



Nucleus[®] SmartNav

Version 3.0

Technical Description

For Professionals

Symbols used in this document



Note: Important information or advice.

Contents

Symbols used in this document.....	2
About.....	4
Intended purpose	4
Technical data.....	5
System requirements.....	5
Using the software on a network	6
Network risk	7
Configuration.....	8
Network specification	10
Nucleus SmartNav data security.....	11
Audit logs	11
Maintenance.....	12
Update Nucleus SmartNav	12
Update the firmware on the surgical processor	12
Remove Nucleus SmartNav	12
Other information	13
Accuracy of measurement values	13
Trademark legal notice	13

About

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.

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.

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 5 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: Refer to the *Nucleus SmartNav User Guide* for all the warnings and important information about how to use Nucleus SmartNav.

Technical data

Product name: Nucleus® SmartNav

Version: v3.0

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>

As new versions of iPadOS are released by Apple, Nucleus SmartNav will discontinue compatibility with previous versions of 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.

The following optional permissions or setting may be requested on the iPad:

- **Camera Access** — for scanning device numbers from data codes on the implant packaging.
- **Notifications** — to inform you of issues you can action.
- **Settings.app** — to allow you to select a supported language for SmartNav independent of the iPad's default language.
- **ActionSheets** — required for manual intraoperative file exports.

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.

The network used to provide internet access must meet the following requirements:

- Access to the following Cochlear Cloud API and AWS API endpoints.
 - <https://smartnav-api.cochlear.link>
 - <https://atlas-api.cochlear.link>
 - <https://intraoperative-file-service-prd-upload-bucket.s3.eu-west-1.amazonaws.com>
 - <http://smartnav-backup-service-landing-bucket-prd.s3.eu-west-1.amazonaws.com>
 - <http://smartnav-backup-service-bucket-prd.s3.eu-west-1.amazonaws.com>
 - <https://api.mixpanel.com>
 - <https://in.appcenter.ms>

Network risk

Cochlear wishes to advise that running this software on a network could cause potential risks to patients, software users or third parties. We recommend you perform your own evaluation to identify, analyse, evaluate and control these risks.

Changes to your network that could introduce additional risks may include:

- changing the network configuration
- introducing new network hardware or software
- updating or upgrading network hardware or software.

Configuration

After Nucleus SmartNav has been installed on an iPad, Nucleus SmartNav and Custom Sound® Pro software must be configured using the settings below if the iPad will be connected to:

- the Wi-Fi network of an organisation
- the local network of a clinic. This includes clinic workstations that are using Custom Sound Pro software.

Requirements	Nucleus SmartNav and Custom Sound Pro software
Firewall Settings on HTTPS port 443 TLS/SSL interception for the following fully qualified domain names (FQDNs) will need to be disabled or permitted for iPads with Nucleus SmartNav installed and clinic workstations using Custom Sound® Pro software.)	myCochlear™ Professional Portal
	FQDN: https://atlas-couch.mycochlear.com
	FQDN: https://secure.mycochlear.com
	FQDN: https://clinician-portal.mycochlear.com
	Authentication for SmartNav services
	FQDN: https://customsoundpro-api.cochlear.link
	FQDN: https://atlas-api.cochlear.link
	FQDN: https://www.cochlear.com
	FQDN: https://cochlear.force.com
	FQDN: https://id.cochlear.com
	Enable functionality for majority of application functions For example, firmware updates, secure cloud data transfer initiation
	FQDN: https://smartnav-api.cochlear.link
	End destination of secure cloud data transfer Completes secure cloud data transfer
	FQDN: https://intraoperative-file-service-prd-upload-bucket.s3.eu-west-1.amazonaws.com
	Secure session data import communication
FQDN: https://data-socket-server.cochlear.link	
Enables functionality to check upon launch of app for newer app versions and notify user	
FQDN: https://discovery.cochlear.link	
Enable functionality to save and retrieve for session data in the Cochlear Cloud	
FQDN: http://smartnav-backup-service-landing-bucket-prd.s3.eu-west-1.amazonaws.com	
FQDN: http://smartnav-backup-service-bucket-prd.s3.eu-west-1.amazonaws.com	

