Remote Check – Nucleus® Smart App

Guide for Clinicians

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Overview

Remote Check is a feature of the Nucleus® Smart App that allows clinicians to invite recipients who have a registered compatible sound processor to complete a series of hearing tests at home. The results of these tests are then securely sent to the clinician for review.

After a recipient is enrolled in Remote Check, Remote Assist will be available to them. Remote Assist is a feature of the Nucleus Smart App that allows clinicians to conduct video calls so that recipients can attend appointments remotely.

Remote Check and Remote Assist are intended for ages 6 and older. Remote Check and Remote Assist features are only visible and accessible if they are enabled by a clinician. Clinicians should consider the suitability of the feature before enabling Remote Check and Remote Assist.

Compatible sound processors

Remote Check is compatible with Cochlear™ Nucleus® 8 Sound Processors, Cochlear™ Nucleus® 7 Sound Processors and Cochlear™ Nucleus® Kanso® 2 Sound Processors.

Important

- Remote Check is compatible with Cochlear Nucleus CI632, CI622, CI612, CI532, CI522, and CI512 implants, CI24M Series, CI24R Series and CI24RE Series implants.
- Remote Check is not recommended for use with Cochlear Nucleus ABI541 and CI551 implants.
- Remote Check is not designed to work for recipients who use an acoustic component.
- Recipients must have access to an iPhone®, iPod touch® or an Android device to use Remote Check or Remote Assist.

Functions of Remote Check

Remote Check performs the following functions.

- Displays information to inform the recipient if Remote Check is due for completion or is not due yet.
- Prompts the recipient to complete Remote Check steps:
  - take implant site photos
  - complete a two part questionnaire
  - complete an audiogram
  - perform a speech in noise test

Functions of Remote Assist

Remote Assist allows pre-scheduled video calls for recipients to attend appointments remotely.

During the video call you will be able adjust the recipient's sound processor settings. You will be unable to access any other settings or apps on the recipient's device.

Warning

Clinicians should recommend the recipients to consider security when connecting the sound processor to devices such as smartphones or tablets. Only connect to devices that are protected, e.g. password or PIN access control. Do not connect to devices that have had their operating system altered.

Remote Check – Nucleus Smart App

Guide for Clinicians

Enrol a recipient

To get started with Remote Check you need to enrol recipients using the myCochlear.com Professional Portal.

Eligibility

Recipients aged 6 or older are eligible to be enrolled in Remote Check and Remote Assist if they have:

- a registered compatible sound processor
- a compatible implant (listed above)
- access to an iPhone/iPod touch or an Android device
- downloaded the Nucleus Smart App from the App Store® to an iPhone/iPod touch or Google Play to an Android device
- paired their processor with the Nucleus Smart App
- created a Cochlear Account using the Nucleus Smart App

Please refer to the relevant *Nucleus Smart App User Guide* and pairing guide for information on how to download the Nucleus Smart App and pair a recipient's processor with the app.

Enrolment process

1. Log into **myCochlear.com** using your Professional Portal username and password.

   If you don't have a Cochlear Professional Portal username and password, please contact Cochlear Customer Service.
2. Click **Search Recipients** in the left-hand navigation bar.
3. Enter the recipient's name and date of birth in the search fields to find the recipient you would like to enrol.

   Note

   The recipient will only appear in the search results if they have registered a sound processor with Cochlear.
4. When search results appear, click on the recipient's name to display their profile.
5. Under the **Remote Check** section of the profile, click **Enrol** to enrol the recipient in Remote Check.
6. Select whether this will be a paediatric or adult Remote Check.
7. Select a *Due Date* for the recipient's Remote Check. Choose the date when you would like the recipient to have completed their Remote Check.

Once you have successfully enrolled a recipient, Remote Check and Remote Assist will appear as menu items in the recipient's Nucleus Smart App.

Remote Check – Nucleus Smart App

Guide for Clinicians

Review results

After a recipient has completed Remote Check you can review their results on myCochlear.com.

1. Log into **myCochlear.com** using your Professional Portal username and password.
2. Click **Remote Check** on the left-hand navigation bar.
3. A list of recipients who have completed Remote Check with results ready for review appears under the *Awaiting Review* tab.
   - Recipients who have a Remote Check scheduled but have not yet completed a Remote Check appears under the *Sent to Recipients* tab.
   - Recipients who have completed a Remote Check and have had their results reviewed by a clinician appears under the *Previously Reviewed* tab.
4. Click on a recipient's name to review their complete results.
5. You can click on any data element in the recipient results dashboard to see more information about a particular result.

   For example, click on *Usage Data* to see a complete visualisation of the usage data from the recipient's sound processor.
6. After you have reviewed the results, scroll to the bottom of the page and select once of the three *Outcome* options:
   - **No action**
   - **Clinic Visit Required**
   - **Other Action**
7. Fill in any appropriate *Clinical Notes* and *Follow-Up Actions*.

