What's New for the Cochlear™ Nucleus® 7 System?

Audiology Online – August 1, 2018

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Learning Objectives

- List three updates to the Nucleus® Smart App, which will assist recipients and caregivers to manage their own or their child's hearing more easily.
- Name two changes to Custom Sound® programming software that will assist the clinician in either programming or counseling their recipients.
- Distinguish among the considerations for upgrading Nucleus 24 implant recipients using various older sound processor models to the Nucleus® 7 sound processor.

Cochlear's Mission

We help people hear and be heard.

We **empower** people to connect with others and live a full life.

We **transform** the way people understand and treat hearing loss.

We **innovate** and bring to market a range of implantable hearing solutions that deliver a lifetime of hearing outcomes.

Nucleus 7 Sound Processor Features

- The smallest, lightest and only Made for iPhone cochlear implant sound processor[1] that delivers clinically proven[2] hearing performance.

Dual microphone technology

Aqua+ for Nucleus 7 Sound Processor*

SmartSound® iQ and MFi

Nucleus Smart App

One button interface

Improved wearing options

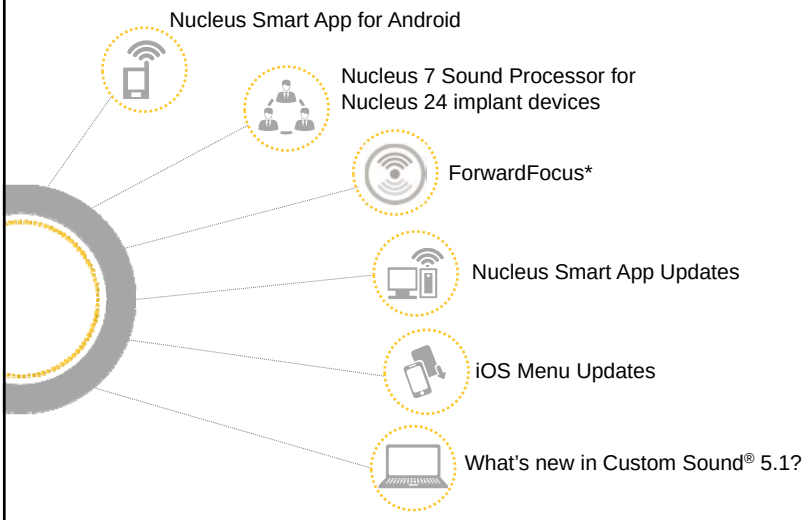
Up to 50% more battery life[3]

True Wireless™ devices

1. Cochlear Limited. D1190805. CP1000 Processor Size Comparison. 2017, Mar; Data on file.
2. Mauger SJ, Warren C, Knight M, Goorevich M, Nel E. Clinical evaluation of the Nucleus 6 cochlear implant system: performance improvements with SmartSound iQ. International Journal Of Audiology. 2014, Aug; 53(8): 564-576. [Sponsored by Cochlear].
3. Cochlear Limited. D1140877. Battery Life and Power Consumption Comparison between CP1000, CP900 Series and CP810 Sound Processors. 2017, Mar; Data on file.

*Nucleus 7 with Aqua+ is water resistant to level IP68 of the International Standard IEC60529. This water protection rating means that the sound processor with the Aqua+ can be continuously submerged under water to a depth of 3 meters (9 feet and 9 inches) for up to 2 hours. This water protection only applies when you use a Cochlear Standard Rechargeable Battery Module or Cochlear Compact Rechargeable Battery Module.

Overview of *New* Features



* ForwardFocus can only be enabled by a hearing implant specialist. It should only be activated for users 12 years and older who are able to reliably provide feedback on sound quality and understand how to use the feature when moving to different or changing environments. It may be possible to have decreased speech understanding when using ForwardFocus in a quiet environment. SNR-NR and WNR are approved for use with any recipient ages 6 years and older, who is able to 1) complete objective speech perception testing in quiet and in noise in order to determine and document performance 2) report a preference for different program settings. SCAN is FDA approved for use with any recipient age 6 years old and older, to be used at the discretion of the recipient/parent/caregiver.

Connect Your Way

Nucleus® Smart App for Android™

Hear now. And always

First for iPhone. Now, first for Android.

With the Cochlear™ Nucleus® 7 Sound Processor, your patients can hear their way with world-first connectivity and control directly from their smartphone.

Connectivity

In a recent clinical trial,

90% of users

found it **more convenient** to control the Nucleus 7 Sound Processor with Nucleus Smart App compared with using a remote control.[1]

Track hearing progress

Control, adjust and monitor hearing

Locate a lost sound processor

1. Cochlear Limited. D1296247. CLTD 5620 Clinical Evaluation of Nucleus 7 Cochlear Implant System. 2017, Sep; Data on file.

Nucleus Smart App Operating System Requirements

Made for iPhone | iPad | iPod

- iOS 10.0 and above
- Pair within “Settings”
- Control with App on iPod® or iPhone*

How to check iOS version: Settings → General → About → Version

- Lollipop 5.0 and Bluetooth® 4 and above**
- Pair within the App
- Control with App

How to check Android version: Apps → Settings → About phone (or About device) → Android version

*For a list of compatible iOS devices visit: www.cochlear.com/nucleus/compatibility
**For a list of verified Android devices visit http://www.nucleussmartapp.com/android.

Android Phones Verified for Nucleus Smart App

Samsung Galaxy S8

Samsung Galaxy S7

Huawei P8lite

Lenovo MOTOG5

Google Pixel

LG G6

HTC U11

**For a list of verified Android devices visit http://www.nucleussmartapp.com/android.

World-First Connectivity

First ever CI sound processor with **direct audio streaming** (including bimodal) from a compatible Apple® device.

Direct Audio Streaming and Control

*Bimodal MFi streaming is capable with compatible hearing aids.
A list of compatible hearing aids is available online at: www.cochlear.com/nucleus/compatibility

Android Connectivity

Stream phone calls, music and entertainment from any Android device using the Cochlear Wireless Phone Clip*.

