Cochlear®
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# Nucleus® SmartNav

## Version 3.0

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 and CP1110S surgical processors 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™ or scan the QR code with the iPad® camera to download and install Nucleus SmartNav to a compatible iPad. Refer to *System requirements* on page 8 for more information.

   **Note:** If you have a Cochlear SmartNav iPad, this step is not required.

2. Run Nucleus SmartNav.
3. Follow the instructions on the screen to log in and set up Nucleus SmartNav with a surgical processor.
4. Start using Nucleus SmartNav.

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

## Intended use

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.

Nucleus SmartNav together with a surgical processor is intended as an intraoperative tool to be used only by surgeons and healthcare professionals working in the operating theatre.

Nucleus SmartNav is intended to be used at the surgeon's discretion. Measurements may be useful during surgery as additional input to other sources of diagnostic tools such as intraoperative imaging, electrode markers, or other standard diagnostic procedures, to support surgical decisions relating to electrode placement.

**Warning:** Nucleus SmartNav and 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.

## 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 Nucleus SmartNav. Surgeons and hearing professionals can request in-surgery support from a Cochlear representative when first using Nucleus SmartNav.

## Compatibility

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

- CP1110S Surgical Processor
- CP1150S Surgical Processor

Nucleus SmartNav is compatible with the following Cochlear Nucleus implants:

- CI1000 Series Implants: CI1012, CI1022*, CI1024*, CI1032
- CI600 Series Implants[1]: CI612, CI622*, CI624*, CI632
- CI500 Series Implants[2]: CI512, CI522*, CI532
- CI24RE Series Implants: CI422*, CI24RE (CA)

* Angular Insertion Depth compatible electrodes

**Warning:** Nucleus SmartNav is not for use with Auditory Brainstem Implants (ABI).

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.

## System requirements

Nucleus SmartNav requires an iPad:

- that supports the latest version of iPadOS® You will need to upgrade your iPad if it does not support the latest version of iPadOS.
- with a screen size of at least 9.7 inches
- with a network connection and access to Bluetooth®.

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

Nucleus SmartNav is not designed for use with other Apple® devices.

The iPad 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.

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

- registration of implants
- transfer of intraoperative results
- send troubleshooting data.

When internet connectivity is unavailable, implant registration and the transfer of session data transition to a pending state until internet access is restored.

**Note:** An active internet connection is required at the time of sending troubleshooting data. This operation does not transition to a pending state and must be completed while the device is online.

Internet access is not required for performing intraoperative measurements.

If network connectivity issues occur, users are given the option to proceed in limited functionality mode. This mode allows surgical measurements to be performed in instances where login is not possible, provided the user has previously logged into Nucleus SmartNav on the iPad to be used and paired it with the surgical processor that will be used. Limited functionality mode does not support any other functionality and can be used for up to 120 hours. After this period, users must log in to Nucleus SmartNav.

# 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:

- requiring a passcode or biometric authentication be set on the iPad before Nucleus SmartNav can be used
- usernames and passwords to control access to Nucleus SmartNav
- secure audit logging of access and activities
- enable device encryption and encrypt transmitted data.

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 iPads where Nucleus SmartNav is installed
- keep all passwords, pins and security codes protected
- locking and managing access to the iPad and the surgical processor when unattended.

# Setup

## Run Nucleus SmartNav

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

**Note:**
You will need to log in to Nucleus SmartNav using your Cochlear Professional Account.
You must provide Bluetooth permission to use Nucleus SmartNav. For more information about Bluetooth privacy settings, refer to the instructions for your iPad.

## Log in to Nucleus SmartNav

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

To get started, log in via Nucleus SmartNav 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 Nucleus SmartNav. 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 to understand what data is collected and how it is used:

https://www.cochlear.com/privacy

**Tip:** You will also be required to periodically log in with your Professional Account when starting Nucleus SmartNav.

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.

# Add a surgical processor

Before you begin using a surgical processor, you need to add the surgical processor to the iPad.

If you have multiple surgical processors, you can add all surgical processors to the iPad and swap surgical processors when needed. Refer to *Swap surgical processors* on page 17.

**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.

**Note:** An active internet connection is required to add a surgical processor.

**Tip:** Ensure that Bluetooth is active on the iPad.

When performing measurements, you must use a surgical processor that is compatible with the implant.