   Note
   Text entered into *Clinical Notes* and *Follow-Up Actions* will be visible only to other clinicians in your clinic and will not be visible to the recipient.
8. Type any *Notes to Recipient* that you would like to send to the recipient. These notes will be securely sent to the recipient's Nucleus Smart App after you have completed the review.
9. Pick a due date for the next Remote Check and select whether it will be a paediatric or adult Remote Check.
10. Click **Done** to complete the review and send the results to the recipient.

Note
- Remote Check is designed to work for recipients where default MAP settings have been used.
- Clinicians should remind recipients to complete Remote Check using their preferred MAP and sound processor settings.
- Results should be compared to baseline testing conducted with Remote Check.
- If significant changes are made to the recipient's MAP, consider collecting a new baseline with Remote Check.

After you have successfully completed a review, the recipient will be able to see the outcome (such as whether a clinic visit is required) and any Notes to Recipient by logging into their Nucleus Smart App.

Troubleshoot

Contact Cochlear if you have any concerns regarding the operation or safety of the sound processor.

Evaluation of Remote Care and Nucleus Smart App with CP1000 Sound Processor (CLTD5704): Summary

Clinical trial description

This study aimed to investigate the overall acceptance and ease of use of Remote Check for Cochlear implant recipients and assessed the equivalence of the Remote Check test battery to in-clinic tests conducted in free-field. An additional exploratory objective was to characterise the test-retest difference for the streamed audiogram and speech-in-noise test.

Study demographics

A total of 32 subjects (53 cochlear implants), which included 28 adults and four children, participated in the study. The mean age of the 28 adult subjects was 67 years (range 29 to 86 years) and the four children were aged between 6 and 10 years. The participants had average experience with their cochlear implant of 9 years (range = 1 to 23 years).

Study inclusion and exclusion criteria

Inclusion criteria

- Adults (≥18 years) or children (≥ 4 years) using cochlear implants.
- Implanted with the CI500 Series, CI24 Series or Freedom Series Cochlear implants in one or both ears.
- At least 3 months experience with the cochlear implant.
- Adults able to complete open set speech perception test as judged by the investigator.
- Children able to complete closed set speech perception of numbers 0 to 9 in English as judged by the investigator.
- Willingness to participate in and to comply with all requirements of the protocol.

Exclusion criteria

- Adults or parents/carers with limited English that would prevent completion of questionnaires.
- Nucleus 22 Cochlear implant recipients.
- Additional handicaps that would prevent participation in evaluations.
- Unrealistic expectations on the part of the subject, regarding the possible benefits, risks and limitations that are inherent to the procedures.

Remote Check – Nucleus Smart App
Guide for Clinicians

Study overview

Stage 1 evaluated developmental versions of Remote Check through the collection of usability feedback and product usage data. Stage 2 formally evaluated and characterised Remote Check performance tests and evaluated usability of the optimised product.

This study duration was 24 months, from the first participant enrolled to the last participant visit. Participants in the study received a Nucleus 7 Sound Processor(s) and the Nucleus Smart App with Remote Check enabled.

Clinical trial results

Primary endpoint

For the usability assessments, recipients were asked to complete Remote Check tasks during the study visit and in their home environment. Feedback was gathered via interviews and written feedback.

The ease of use for Remote Check was evaluated based on the response to the following question: 'Overall, how easy was it for you/your child to use Remote Check to complete the remote check?' A significantly high proportion of the subjects (27/32) rated Remote Check as easy to use.

Secondary endpoint

Aided threshold tests (ATT) were used for audiogram measurements and digit triplet tests (DTT) were used to measure speech-in-noise. The ATT and DTT were conducted through direct stream with Remote Check. For comparisons, the ATT and DTT in-clinic equivalent tests were conducted via the free field (FF) in a sound treated room (booth). Each booth, including speakers, amplifiers and software, was calibrated regularly. Where possible, the test order was balanced across subjects and across conditions to control for order effects.

Aided threshold test in Remote Check

This is an audiogram measured with the sound processor in use. Sounds of specific frequencies are streamed via Bluetooth from the iOS device to the sound processor and the recipient is asked to indicate whether they hear the sound or not. The objective of the test is to determine the lowest level at which the recipient is able to detect the sounds at each frequency selected.

The mean difference between the ATT stream and FF results was 6.724 dB ($P<0.001$).

Digit triplet test in Remote Check

This is a speech-in-noise test where the recipient listens to numbers in noise and responds to the numbers heard on the keypad in the app. The signals are streamed via Bluetooth from the iOS device to the sound processor. The level of the signal and noise is varied adaptively to find the signal to noise ratio where 50% of the digits are correctly identified.

The mean difference between the DTT stream and FF results was -1.795 dB ($P<0.001$). The thresholds collected in the FF were lower than the streamed thresholds. However there was a significant positive correlation ($r=0.6$, $p<0.001$) between the FF and streamed thresholds, which means that results from both test presentation methods trend in the same direction.