*Bimodal streaming via Phone Clip is capable with compatible hearing aids.
A list of compatible hearing aids is available online at: www.cochlear.com/nucleus/compatibility

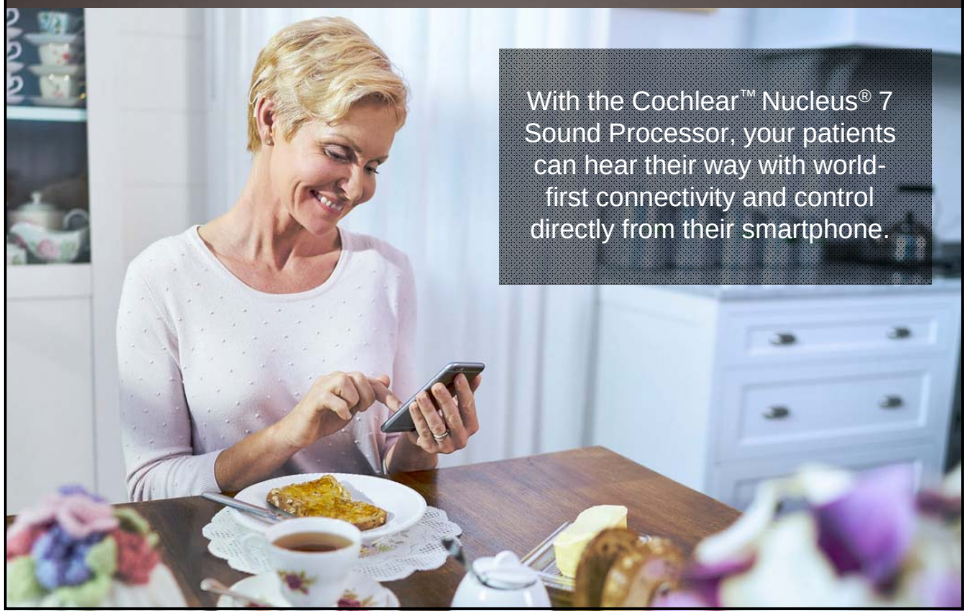
Pairing to Android

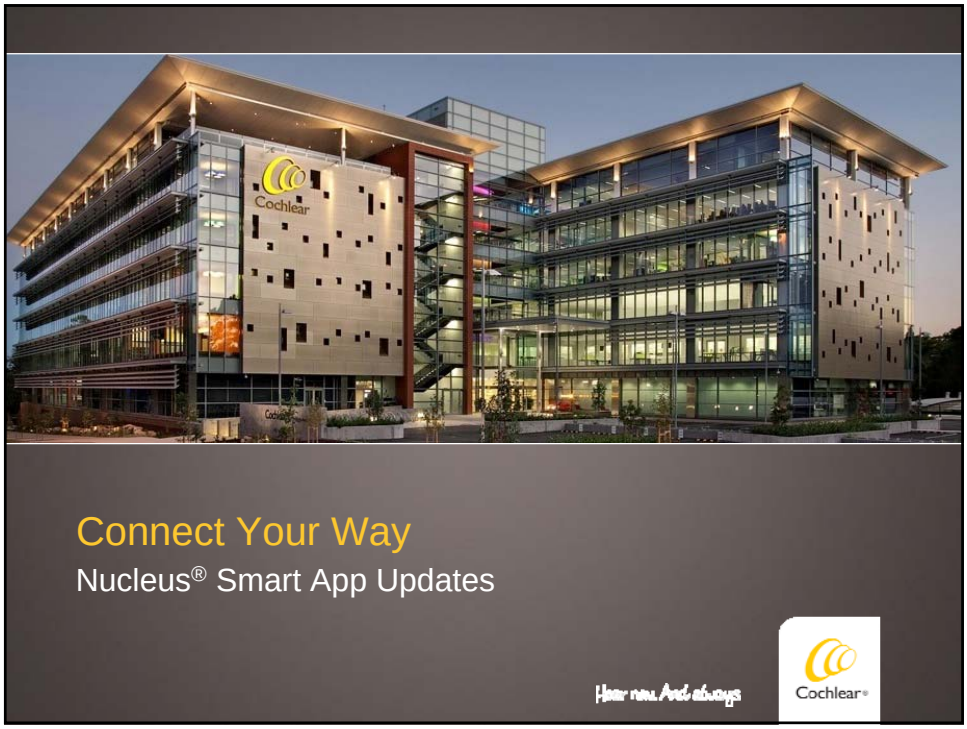
If an Android phone user would like to use the Nucleus Smart App:

- The firmware **MUST** be updated on the Nucleus 7 Sound Processor using Custom Sound 5.1.
- Nucleus Smart App should be downloaded, which is free on the Google Play Store.
- Pairing for Android devices is done within the Nucleus Smart App. Please refer to the steps and instructions provided in the Quick Guide.

GET IT ON Google Play

First for iPhone. First for Android





Connect Your Way

Nucleus® Smart App Updates

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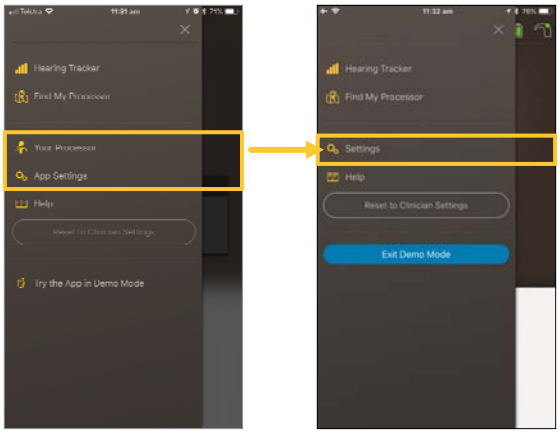
Overview of Nucleus Smart App Updates

- Settings menu
- Coil notifications
- Program number labeling
- Hearing Tracker Data Protection message
- Parental consent
- Data synchronization*
- Nearby (proximity locator)*

*Coming soon for Android

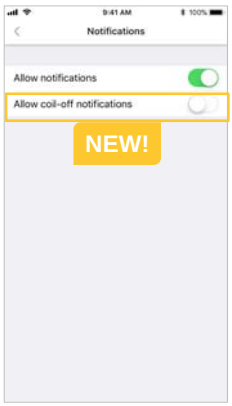
Settings Menu Update

Previously, settings for the app and for the sound processor were separate. Now, they are combined to keep all settings in one accessible place.

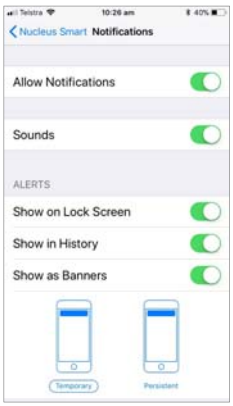


Coil Notifications Update

Previously, notifications were only available while within the Nucleus® Smart App. Now, 'coil offs' are in notifications as well as alerts. The user may decide to see these notifications or not.



Notifications enabled/disabled in Nucleus Smart App Settings

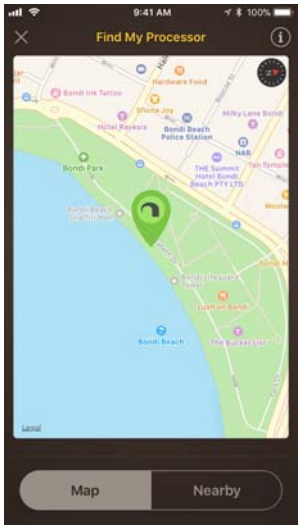


Notifications enabled/disabled in iPhone Settings

iOS

Android

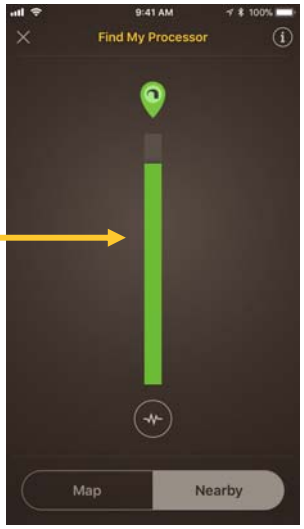
Find My Processor Update*



The user will now see the additional feature '**Nearby***'.