The CP1110S Surgical Processor is compatible with the following implants:

- CI1000 Series Implants: CI1012, CI1022, CI1024, CI1032

The CP1150S Surgical Processor is compatible with the following implants:

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

To add a surgical processor:

1. Search for a surgical processor.

   When no surgical processor has been added to the iPad:

   - The Searching screen opens automatically after you log in for the first time.
     Nucleus SmartNav searches for a surgical processor to pair with the iPad.

   When a surgical processor has been added previously or you cancelled the automatic search after your first login:

   - Tap **Manage processors** from the Nucleus SmartNav menu and then tap **Add processor**.
     The Searching screen opens.
     Nucleus SmartNav searches for a surgical processor to pair with the iPad.

   Tap **Cancel** to stop searching for a surgical processor.

2. Turn all processors off.
   - For the CP1110S Surgical Processor: disconnect the battery or press and hold the button for 5 seconds.
   - For the CP1150S Surgical Processor: triple tap the front cover.

   The light will change to steady orange as the surgical processor turns off.
3. Turn on the surgical processor you want to add.
   - For the CP1110S Surgical Processor: connect the battery or, if the battery is already connected, short-press the button.
   - For the CP1150S Surgical Processor: double tap the front cover.

   The light will briefly flash green and then it will continuously flash orange.

   The Pairing screen opens. It may take up to 30 seconds for the surgical processor to connect.

   If the surgical processor is not found:
   - Check that the iPad Bluetooth is on and Bluetooth permissions given.

   

   **Note:** For more information about Bluetooth privacy settings, refer to the instructions for your iPad.

   - Ensure the surgical processor is fully charged.
   - Turn your surgical processor off and then on.

   The Verify processor screen opens. The surgical processor model number and the last four digits of the device serial number are displayed.
4. Check that the surgical processor model and device numbers displayed in Nucleus SmartNav match your surgical processor.
5. Verify the processor.
   - For the CP1110S Surgical Processor: Short-press the button.
   - For the CP1150S Surgical Processor: Double tap the surgical processor.

   The light will briefly flash blue and then flash orange continuously.

   Your professional identifiers will be sent to Cochlear for verification which requires internet access.

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

6. (Optional) Tap **Add another processor** and follow steps 2 - 5 to set up additional surgical processors.
7. Tap **Done**.

# 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.
- **Add surgical 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 iPad and update location information.
- **App settings** - view and change settings such as announcements, electrode conditioning and enable advanced features like Electrical Stapedius Reflex Threshold (ESRT) and Advanced NRT.
  - **Announce angle for angular depth of insertion**: enables audio announcement of angular depth of insertion during insertion diagnostics.
  - **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.
- **About** - view information about Nucleus SmartNav and the connected surgical processor, and access the application audit log.
- **Help** - View help options within Nucleus SmartNav to either back up and restore data or send troubleshooting diagnostic files to Cochlear.

## Session actions

During a surgical session the following session actions are available through the side menu:

- **Discontinue session** - finalises the current session as discontinued.
- **Same patient: New implant** - finalises the current session as discontinued and begins a new session with the same patient information but prompts for new implant information.
- **Same patient: Current implant** - finalises the current session as discontinued and begins a new session with the same patient and implant information.

**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. Select an **Ear**.
6. Select a **Cochlear anatomy**.
7. Enter the **Skin flap thickness** (Optional).
8. Enter the **Cochlear diameter**.

   **Note:** The cochlear 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 the **Fitting Clinic** associated with the patient (Optional).

10. Select 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**.

11. Check the **Surgery location**.
12. Select the **Surgery date** (Optional).
13. Scan the implant code using the iPad camera

    
    

    or

    Enter the serial number for the implant.

    **Tip:** The implant code is located next to the SN symbol (serial number) on the implant packaging.

14. Tap **Save as upcoming** to save the details for a future session

    or

    Tap **Start session**.

## Editing and deleting upcoming sessions

Upcoming sessions can be edited by tapping on the session under **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

Start surgery with a fully charged surgical processor. To ensure the battery is fully charged, recharge the surgical processor or battery module and the iPad 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** to make them available during a session.