Exploratory endpoint

Exploratory analysis was conducted to measure the variation in results of ATT and DTT tested via streaming in the clinic vs in the home environment.

The test-retest difference (mean) for DTT streamed in-clinic compared to streamed at home was 0.157 (SD=2.24).

The test-retest difference for ATT streamed in-clinic in the same testing session was 0.9-dB (SD=1.298) and 1.4-dB (SD=1.972) when streamed at home.

Adverse events

There were no serious adverse events reported in this study. A total of 11 adverse events (AE) were reported: 1 moderate and 10 mild in severity.

Four AEs were classified as 'definitely related' to an investigational device. One AE, 'DTT noise too loud', was related to the Nucleus Smart App with Remote Check. The remaining 3 AEs, 'mild pain over left implant site', 'itchiness over implant site on right ear' and 'subject reported discomfort and poor hearing performance listening to p4 outside test environment', were related to the Nucleus 7 Sound Processor.

Two adverse events were classified as 'possibly' or 'probably related' to the investigational device. These were 'buzzing noise' associated with Remote Check and 'aided thresholds was too loud' associated with the Nucleus 7 Sound Processor, respectively. All other adverse events were classified and 'unlikely related' or 'not related'.

Discussion of the endpoints

Remote Check in the Nucleus Smart App was found to be easy to use by a significantly high proportion of participants. The difference in results between FF and ATT stream cannot be attributed to the noise floor of the FF as the sound room used for the in-clinic testing meets the ISO and ANSI standards (ISO 8253-1 & 2, ISO 226, and ANSI S3.1-1999).

There are several factors that can cause differences in the ATT stream and FF results, based on the design of Remote Check and use of direct streaming.

1. Self-initiated: In clinician-driven pure tone audiometry, false negative responses can occur when the patient fails to respond because they want to be sure that the tone is there (Gelfand, 1997). The hearing threshold testing in Remote Check is patient-initiated, so the patient knows when the sound will be presented which can reduce the uncertainty of the timing and presence of the stimulus, and is thereby likely to reduce false negatives.
2. Multiple presentations: In clinician-driven pure tone audiometry, only one presentation is presented for each level. With Remote Check, the subject can press to have the sound presented more than once which can increase the chance for the patient to respond at the softest level they can hear.
3. Smaller step size: The FF clinician-driven test, when using the Hughson Westlake procedure (Hughson & Westlake, 1944), uses a 5 or 10 dB step size which can result in higher thresholds. Remote Check progressively reduces the stimulus level until it is no longer heard by the participant. Then, the stimulus level is increased to a level where it is audible again. At the beginning of the test, larger step sizes of 8 dB and 4 dB are used, and when the stimulus is closer to the threshold the step size reduces to 1 dB. Smaller step size allows for more precision at levels closer to the real thresholds and thus can also reduce the recorded thresholds.
4. Standard error: In an FF setup, the threshold is set after two ascending runs (Hughson & Westlake, 1944). For Remote Check the ATT test will continue to present stimuli until the standard error at the test frequency is ≤1dB, to improve the reliability of the threshold result. The threshold is set as the average of the last trials. Since the average of the trials with response and no response is used rather than the level at which there was a response, the thresholds with ATT can be lower.
5. Non stimulus trials: In clinician-driven pure tone audiometry, false negative responses can occur where the patient responds when they should not have responded (Gelfand, 1997). In Remote Check, there are non-stimulus trials (no sound presented) designed to reduce the false positive rate.

The above-mentioned features of ATT that were designed to improve the reliability of the test also increase the likelihood of lower thresholds with ATT, which is what was found in this study.

The small differences seen between the DTT streamed and FF results may be explained by the differences in seating position of subjects. Several steps were taken to ensure that the sound reaching the subject's sound processor was at a uniform level such as a) seating in an immovable chair and b) asking the subjects to face the speaker; however subtle changes in the way subjects position themselves in the chair could lead to level differences.

Recommendations

The implementation of Remote Check will be used to manage clinic flows, such as determining if an appointment is required and planning out the duration of the appointment.

After the patient completes the tests, clinicians will review the data and compare to results captured with an in-app baseline to help determine whether a recipient needs further intervention. Comparison data should be captured via the same method to enable stable comparisons over time.

It is not recommended that Remote Check stream results are compared to free field results.

It is important that Remote Check users have an appropriate level of technology fluency in order to engage with the Nucleus Smart App as intended.

References

Gelfand, S. A. (1997). *Speech audiometry. In Essentials of audiology.* New York: Thieme.

Hughson, W., & Westlake, H. D. (1944). Manual for program outline for rehabilitation of aural casualties both military and civilian. *Trans Am Acad Ophthalmol , Otolaryngol, Suppl,* 3–15.

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