT

- Electrodes not measured
- NRT OK
- Short circuit
- Open circuit
- No neural response

Finalisation, Retest missing or Retest AutoNRT

When AutoNRT is complete, you are given the option to finalise results or retest AutoNRT. If the threshold for any electrode is missing, you can retest missing thresholds.

- Press **Retest missing** to retest electrodes with missing thresholds.
- Press **Retest AutoNRT** to retest AutoNRT on all electrodes.

Note: Retesting AutoNRT may take up to 7 minutes for automatic measurement.

- Press **Finalisation** to finalise the results.

Run Advanced NRT

You should run AutoNRT first as it is effective in 90% of cases[3]. You may choose to run Advanced NRT if you do not get the desired results.

Note: Advanced NRT must be enabled from **App Settings** in the application menu. This is an advanced measurement and users should be trained in the function.

Advanced NRT is not available in demo mode.

To run Advanced NRT measurements:

1. Press ⌄ next to **AutoNRT** and select **Advanced NRT.**

   The **Configure NRT** settings open.
2. Modify the parameters as required and press **Apply**.
3. Press **Start** to commence the measurement.

   When the Optimise Recording Series is running, the active measurement is highlighted in purple. The measurement will automatically stop but you can manually press **Stop** to end the measurement if required.

   After the measurement has stopped, determine the best trace by inspecting its shape and values. You can pinch and zoom on the graph to view the trace in more detail.
4. Select the best looking trace so that the parameters used to obtain this trace can be used for all subsequent amplitude growth measurements.
5. Press **Amplitude Growth Series**.

   This opens and populates the **Configure NRT** pop-over with the parameters from the Optimise Recording Series as a new Amplitude Growth Series.

   Review the settings and make any changes as required.

   Note: The NRT parameters can still be updated.

   The **Trace** view is displayed by default, but you can toggle between the **Trace** and **Profile** views.
6. Press **Apply.**
7. Press **Start.**

   SmartNav will select electrodes from across the array. Individual electrodes are measured with a decreasing range of current levels.

   When the measurement is complete the **Stop** button changes to **Next Electrode**.

   Note: you can navigate to the Finalisation screen with the upper navigation tabs if you do not wish to complete Advanced NRT.
8. Tap a trace to select it. To deselect a trace, tap it again.
9. Press **Next Electrode**.
10. When all thresholds are set, press **Profile view** to review all thresholds.
11. Press **Finalisation**.

[3] Botros et al, 2007

Finalise surgery details

From the Finalisation screen, review the patient details, choose the Surgery details, register the implant and transfer the data to a file or the Cochlear Cloud.

Note: Results exported to file are encrypted in a .crf3 file format and password protected.

Review patient, implant and surgery details

1. Review patient details.
2. Register the implant:
   - Press **Register Implant**

   The implant registration will be submitted.

   Note: If patient details were not provided you will be asked to enter the first and last name, gender and date of birth for implant registration.
3. Add surgery details:
   - Modify the Skin Flap Thickness.
   - Select a Cochlea opening.
4. Export or transfer the data.
5. Press **Save and finalise** to end the session and finalise the surgery details.

Data transmission

To export data to a file:

1. Enter a note to the receiver.
2. (Optional) Select **Anonymise session data** to remove the patient's personal details from the exported file.
3. Press **Export File** and select where to save or share the file.

Note: Notes from the data transmission are recorded within the app and shared with the receiver.

To transfer data to the Cochlear Cloud:

1. Enter a note to the receiver.
2. Press **Transfer Data**.
3. Confirm the fitting clinic details are correct.
4. To add or modify fitting clinic details:
   - Press **Change Fitting Clinic**.
   - Search or select a clinic.
5. Press **Transfer Data**.

Anonymise session data

When exporting data to a file there is the option to Anonymise session data. Selecting this option when exporting data to a file will remove implant data and patient's personal details from the exported file. Anonymous data cannot be uploaded to the Cochlear Cloud.

Note: The Anonymise session data option can be used when sending data to Cochlear for troubleshooting or research purposes. It is not recommended to use this option for the transfer of data into Custom Sound® Pro.

Data transmission history

The data transmission history records past transmissions of data and passwords used to encrypt file exports.

Transmission passwords

Nucleus SmartNav automatically generates unique passwords for each instance of data transmission. Passwords can be found in the data transmission history and are hidden by default. Tap the reveal icon in front of the password in the data transmission history list to make it readable.

After surgery

Review previous sessions

To review previous sessions stored on the device, select the **Previous sessions** option on the home screen.

This will then take you to a searchable list of previous sessions stored on the device.

Sessions are grouped by surgery location linked to the account and can be searched by keywords like patient name, implant model and gender.

Selecting a session will show the stored patient information including any saved surgical notes, the results for post-insertion diagnostics, Impedance, ESRT, NRT and a history list of previous data transmission.