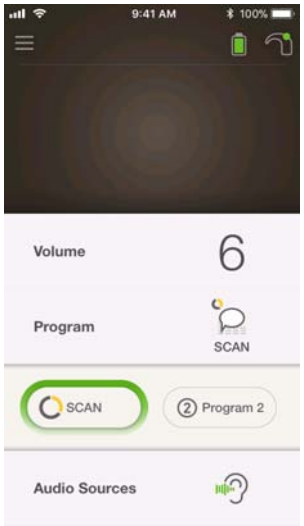
This will display how close the mobile device is to the switched on sound processor (the higher the green bar, the closer they are to the sound processor).

If it is a bilateral user, blue and red bars will be seen.



*Coming soon for Android

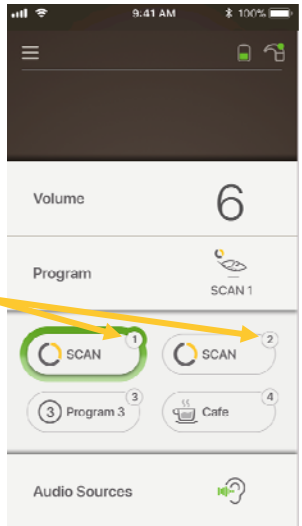
Program Number Labeling Update



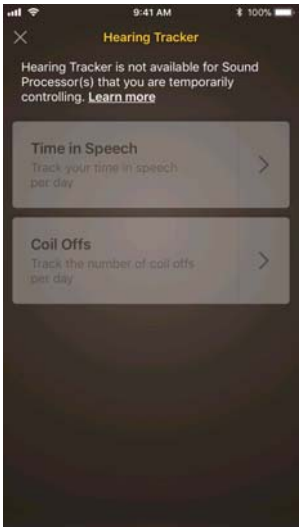
NEW!

Previously, if the user had two programs with the same name (i.e. SCAN, SCAN, etc.), it did not specify program number.

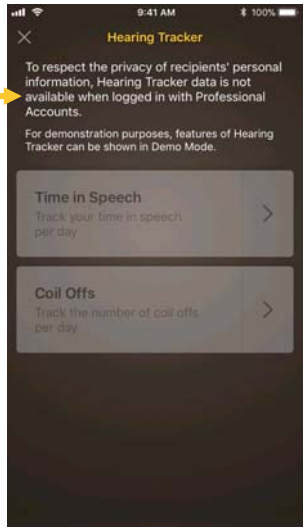
Now, each program is labeled with a number.



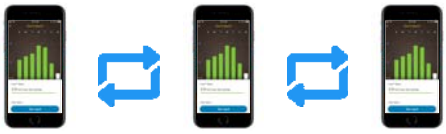
Hearing Tracker Data Protection Message



To support patient privacy and the access to patient data, if the user has identified themselves as a "temporary carer" or is the user of a professional account, they will now see a message that Hearing Tracker is not available.



Data Sync



Data Sync enables data from the sound processor (e.g. Hearing Tracker) to be synchronized to Cochlear and shared for a single recipient across multiple devices
e.g. two parents who each have a phone (and a Cochlear Account) associated with a child

User Controlled
A Cochlear account holder will be asked if they wish to enable Data Sync as part of the App setup process. Enabling this feature is optional, and not controlled by Cochlear.

iOS only
Data Sync is not yet available on Android.

Data Sync feature is NOT available for:
- Professional Accounts
- Staff Accounts
- People who identify themselves as Temporary Users

Enabling Data Sync During Setup Process

Once a user has completed the on-boarding process and verification of the sound processor, **Data Sync** will be presented during the setup process:

Data Sync and Privacy URL

or

or

Enable
This is presented when Data Sync has not been enabled.

Not now
If a user selects, "Not Now" a message is displayed to confirm the choice. If the user does not enable Data Sync, then the feature will be disabled.

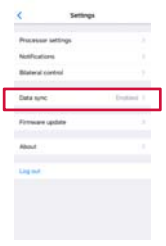
Already Enabled
This is where Data Sync has already been enabled by a Cochlear Account holder related to the recipient.
e.g. one parent creates an account before the other.

iOS only

Note:
Data Sync is not available on Android at the time of Expanded Features launch in July 2018

Toggling Data Sync within Nucleus® Smart App at any time

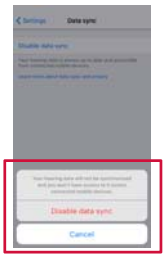
Data Sync is also controlled via the **in-app Settings menu**.
If a user wishes to enable or disable Data Sync *after* the initial setup, they can make the change from the **Data Sync** option in Settings.



1 Settings – new option **Data Sync**

2 **Enable Data Sync**

3 **Disable Data Sync** – no more data is synchronized



4 **Warning message displays** when user selects **Disable Data Sync**

Parental Consent

iOS and Android

What is changing?

Age for creation of a Cochlear Account
Previously, recipient needed to be 18 years of age or older
Now, recipients must be over 13 years of age

Parental consent is a legal requirement designed to protect children's privacy online.

Before a "child" can provide information to Cochlear, their parent must provide consent.

This means that a child cannot create a Cochlear Account – their parent must provide the child's details and consent for their account to be created.

The age definition for a child ranges between 13 and 16 and is dependent on country.

What else should I know?

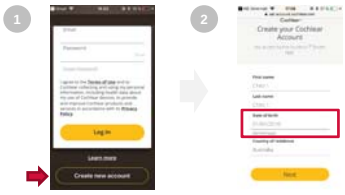
A parent can create a Cochlear Account for their child.
A parent should only create a Cochlear Account for their child if they expect their child to actively use the Nucleus Smart App on their own (child's) mobile device.

Nucleus Smart app has a new on-boarding flow that includes:

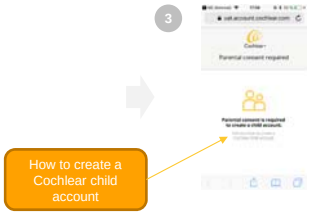
- Blocking a child from on-boarding and creating a Cochlear Account.
- Enabling a parent (who has their own Cochlear Account) to create a Cochlear Account for their child and provide consent.

NOTE:
A child will no longer be able to create an account for online store or myCochlear Recipient (mCR) through those on-boarding points, but if their parent has created an account via Nucleus Smart App they will be able to access those services.

Parental Consent Prompt within Nucleus® Smart App



Steps 1-2
User enters their details to create a Cochlear Account (no change from current process)



Step 3
If the user's age is below the defined age threshold, a notification message appears indicating **Parental Consent** is required.