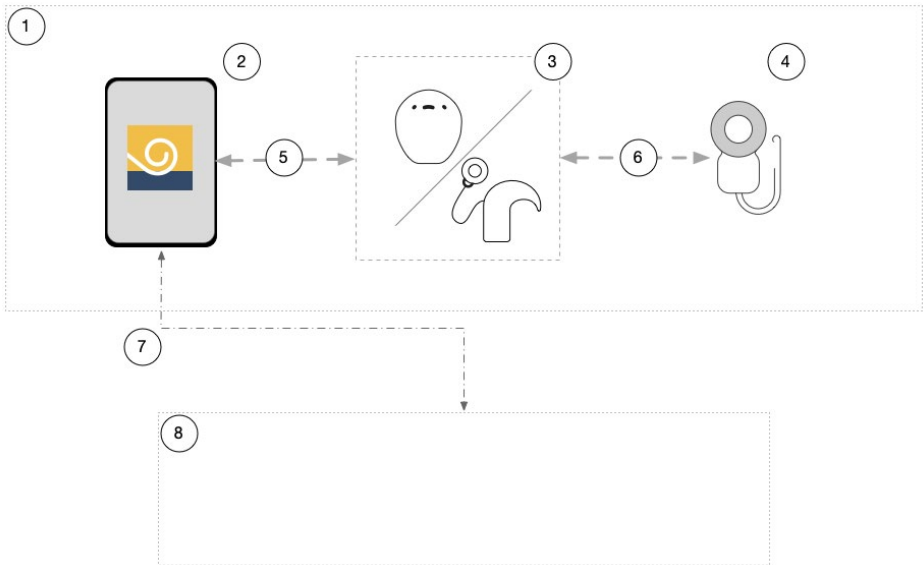
Requirements	Nucleus SmartNav and Custom Sound Pro software
Port settings (Basic)	80 and 443 (HTTP and HTTPS)
USB ports	Apple® Lightning® to USB adapter (for USB data transfer only)
Camera (Optional)	For scanning implant details from data codes on the implant packaging
Notifications (Optional)	To inform users of actions required
Bluetooth® (Required)	To enable connectivity between the Cochlear Surgical Processor and Nucleus SmartNav
Secure Cloud Data Transfer (Intraoperative data)	To ensure cloud data transfer is available, ensure the following are allowed and open outbound port 443 on the iPad. After a user authenticates using Professional Account credentials in Custom Sound Pro software, data download can be initiated.
	Data import to Custom Sound Pro software:
	FQDN: https://customsoundpro-api.cochlear.link
	Data upload to Cochlear Cloud from SmartNav:
	FQDN: https://intraoperative-file-service-prd-upload-bucket.s3.eu-west-1.amazonaws.com
	Baseline functionality that enables data upload to Cochlear Cloud:
	FQDN: https://smartnav-api.cochlear.link
	Enable user login to initiate Cochlear Cloud data upload / download:
FQDN: https://atlas-api.cochlear.link	
Proxy Settings (If a proxy server is utilised)	Transparent proxy or it must be configured in the browser for HTTPS connections



Note: Information provided is correct as of date of publication but is subject to change without notice.

Network specification

The following diagram shows the flow of information between Nucleus SmartNav and other software applications. This diagram shows a description of the connected services or applications as well as the specification of the connection type.



1. Intraoperative components
2. Nucleus SmartNav
3. Surgical processor: CP1150S or CP1110S
4. Cochlear implant
5. Sound Processor API (SPAPI) over Bluetooth Low Energy (BLE)
6. Radio Frequency (RF) link
7. HTTPS / TLS 1.2
8. Cochlear Cloud

Which includes:

- Amazon Web Services (AWS)
- Atlas Services API
- SmartNav Cloud API
- S3 API (Intraoperative File Storage)

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.

Audit logs

Nucleus SmartNav includes audit logging functionality. An audit log is maintained that chronologically records access, activity and activity time. The audit log may be exported as a CSV file.

Audit logs can be accessed from **Settings > About** in the Nucleus SmartNav menu.

Audit logs allow you to review logs entries and find log entries relating to specific surgical sessions.

The audit logs do not contain implant IDs, serial numbers or recipient details.

Maintenance

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®.



Note: If you have a Cochlear SmartNav iPad, this is managed remotely and the Nucleus SmartNav update will be pushed to your device automatically.

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.

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.

Other information

Accuracy of measurement values

The details for accuracy of the values measured by Nucleus SmartNav can be found under *Accuracy of measurement values* topic in the *Nucleus SmartNav User Guide*

Trademark legal notice

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

Bluetooth is a registered trademark of Bluetooth SIG. Apple, App Store, iPad, iPadOS and Lightning are trademarks of Apple Inc, registered in the U.S. and other countries.

Hear now. And always

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