Each record will also give a visual representation on the status of any data transmission or implant registration for each session.

Note: Patient details cannot be edited.

Close Nucleus SmartNav

To close Nucleus SmartNav on the device:

1. Open the App Switcher by either
   - Swiping up from the bottom edge and pausing in the centre of the screen.
   - Double-pressing the Home button (on an iPad with a Home button).
2. Swipe up on Nucleus SmartNav.

Clean and store the surgical processor

After surgery, ensure the surgical processor is not contaminated by blood or other contaminants as it is removed from the sterile bag.

Please see the *Cleaning* section in your Surgical Processor User Guide for more details on cleaning and caring for the surgical processor.

Troubleshoot

Please contact your Cochlear representative if you have any concerns regarding the operation or safety of the Nucleus SmartNav or CP1150S Surgical Processor.

Status and alerts

	Bluetooth is disabled on your device – Please enable Bluetooth on your device to continue setup.
	Processor battery too low to complete surgical session – Recharge surgical processor before proceeding or use another processor with sufficient charge.
	Device battery too low to complete surgical session – Recharge device before proceeding.
	Can't find processor – Switch on processor and bring into range.

Performance changes

If Nucleus SmartNav has unexpected performance changes, for example, closing unexpectedly, becoming non-responsive or responding slowly, Cochlear suggests that you follow the recommendations below:

- Check that the device with Nucleus SmartNav installed meets the recommended system specifications.
- If Nucleus SmartNav becomes unresponsive, wait for a few minutes or end the Nucleus SmartNav process on the device.
- Restart the device to free system resources.

Please contact your Cochlear representative for further support if you continue to have problems.

Placement Check messaging

The following message may be displayed if Placement Check is not able to be run.

Message	Description
Placement Check not possible Cannot calculate Placement Check without exceeding stimulation compliance limits. Continue to Impedance Check.	This message occurs if Nucleus SmartNav cannot get a result without exceeding 250 current levels (compliance limit). Impedance Check can be safely run without a Placement Check result.
Placement Check not possible Cannot find a satisfactory current level to run the Placement Check. Continue to Impedance Check	This message occurs when there is no conduction path. This can happen for a variety of reasons, for example, an air bubble prevents it from having a good electrical pathway. Placement Check needs a minimum current level of 160 to ensure that the measurements are accurate. Impedance Check can be safely run without a Placement Check result.
Placement Check not possible SmartNav could not get a response from the ExtraCochlear electrodes. Ensure they are placed correctly.	This message occurs when extracochlear electrodes have not been placed correctly. Placement Check can be retried after the extracochlear electrodes have been placed correctly.
Placement Check not possible Too many electrodes are reporting an open circuit to perform Placement Check. Continue to Impedance Check.	This message occurs when there are four or more consecutive open electrodes. Or three or more non-consecutive electrodes. Impedance Check can be safely run without a Placement Check result.
Placement Check not possible There was a problem communicating with the implant. Check the placement and alignment of the implant and the surgical processor coil.	This message occurs when the surgical processor has come off or is misaligned from the implant. Placement Check can be retried after the surgical processor has been placed correctly on the implant.

Warnings

- Data obtained from Nucleus SmartNav may provide supplementary information to the implanting surgeon, however clinical decisions should be made based on a range of data. For example, electrode markers, surgical reports, imaging and NRT response data. Live and post-surgery diagnostics should only be viewed as a guide.
- Neural responses measured via NRT indicate that auditory nerve fibres are firing synchronously. NRT is not a test of implant function.
- Unnecessary or excessive manipulation of the electrode array in the cochlea may lead to damage of cochlear tissues.
- Angular insertion depth and placement check are intended for use on normal cochlear anatomy and optimised for use with round window insertions.
- Your surgical processor and device radiate electromagnetic energy that may interfere with life supporting devices (e.g. cardiac pacemakers and ICDs). Keep your processor and device at least 15 cm (6 in) from such devices. Contact the manufacturer of the specific device to find out more.
- Nucleus SmartNav and the surgical processor is to be used for surgery only, and should only be used while the recipient is under general anaesthetic. Some diagnostic measurements may cause discomfort in conscious patients.
- Do not attempt stimulation of unsupported implants with Nucleus SmartNav or the surgical processor.
- Do not connect to devices that have had their operating system altered. Only connect to devices that are protected, e.g. password or PIN access control. Consider security when connecting your surgical processor to devices.
- The surgical processor is not sterile. Place the surgical processor in a sterile bag before use in the sterile field.

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

Summary of safety and clinical performance

For people in the European Union a summary of the safety and clinical performance of Nucleus SmartNav can be found at:

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

Other information

Update Nucleus SmartNav

If there is an update to Nucleus SmartNav, it is automatically updated on your iPad. If the automatic updates feature has been turned off in iOS settings, you manually update SmartNav through the App Store®.