**Note:**
SmartNav retains the settings for advanced features in subsequent sessions.
Advanced features can be enabled during a surgical session but can only be disabled outside a surgical 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 refer to *Create a new session* on page 14.
2. Review and update the session details.
3. Tap **Start session**.

## Connect to the surgical processor

**Tip**

Ensure Bluetooth is enabled on the iPad.
If the surgical processor has gone into sleep mode, turn on the surgical processor.

Connect Nucleus SmartNav and the surgical processor:

1. Turn off all other surgical processors.
2. Turn on the surgical processor to be used in the surgical session.
   - For the CP1110S Surgical Processor: connect the battery or, if the battery is already connected, short-press the button.
   - For the CP1150S Surgical Processor: double tap the front cover.

   The light will briefly flash green and then it will continuously flash orange.
3. Check that the surgical processor is connected to the iPad.

   **Note:** If the surgical processor is not paired to the iPad you may need to repeat the procedure to add a surgical processor (Refer to *Add a surgical processor* on page 11).
4. Check the battery status of the iPad and the surgical processor.

## Swap surgical processors

If you have multiple surgical processors, you can add all processors to the iPad and swap surgical processors when needed.

Swap surgical processors:

1. Turn off all other surgical processors.
2. Turn on the surgical processor you want to use.

   The surgical processor connects to the iPad.
3. Check that the surgical processor is connected to the iPad.

   **Note:** If the surgical processor is not paired to the iPad you may need to repeat the procedure to add a surgical processor (Refer to *Add a surgical processor* on page 11).
4. Check the battery status of the iPad and the surgical processor.

# During surgery

During surgery, Nucleus SmartNav can be used to measure angular insertion depth (for compatible electrode types) and speed, the electrode placement, the impedance, ESRT and NRT thresholds 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, position the surgical processor again and follow the on-screen prompts in Nucleus SmartNav 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 so 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 adhesive tape 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 iPad is only to be used outside the sterile field. If your procedures introduce a potential risk of contamination of the iPad during surgery please take steps to protect the iPad from contamination.

# Device setup

1. Place the surgical processor or surgical coil onto the implant.
   A green light will blink when the processor is communicating with the implant.

**Note:** When a CP1110S Surgical Processor connects with a CI1000 Series implant for the first time, you must keep the surgical coil in place while the surgical processor establishes communication with the implant. This may take up to 10 seconds.

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 CI600 and CI1000 Series implants

With CI600 and CI1000 Series implants, avoid sliding the surgical processor or surgical coil sideways onto the implant. This could cause the processor or coil magnet to misalign with the implant. Always place the surgical processor or surgical coil down onto the implant.

To place the surgical processor or surgical coil onto the implant:

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

***Figure 1:*** *Cochlear CP1150S Surgical Processor*

***Figure 2:*** *Cochlear CP1110S Surgical Coil*

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

# Run insertion diagnostics

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

To run live diagnostics during surgery:

1. Tap **Start** on the Insertion Diagnostics screen before starting insertion.
2. Tap **Stop** once the insertion is complete to end the measurement.

**Tip:** Ensure that the area outside the cochlea opening is free of fluid prior to beginning insertion.

## Angular insertion depth

If performing surgery with a compatible electrode type, Nucleus SmartNav will simultaneously provide visual and audio readout at preset angles as real-time[1] feedback of the electrode location.

Angular insertion depth is compatible with the following Cochlear Nucleus implants:

- CI1000 Series Implants: CI1022, CI1024
- CI600 Series Implants: CI622, CI624
- CI500 Series Implants: CI522
- CI24RE Series Implants: CI422

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

## Speed of insertion

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

1 SmartNav obtains measurement updates approximately 4 times a second, giving a measurement resolution of 250mS, which is sufficiently responsive for the user to feel like they are in direct control of the system in “Real Time” [1]

[1] R. A. Doherty and P. Sorenson, “Keeping Users in the Flow: Mapping System Responsiveness with User Experience,”ProcediaManufacturing, vol. 3, pp. 4384–4391, 2015, doi: 10.1016/j.promfg.2015.07.436.

# View placement check report

The post-insertion result displays placement check, angular insertion depth (for some compatible electrodes) and speed of insertion. After insertion, placement check indicates if there is a likelihood of fold over and gives the affected electrode range.