The user cannot proceed and no information is captured by Cochlear systems.

Note
The user is not advised that they are too young as this may encourage them to re-attempt the account creation process and enter a different date of birth.

Connect Your Way

iOS Menu Updates

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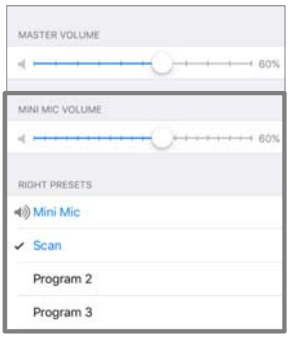
iOS 11 Menu Updates

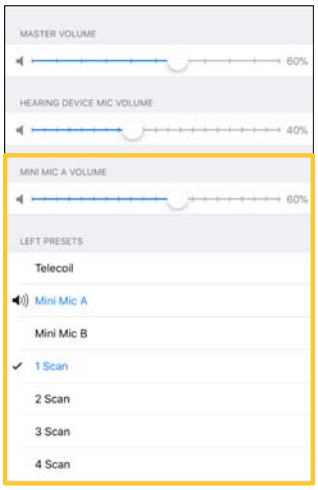
- Hearing Devices Menu Update
- Triple-Click to Short Menu
- Control Center to Short Menu

iOS 11 Hearing Devices Menu Update

iOS 10 display

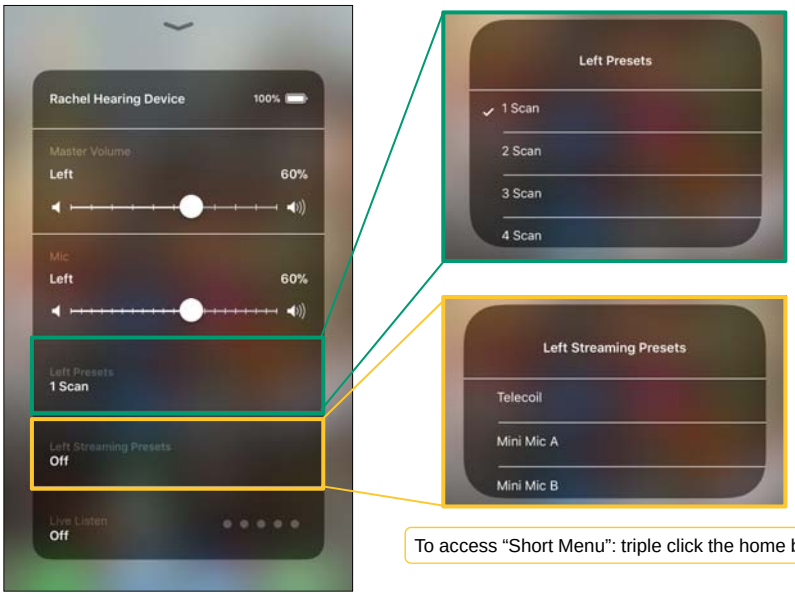


iOS 11 display



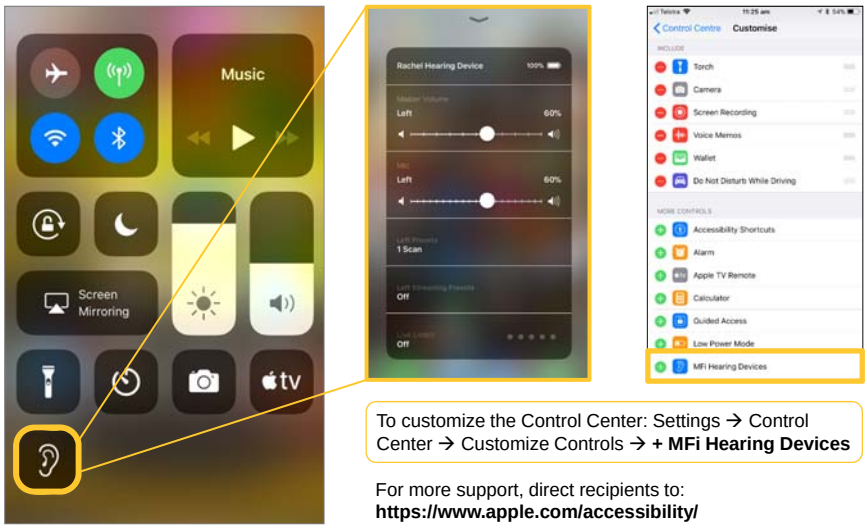
To access “Long Menu”: Settings → General → Accessibility→ MFi Hearing Devices → Devices

iOS 11 Triple-Click to Short Menu



To access “Short Menu”: triple click the home button

iOS 11 Control Center to Short Menu



To customize the Control Center: Settings → Control Center → Customize Controls → **+ MFi Hearing Devices**

For more support, direct recipients to:
https://www.apple.com/accessibility/

Hear Your Way

ForwardFocus

** ForwardFocus can only be enabled by a hearing implant specialist. It should only be activated for users 12 years and older who are able to reliably provide feedback on sound quality and understand how to use the feature when moving to different or changing environments. It may be possible to have decreased speech understanding when using ForwardFocus in a quiet environment.

Hear now. And always

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Industry-Leading Technology

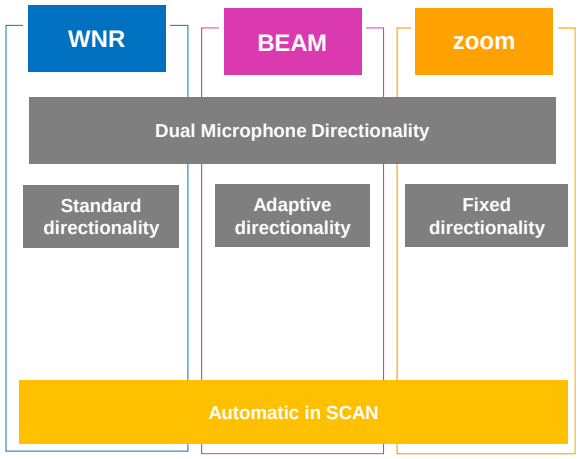
Hearing in noise is the most challenging listening situation for any individual. Using SmartSound® iQ with SCAN*, you can help your patients hear their best, wherever they are.

*It is recommended that SNR-NR, WNR, and SCAN be made available to any recipient, ages 6 and older, who is able to 1) complete objective speech perception testing in quiet and noise in order to determine and document performance and 2) report a preference for different program settings.

S.J. Mauger, C.D. Warren, M.R. Knight, M. Goorevich, E. Nel, Clinical evaluation of the Nucleus1 6 cochlear implant system: performance improvements with SmartSound iQ, Int. J. Audiol. 53 (2014) 564–576.