Update the firmware on the surgical processor

Nucleus SmartNav automatically checks for firmware updates. Regular firmware updates will improve your surgical processor's performance. You need internet access to update the firmware. The update occurs after you confirm to proceed. Updates will not be triggered during an active session.

Note: If the firmware fails to download or install correctly, the previous firmware version will be restored. The performance of your surgical processor will not be affected if the update is unsuccessful.

Accuracy of measurement values

The accuracy of the values measured by Nucleus SmartNav are:

Measurement	Accuracy
Angular depth	±45 degrees at the final insertion angle.
Placement check	Fold over detection sensitivity of ≥ 90% at 90% confidence (two-tailed). Fold apex localisation of 90% chance that an estimate of the electrode apex is within ±1.40 electrodes of the estimate.
Speed of insertion	For speeds ranged from 0.00 mm/s to 4.05 mm/s, testing the accuracy shows a mean deviation of 0.06 mm/s and a standard deviation of the difference of 0.48 mm/s.
Impedance measurements	±20% or ±1 kΩ, whichever is larger.

Remove Nucleus SmartNav

If you are sending your device for repair, decommissioning or recycling your device at end of life, Cochlear recommends removing SmartNav from your device.

To remove Nucleus SmartNav from your device:

1. Touch and hold the Nucleus SmartNav icon.
2. Select **Remove App**.
3. Select **Delete App**, then select **Delete** to confirm.

Nucleus SmartNav and all data will be deleted from the device.

Labelling symbols

The following symbols may appear on the device.

Symbol	Description
	Manufacturer
	Date of manufacture
EC REP	Authorised representative in the European Community/European Union
CH REP	Authorised representative in Switzerland
	Refer to instruction manual
	Specific warnings or precautions associated with the device, which are not otherwise found on the label.
CE 0123	CE registration mark with notified body number
MD	Medical Device
UDI	Unique Device Identification
Rx Only	By prescription

Trademark legal notice

Hear now. And always

AU 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

EC REP DE Cochlear Deutschland GmbH & Co. KG
Mailänder Straße 4 a, 30539 Hannover, Germany
Tel: +49 511 542 770 Fax: +49 511 542 7770

CH REP CH Cochlear AG
Peter Merian-Weg 4, 4052 Basel, Switzerland
Tel: +41 61 205 8204 Fax: +41 61 205 8205

US Cochlear Americas
10350 Park Meadows Drive, Lone Tree, CO 80124, USA
Tel: +1 303 790 9010

CA Cochlear Canada Inc
2500-120 Adelaide Street West, Toronto, ON M5H 1T1, Canada
Tel: +1 (800) 483 3123 Fax: +1 416 972 5083

GB 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

BE Cochlear Benelux NV
Schaliënhoevedreef 20 i, B-2800 Mechelen, Belgium
Tel: +32 15 79 55 11 Fax: +32 15 79 55 70

FR 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

IT Cochlear Italia S.r.l.
Via Trattati Comunitari Europei 1957-2007 n.17,
40127 Bologna (BO), Italy
Tel: +39 051 601 53 11 Fax: +39 051 39 20 62

SE Cochlear Nordic AB
Konstruktionsvägen 14, 435 33 Mölnlycke, Sweden
Tel +46 31 335 14 61 Fax +46 31 335 14 60

www.cochlear.com

TR Cochlear Tıbbi Cihazlar ve Sağlık Hizmetleri Ltd. Şti.
Küçükbakkalköy Mah, Defne Sok, Büyükhanlı Plaza No:3 Kat:3
Daire: 9-10-11-12, 34750, Ataşehir, İstanbul, Türkiye
Tel: +90 216 538 5900 Fax: +90 216 538 5919

HK Cochlear (HK) Limited
Room 1404-1406, 14/F, Leighton Centre, 77 Leighton Road,
Causeway Bay, Hong Kong
Tel: +852 2530 5773 Fax: +852 2530 5183

KR Cochlear Korea Ltd
2nd Floor, Yongsan Centreville Asterium, 25,
Hangang-daero 30 gil, Yongsan-gu, Seoul, Korea (04386)
Tel: +82 2 533 4450 Fax: +82 2 533 8408

CN Cochlear Medical Device (Beijing) Co., Ltd
Unit 2608-2617, 26th Floor, No.9 Building, No.91 Jianguo Road,
Chaoyang District, Beijing 100022, P.R. China
Tel: +86 10 5909 7800 Fax: +86 10 5909 7900

IN 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

JP 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

AE 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

PA Cochlear Latinoamérica S.A.
International Business Park, Building 3835, Office 403,
Panama Pacifico, Panama
Tel: +507 830 6220 Fax: +507 830 6218

NZ 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

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