**Warning:** Clinical actions should be assessed based on a range of data (e.g. intraoperative imaging, electrode markers, or other standard diagnostic procedures) and addressed based on the treatment plan for an individual patient case. Nucleus SmartNav provides only one source of data to support clinical decision.

**Note:** The placement check and conditioning process can take a few minutes to complete. Please do not remove the surgical processor during this time.

After insertion:

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

The post-insertion diagnostics show the following:

**Angular Depth** – shows the angular depth of the electrode insertion in degrees calculated based on feedback from the electrode, the cochlear diameter and ±45 degrees (1 standard deviation (SD)) relative to postoperative CT scans at the final insertion angle. This measure is currently shown only for some compatible electrode types (refer to *Compatibility* on page 7).

For more information on the spatial accuracy of the angular insertion depth, refer to *Angular Insertion Depth validation test: Summary* on page 41.

**Placement check** – to identify the likelihood of a fold over and indicates the range of electrodes where this occurs in red on the display.

For more information on the specificity and sensitivity of the Placement Check algorithm, refer to *Specificity of the Placement Check algorithm to detect anomalous perimodiolar electrode position (CLTD5676): Summary* on page 38, *Specificity of the Placement Check algorithm to detect anomalous lateral wall electrode position (CLTD5663): Summary* on page 39 and *Sensitivity of the Placement Check algorithm validation test: Summary* on page 40.

**Total Time** – to complete insertion.

**Average speed** – in seconds per electrode.

**Time of insertion per electrode** – a graph representation of the speed of insertion shown in seconds per electrode.

For more information on the accuracy of the speed of insertion, refer to *Speed of Insertion accuracy analysis: Summary* on page 42.

After viewing the results:

- Tap **Impedance Check** to continue
- Or tap **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, tap **Start**.

To retest:

- After the results are displayed, tap **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:

- Tap **NRT**
- Or tap **ESRT** if 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 settings.

   **Note:** Available ESRT parameters depend on implant type.

2. Tap **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, tap the **Response** check symbol. If there is no response, tap the **No response** cross symbol.

   The system will automatically step up or step down the current level for the next stimulation.
5. Continue for remaining electrodes.
6. Tap **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.

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 muscle 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 tap **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 tap **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 AutoNRT is complete the results will be displayed.

Final AutoNRT results 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.

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

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

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

# Run Advanced NRT

You should run AutoNRT first as it is effective in 90% of cases[1]. 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. Tap ⓘ next to **AutoNRT** and select **Advanced NRT.**

   The **Configure NRT** settings open.
2. Modify the parameters as required and tap **Apply**.
3. Tap **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 tap **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.

   The **Trace** view is displayed by default, but you can toggle between the **Trace** and **Profile** views.
5. Tap **Amplitude Growth Function**.

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

   Review the settings and make any changes as required.

   **Note:** The NRT parameters can still be updated.
6. Tap **Apply.**
7. Tap **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. Tap **Next Electrode**.
10. When all thresholds are set, tap **Profile view** to review all thresholds.
11. Tap **Finalisation**.

[1] 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:
   - Tap **Register Implant**

   The implant registration will be submitted.
3. Add surgery details:
   - Modify the Skin Flap Thickness.
   - Select a Cochlea opening.
4. Export or transfer the data.
5. Tap **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. Tap **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. Tap **Transfer Data**.
3. Confirm the fitting clinic details are correct.
4. To add or modify fitting clinic details:
   - Tap **Change Fitting Clinic**.
   - Search or select a clinic.
5. Tap **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 iPad, select the **Previous sessions** option on the home screen.

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

If enabled for your clinic it is possible to search for previous sessions conducted on other iPads used within your clinic. An internet connection is required to search for previous sessions conducted on other iPads.

Sessions are grouped by surgery location linked to the account and can be searched by keywords. For example, patient name.

Selecting a session will show details of the session, for example:

- Saved surgical notes.
- Results for post-insertion diagnostics.
- Impedance measurements.
- ESRT measurements.
- NRT measurements.
- A history list of previous data transmission.
- The audit log for the session.

**Note:** Patient details cannot be edited.

## Close Nucleus SmartNav

To close Nucleus SmartNav on the iPad:

1. Open the App Switcher by either
   - Swiping up from the bottom edge and pausing in the centre of the screen.
   - Double-tapping 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.