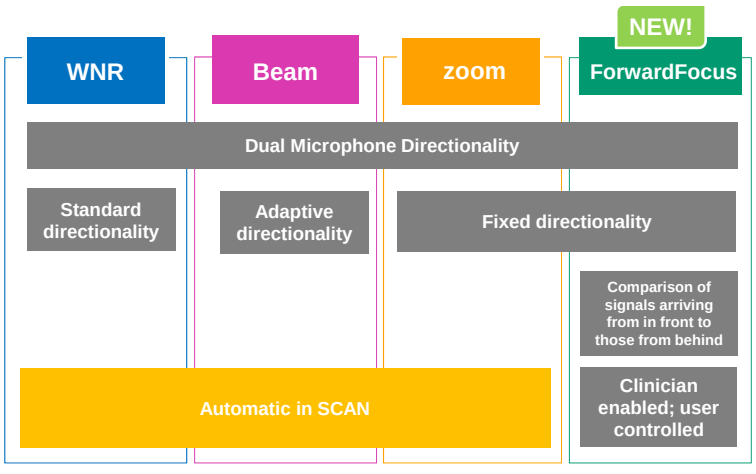
What is ForwardFocus?

Cochlear Noise Processing Technology



1. Combining directional microphone and single-channel noise reduction algorithms: a clinical evaluation in difficult listening conditions with cochlear implant users. Hersbach AA, Arora K, Mauger SJ, Dawson PW. Ear Hear. 2012 Jul-Aug;33(4):e13-23. 2. Benefit of a commercially available cochlear implant processor with dual-microphone beamforming: a multi-center study. Wolfe J, Parkinson A, Schafer EC, Gilden J, Rehwinkel K, Mansanares J, Coughlan E, Wright J, Torres J, Gannaway S.

Cochlear Noise Processing Technology



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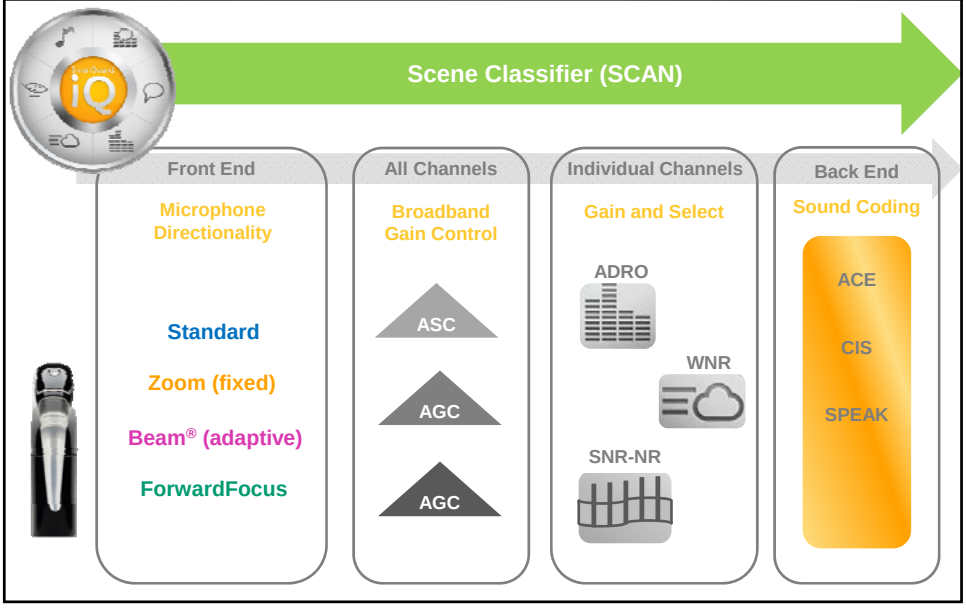
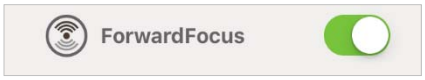
SmartSound® iQ



What remains active while ForwardFocus is being used?

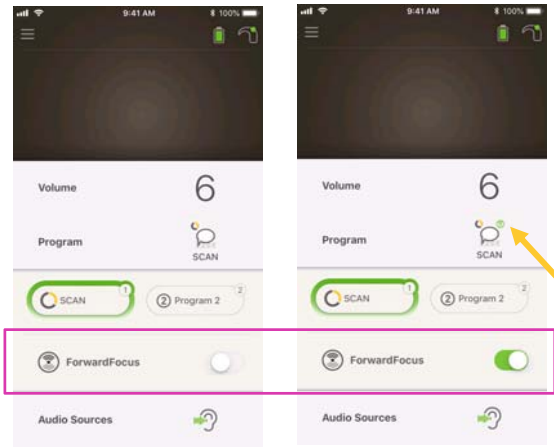
Autosensitivity™ Control (ASC)	Designed to prevent background noise becoming too loud.	Decreases gain slowly (seconds) if background noise is too high.
Automatic Gain Control (AGC)	Designed to prevent distortion of loud sounds.	Decreases gain quickly (milliseconds) if peaks get too big.
ADRO	Designed to improve the overall hearing ability in dynamic environments by ensuring sounds are not too loud or too soft in each channel.	Automatically and smoothly adjusts the individual gain in each channel to optimize the loudness.
SNR-NR	Designed to reduce steady state noise.	Identification of channels with good signal quality compared to noise for the use of selecting maxima

User Controlled



- User toggles between ON/OFF to enable ForwardFocus.
- When the clinician enables ForwardFocus, the icon and toggle will be visible to the user within the Nucleus® Smart App.
- If the sound processor is turned OFF (battery disconnected or button pressed), ForwardFocus will turn off.

ForwardFocus Activated



- Can be used with any program
- Remains active when program, sensitivity or volume is changed
- Private alert to user will indicate activation and deactivation of ForwardFocus. If private alarms are disabled this will not occur.

The icon will change from green to grey to indicate ForwardFocus is not active (wind, MFi, or streaming via an accessory).

Custom Sound 5.1 update **REQUIRED** for Nucleus 7 Sound Processor use with ForwardFocus via the Nucleus Smart App.

Who should use ForwardFocus?

- Those with the ability to provide feedback about sound quality.
- Those who demonstrate good head control and ability to look in the direction of the speaker.
- Those often in noisy or challenging listening situations.
- Those who are 12 years and older.

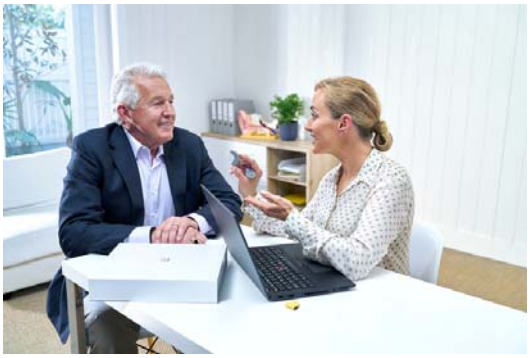
Counseling Points for ForwardFocus

1. FowardFocus can be activated with any program.
2. It is designed to work best when noise is behind the listener and the person speaking is directly in front of the listener. It is not recommended for use in quiet.
3. Recipients should be reminded to manually switch ForwardFocus OFF, when it is no longer needed.
4. ForwardFocus will be disabled whenever the following conditions are detected: Wind, streaming (via MFi or accessory), telecoil.
5. If the listener has functional residual hearing present, the perceived benefit of ForwardFocus may be less.