Refer to 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 Nucleus SmartNav, CP1110S Surgical Processor or CP1150S Surgical Processor.

## Status and alerts

| Icon | Suggested action |
|---|---|
| **iPad** | |
|  | On the iPad, ensure Bluetooth is turned on.<br>Allow SmartNav to use Bluetooth. You may need to restart SmartNav.<br>Bluetooth is required to connect the surgical processor to SmartNav. |
|  | Recharge the iPad. The battery level on the iPad is too low to complete a surgical session. |
|  | Check internet connection. The action you want to perform requires an internet connection. |
| **CP1110S Surgical Processor** | |
|  | Place the coil on the implant. Check the placement of the processor relative to the implant. |
|  | Improve the position of the coil. Implant communication could not be successfully established. This can be due to the position of the surgical processor coil relative to the implant.<br>Change to a CP1110S Surgical Coil - The coil detected cannot be used with SmartNav. Change to CP1110S Surgical Coil. For information about compatible surgical coils for use with SmartNav, refer to the Cochlear CP1110S Surgical Processor User Guide.<br>Use another surgical coil - The surgical coil is not working. Use another CP1110S surgical coil if available or contact your Cochlear representative.<br>Check the surgical coil is connected to the processing unit. The surgical coil is disconnected from the processing unit. |

| Icon | Suggested action |
|---|---|
|  | Change processor battery. The processor battery is low. It is recommended to fully charge the processor battery before starting a surgical session. Change battery if available.<br>For information about compatible battery modules for use with SmartNav, refer to the Cochlear CP1110S Surgical Processor User Guide. |
|  | Replace the processor battery or finalise session. The battery is critically low to communication with the implant and may stop unexpectedly.. |
| **CP1150S Surgical Processor** | |
|  | Recharge the surgical processor or use another processor with sufficient charge. The processor battery is too low to complete a surgical session. |
|  | Place the processor on the implant. The surgical processor is not connected to the implant. Check the placement of the processor coil relative to the implant. |
| **Implant** | |
|  | Remove the coil and place the coil back on the implant. The implant cannot be identified or there is a problem communicating with the implant. |
| | Contact Cochlear - Return this implant to your local Cochlear Representative. It cannot be used.<br>or<br>Use backup implant - Return this implant to your local Cochlear Representative. To continue, enter the backup implant details. A new session will be created with the same patient details. |

## 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 iPad 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 iPad.
- Restart the iPad to free system resources.

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

# Troubleshoot placement check

The following troubleshooting options may help if:

- test results are inconclusive
- test results are incomplete
- it was not possible to run placement check.

| Message title | Possible issues | Recommended action |
|---|---|---|
| Check plate electrode | • The extracochlear plate electrode (ECE2) could be open circuit<br>• Compliance issue<br>• Saturation issue | Check extracochlear plate electrode (ECE2) and try running placement check again. Refer to *Extracochlear electrodes* on page 18.<br>If the issue is not resolved, continue to impedance check. |
| Check processor placement | • Poor communication between the surgical processor and the implant<br>• Possible coil off during placement check | Improve the position of the surgical processor in relation to the implant.<br>If the issue is not resolved, continue to impedance check. |
| Check processor coil placement and plate electrode | • Poor communication between the surgical processor and the implant<br>• Compliance issue | Improve the position of the surgical processor in relation to the implant.<br>Check extracochlear plate electrode (ECE2) and try running placement check again. Refer to *Extracochlear electrodes* on page 18.<br>If the issue is not resolved, continue to impedance check. |
| Rerun placement check | • Placement check results were inconclusive<br>• Placement check was forced to stop by tapping **Stop Check** | Try retesting placement check or continue to impedance check. |

# 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.
- Nucleus SmartNav is not for use with Auditory Brainstem Implants (ABI).
- 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.
- Clinical actions should be assessed based on a range of data (e.g. intraoperative imaging, electrode markers, or other standard diagnostic procedures) and addressed based on the treatment plan for an individual patient case. Nucleus SmartNav provides only one source of data to support clinical decision.