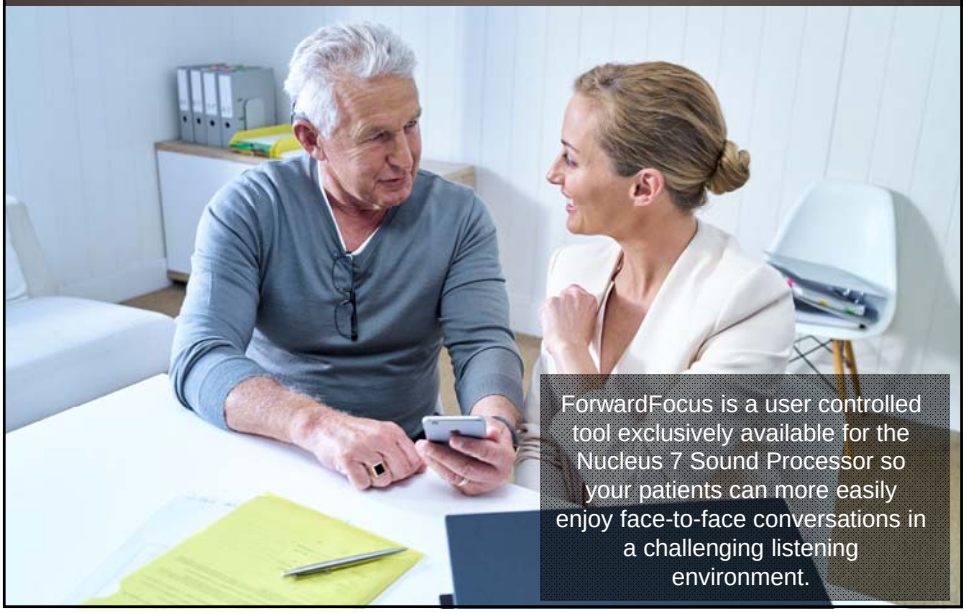
NOTE: For recipients wishing to improve speech understanding in noise over longer distances, devices such as the Cochlear Mini Microphone 2/2+ or an FM system can be considered.

How do I troubleshoot the use of ForwardFocus?

- Review and demonstrate the use of ForwardFocus.
- Discuss the listening situations in which ForwardFocus was tried and re-instruct if needed.
- Review the level of residual hearing on the contralateral and/or implanted ear, as sometimes this reduces the perceived benefit of ForwardFocus.



ForwardFocus



Care Your Way

What's new in Custom Sound® 5.1?

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Custom Sound 5.1 Updates

- Auto Power Level Conversion
- NRT®/Objective Offset Method update
- ForwardFocus control and datalogging
- 'mySmartSound™ Settings' heading replaces 'Recipient Hearing Adjustments'
- Battery life calculation based on mercury-free batteries

Power Optimization

Auto Power Level Conversion

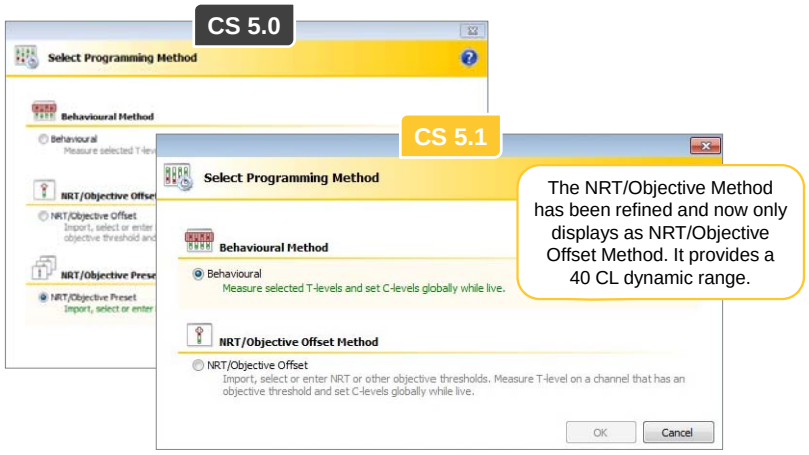
Maintains Auto Power Level settings from previous processor.

Auto Power Level Conversion

- The current practice to upgrade a sound processor when the recipient is not in the room involves changing to Manual Power and using a fixed offset in power level.
- Auto Power Level Conversion for upgrades **avoids the need to change to Manual Power and keeps the patient on Auto Power**.

- N24 implants and newer using a Nucleus 7 Sound Processor
- Auto Power MAPs not available for MAPs using Manual Power
- Runs in standalone mode and is enabled upon writing MAPs to the sound processor using Custom Sound 5.1
- Estimated power level provided at the time of MAP conversion

Objective Method update

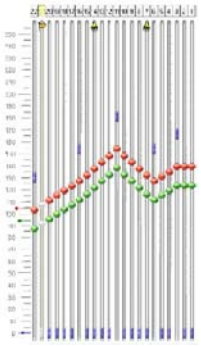


The NRT/Objective Method has been refined and now only displays as NRT/Objective Offset Method. It provides a 40 CL dynamic range.

Custom Sound 5.0 vs 5.1

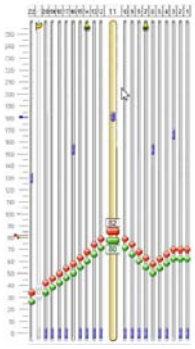
Objective Preset and Offset Methods

Custom Sound 5.0 Objective Preset



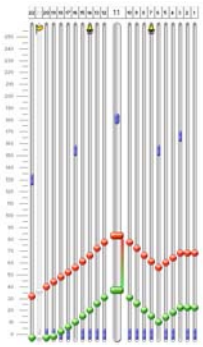
- 4 MAPs created
  - 1st is 10 CL DR
  - 2nd is 20 CL DR
  - 3rd is 30 CL DR
  - 4th is 40 CL DR