# Other information

## Update Nucleus SmartNav

If there is an update to Nucleus SmartNav, it is automatically updated on your iPad. If automatic updates 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 (1 SD) relative to post-operative CT scans at the final insertion angle. |
| Placement check | Fold over detection sensitivity of ≥ 90% at 90% confidence (two-tailed).<br>Fold apex localisation of 90% chance that an estimate of the electrode apex is within ±1.40 electrodes of the estimate. |
| Speed of insertion | 95% of insertions will have an error of less than 5% of total duration. |
| Impedance measurements | ±20% or ±1 kΩ, whichever is larger. |

# Remove Nucleus SmartNav

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

To remove Nucleus SmartNav from your iPad:

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 iPad.

# Labelling symbols

The following symbols may appear on the iPad.

| 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 Identifier |
| Rx Only | By prescription<br>Caution: US law restricts this device to sale by, or on the order of, a physician |
| REF | Catalogue number |

# Trademark legal notice

# Appendix: Summaries of clinical and test data

## Specificity of the Placement Check algorithm to detect anomalous perimodiolar electrode position (CLTD5676): Summary

### Clinical trial description

This study measured the specificity of the Placement Check algorithm to detect electrode fold.

### Study demographics

A total of 148 adult subjects were enrolled across six investigational sites and with 15 implanting surgeons.

The mean age of the subjects whose data points were included was 58 years (range 19 to 88 years). A total of 44 ears were implanted with the CI512 cochlear implant, and 104 ears were implanted with the CI532 device.

### Study inclusion and exclusion criteria

#### Inclusion criteria

- Candidate for cochlear implantation with the CI532 or CI512 devices
- 18 years of age or older at the time of enrolment
- Normal cochlea anatomy, established via pre-operative CT
- Willingness to participate in and to comply with all requirements of the protocol

#### Exclusion criteria

- Prior cochlear implantation in the ear to be implanted
- Ossification or any other cochlear anomaly that might prevent complete insertion of the electrode array
- Abnormal cochlear anatomy on pre-operative CT or MRI imaging
- Additional handicaps that would prevent participation in evaluations
- Pregnant and breastfeeding women, prisoners, or anyone in custody

### Method

Placement Check algorithm analysis of the TIM measurement after electrode insertion for electrode fold where the most apical point of the array is E20 or less, was compared to post-operative CT/DVT Scan at 90% confidence (two-tailed).

### Results

Analysis identified 146 true negative and 2 false positive classifications, with a central estimate of specificity of 98.64% (95.81% - 99.76%).

### Adverse events

Ten Adverse Events were reported within the study with none leading to a Serious Adverse Device Effect (SADE ). There were two Serious Adverse events (SAE) due to hospitalisation unrelated to the device.

# Specificity of the Placement Check algorithm to detect anomalous lateral wall electrode position (CLTD5663): Summary

## Clinical trial description

This study aimed to collect specificity of Placement Check algorithm to detect electrode fold based on normative measures during and/or immediately after electrode insertion into the cochlea.

## Study demographics

A total of 20 adult subjects (i.e. ears) were enrolled in the study and were implanted with CI522 implants. The mean age of the subjects was 70.3 years (range 50 to 89 years).

## Study inclusion and exclusion criteria

### Inclusion criteria

- Meet current cochlear implant indications at the implanting centre for a CI512, CI422, CI522 or CI532 cochlear implant
- Aged 18 years and older at the time of implantation.

### Exclusion criteria

- Recipient of a Nucleus 24 ABI device
- Medical or psychological conditions that contraindicate undergoing general anaesthesia or surgery.
- Ossification, malformation or any other cochlear anomaly, such as common cavity, that might prevent complete insertion of the electrode array, as confirmed by medical examination.
- Unwillingness or inability of the candidate to comply with all investigational requirements.

## Method

The cochlear implant surgery visit served as the primary endpoint for data collection related to normative voltage tomography data during electrode insertion and/or immediately post-insertion for the CI522 cochlear implants as recorded using CSEP 5.0 software.

X-Rays were performed prior to activation, post discharge.

The clinical study collected sets of normative trans-impedance matrix (TIM) measurements for the potential purposes of:

- Characterisation of TIMs to identify normative responses
- Testing of the Placement Check algorithm for folds in lateral wall electrode arrays

## Results

Measures of 20 subjects were visually screened for common features and 1 anomalous was identified and excluded. The Placement Check detection algorithm correctly classified all 19 for no electrode fold 100% (85.4% - 100%).

## Adverse events

No Adverse Events were reported within the study

# Sensitivity of the Placement Check algorithm validation test: Summary

## Validation test description

This study summarises the outcomes of the validation testing conducted on the Placement Check algorithm sensitivity of the Nucleus SmartNav system.

## Items tested

The tests were conducted in 6 different temporal bones. 35 insertions were performed with intentional electrode array fold overs. For each insertion the existence of a fold was confirmed using CT imaging.

## Test overview

This validation test protocol generates, in implanted temporal bone, a dataset of:

1. Observed fold apex;
2. Fold classification;
3. Estimated fold apex;

Test end point

The primary end point of the sensitivity validation protocol was to test whether the Placement Check algorithm achieved the sensitivity target.

The Placement Check sensitivity target was ≥ 90% at 90% confidence (two-tailed).

The secondary end point was to characterise the ability of an electrode array fold over detection algorithm to locate the fold over apex.

The apex of a fold was defined as the electrode that is located deepest in the cochlea. The Placement Check algorithm is designed to identify folds of greater than 2 electrodes.

## Results

The Placement Check algorithm was able to correctly classify all 35 samples having a fold over; a central sensitivity estimate of 100% (91.8% - 100%).

Fold apex localization provided a good estimation of the fold apex location. There is a 90% chance that an estimate of the electrode apex is within ±1.40 electrodes of the estimate.

# Angular Insertion Depth validation test: Summary

## Validation test description

This study summarises the outcomes of the validation testing conducted on the Angular Insertion Depth algorithm of the Nucleus SmartNav system.

## Items tested

The tests were conducted in 21 different temporal bones. The average cochlear diameter of the bones under test was 9.26mm which closely matches the population mean diameter of 9.25mm.

56 insertions were performed to a certain target depth (18, 20 or 25 mm). Final linear depth was estimated via visual inspection and compared to the Angular Insertion Depth algorithm and angular depth from CT images.

## Test overview

This validation test protocol generates, in implanted temporal bone, a dataset of:

1. Angular Insertion Depth measurement;
2. Angular depth estimations based on CT imaging; and
3. Linear depth estimation based on white marker position;

## Test Hypothesis

The hypothesis of the test was testing non-inferiority of Angular Insertion Depth algorithm which involves comparing the dispersion of angular insertion depth, as measured using the Angular Insertion Depth algorithm, or angular depth derived from Linear Insertion Depth (LID) techniques against the angular depth measured using imaging.

## Results

The Angular Insertion Depth algorithm was found to be non-inferior in estimation of angular insertion depth when compared to the Linear Insertion Depth (LID) technique of estimating the angular depth based on CT imaging at the linear depth of the inserted electrode array.

The accuracy of the angular depth relative to postoperative CT scans is +/-45 degrees[1] (1 SD).

1 With preoperatively measured cochlear diameter.

# Speed of Insertion accuracy analysis: Summary

## Accuracy analysis description

This analysis investigated the accuracy of the Speed of Insertion algorithm included in the Nucleus SmartNav system.

## Items tested

Tests were conducted across each electrode variant (EA12, EA22* and EA32), with a total of 108 electrode array insertions. Insertions were performed into transparent models which could be monitored visually and via software. The visual speeds (recorded via video) were then compared to the Speed of Insertion measured via the Nucleus SmartNav software.

* EA22 and EA24 are considered equivalent for this validation as the active component of the electrode arrays have identical mechanical designs.

## Data collection overview

Cochlear implant electrode array insertion tests were performed into transparent models and used to create a dataset of:

1. SmartNav Speed of insertion timepoint for each electrode. Each insertion generated 21 data points.
2. Visual inspection data-time difference between adjacent electrode pad centres becoming submerged. Each insertion generated 21 data points.

## Comparison of data

Testing compared speed of insertion data gathered from the 2 methods, Nucleus SmartNav and visual data, to determine the 95% limits of agreement of the 2 measurement methods as a percentage of the total insertion duration.

## Results

Total insertion times measured were 10, 120 and 300 seconds and all insertions were analysed in aggregate. When analysing the differences between the two measures, speed of insertion per electrode in 95% of cases was accurate to within 5% of total insertion duration.

# Hear now. And always


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