Custom Sound 5.0 Objective Offset



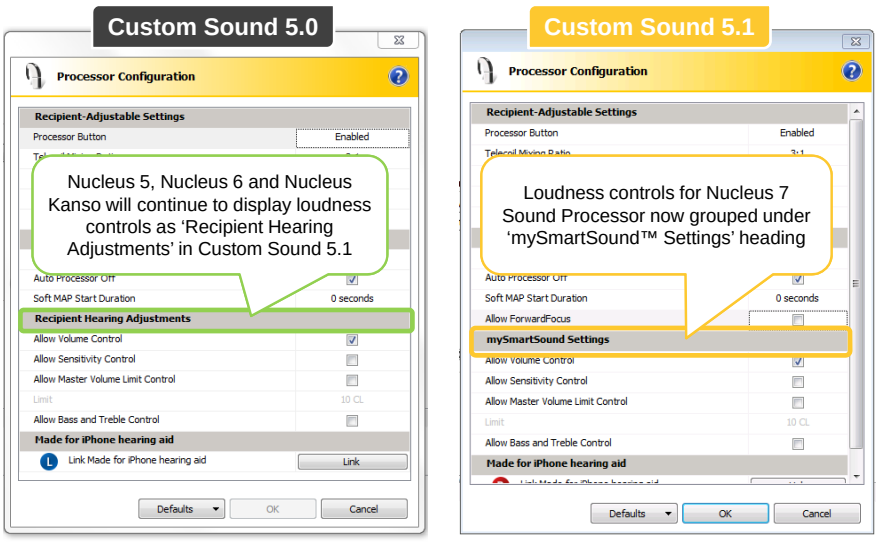
- 1 MAP created
- Profile of NRT used
- Cs on channel 11 always set at 82 CL
- 2 CL dynamic range

Custom Sound 5.1 Objective Offset

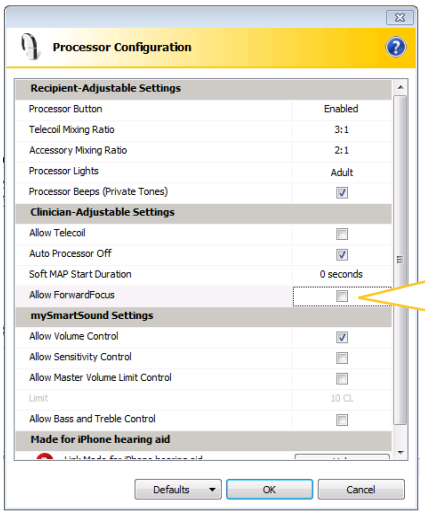


- 1 MAP created
- Profile of Ts and Cs mimics NRT
- Cs on channel 11 always set at 80 CL
- 40 CL dynamic range

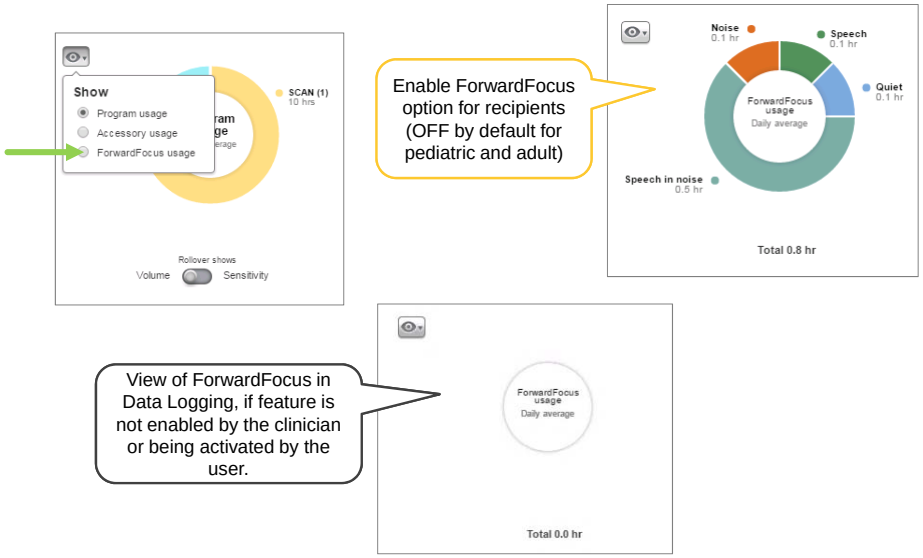
mySmartSound™ Settings



Allow ForwardFocus

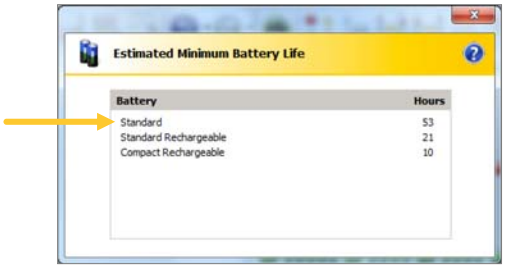


ForwardFocus
Data Logging



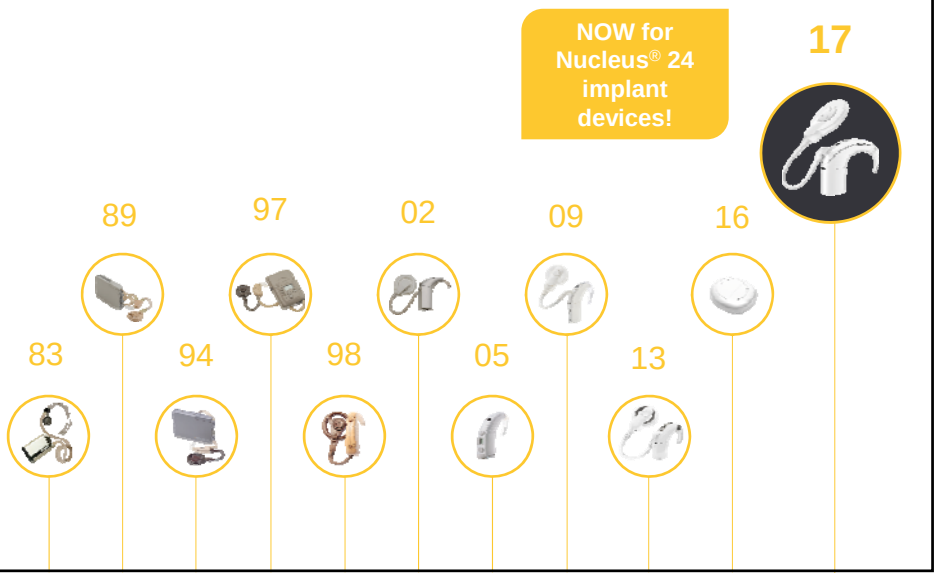
Mercury-free Battery Life Estimation Update

- Zinc-air manufacturers are moving toward mercury-free batteries.
- Using mercury-free batteries results in less battery life (~15% less) for all devices that use zinc-air batteries (Nucleus 5, Nucleus 6, Nucleus Kanso and Nucleus 7 sound processors).*
- The calculations for standard battery life estimation in Custom Sound 5.1 have been updated.



*Internal data on file: D1202160, D709343, D727488 and 546201

Cochlear Nucleus Sound Processors: A History of Innovation



Cochlear™ Nucleus® Implants in the CI24M/R Series

Series	CI24M	CI24R
Common Model Name	24	24
Implant Body (all have removable magnet)		
Available Electrode Arrays (all models have monopolar ground electrodes)	Straight Double Array ABI	Straight Contour
Year of Release	1998	2000
Total Stimulation Rate Available	14,400 Hz	14,400 Hz
Telemetry	Impedance Compliance NRT	Impedance Compliance NRT

SPrint

- Holds four programs
- SPeak released first, then ACE and CIS
- Input Dynamic Range of 30 dB* + range of AGC
- May use Sensitivity setting lower than present-day recommended setting*
- Autosensitivity (ASC) *or* ADRO
- Only a microphone on the ear
  - Lighter weight than a full processor on the ear
  - Not water resistant – therefore moisture may have damaged over time
- Users may connect directly to phone (ear-level microphone becomes inactive)
- Uses either 1 or 2 AA batteries

*Contributors to typical soundfield detection thresholds of 30-35 dB HL

ESPrit

- Holds two programs
- SPeak only (battery life)
- Rotary control: Sensitivity *or* Volume (or disabled)
  - Sensitivity setting typical lower than current recommendations*
- Autosensitivity (ASC)
- Input Dynamic Range of <30 dB* + range of AGC
- May have a frequency allocation table not available in Nucleus 7
- Uses 2 size 675 high power Zinc Air batteries
- Different battery cover for accessories
  - External Telecoil or Audio cables

*Contributors to typical soundfield detection thresholds of 30-35 dB HL

ESPrit 3G

- Holds two programs
- One Piece Cable/Coil
  - Easy Fit (typical adjustable magnet)
  - Screwset (historical – shown here – magnets under a cover accessed by removing screws)
- Rotary control: Sensitivity* *or* Volume (or disabled)
- Input Dynamic Range of 30 dB* + range of AGC
- Autosensitivity (ASC), Whisper
- May have a frequency allocation table not available in Nucleus 7
- Not water resistant (moisture may have degraded microphone over time)
- Inbuilt telecoil
  - 3:1 mixing ratio or T-only
- Uses 3 675 high power Zn Air batteries

*Contributors to typical soundfield detection thresholds of 30-35 dB HL

Freedom

- Holds four programs
- SmartSound 2 options
  - ADRO, ASC, Beam, Whisper: alone or in combination(s); or None
- Each program could have different mixing ratios (Accessory & Telecoil)
- Could create program for immediate Telecoil access (“Telecoil Always On”)
- One-piece cable/coil
- Input Dynamic Range of 40 dB + range of AGC
- Access to both Sensitivity & Volume
- First water resistant processor
  - However if microphone protector not changed as recommended, may be listening to degraded sound

Nucleus 5 Sound Processor

- Holds four programs
  - Everyday, Noise, Focus, & Music
    - Default & customizable SmartSound options under each type
    - Including new Zoom functionality (fixed directionality)
- Auto Telecoil option
- Introduction of MAP, Program, and Processor Settings
- Detachable cable (from coil)
- Input Dynamic Range of 40 dB + range of AGC
- Access to both Sensitivity & Volume
- First processor with Auto Off
  - Does NOT automatically turn ON
- Uses CR110 Remote Assistant

Nucleus 6 Sound Processor

- CP910 or CP920 option
- Holds four programs
  - Default: P1 SCAN, P2 Standard
- Auto Telecoil option
- Detachable cable (from coil)
- Input Dynamic Range of 40 dB + range of AGC
- Access to both Sensitivity & Volume
- Auto On as well as Auto Off
- CR 230 Remote Assistant or CR 210 Remote Control
- True Wireless™ accessories
- Data Logging
- Hybrid™ Hearing*

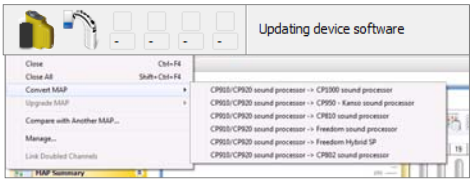
*The Acoustic Component should only be used when behavioral audiometric thresholds can be obtained and the recipient can provide feedback regarding sound quality. The Hybrid L24 Implant is approved in the U.S. for adults ages 18 and older.

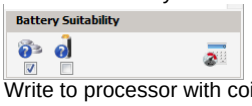
Nucleus 7 Sound Processor for Nucleus 24 Implant Devices

- No new hardware required for Nucleus® 24 implant device users
- Nucleus 7 Sound Processor Slim Coil is compatible
- A range of Nucleus 24 implant devices are supported:
  Contour Advance® CI24R (CA), 24K CI24R (ST), Contour® CI24R (CS), ABI*, Double Array*, CI24M

Upgrade Process – Custom Sound 5.1

Upon connecting the sound processor to the programming pod, an automatic firmware update (for any processor that was previously programmed using Custom Sound® 5.0 or older) will begin.

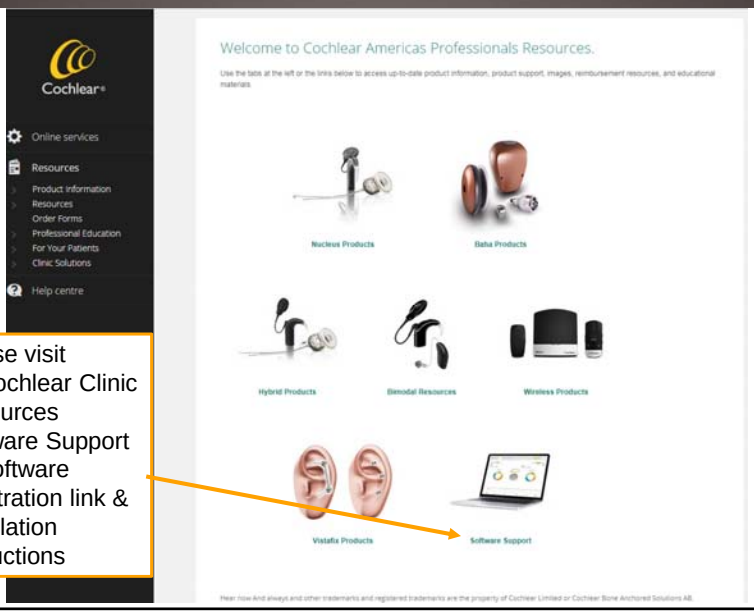


1. Convert current MAP to "CP1000 sound processor"
2. Go 'live' with the converted MAP to check the volume and sound quality
3. Ensure Auto Power is used
4. Determine battery suitability
5. 

6. Write to processor with coil on head

Note: Sound processors prior to Freedom will require a conversion to CP900 series and then a conversion from the CP900 MAP to a CP1000 MAP.

Custom Sound 5.1 Logistics



Please visit myCochlear Clinic Resources Software Support for software registration link & installation instructions

If you need help with installation …

- Pre-schedule a software installation appointment
  - 30 minute appointments available for booking at https://calendly.com/peells/software-installation-appointment
  - Please ensure only ONE support session is scheduled per clinic (with all computers available at that time). Coordinate with your IT support department as required.
- Review the Custom Sound 5.1 Installation Instructions prior to the support session.

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Cochlear

Hear now. And always

Cochlear

Hear now. And always