

## ASX / MEDIA RELEASE

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### **Cochlear receives expedited FDA approval of Remote Check solution for cochlear implants**

- FDA approves Remote Check for Cochlear's implant users
- First telehealth patient assessment tool to provide performance data to clinicians
- Accelerated global rollout, where approved by regulators, to build on experience gained across five countries
- Remote Check will enable hearing healthcare providers and hospitals to quickly identify those in need of audiological care during the COVID-19 pandemic
- Offers patients convenience while reducing the cost of care

Cochlear Limited, the global leader in implantable hearing solutions, has obtained US Food and Drug Administration (FDA) approval for its Remote Check solution. Remote Check is the first telehealth patient assessment tool for cochlear implant recipients. It is designed to be a convenient, at-home testing tool that allows people with a Cochlear™ Nucleus® 7 Sound Processor to complete a series of hearing checks from their compatible iOS device using the Nucleus Smart App<sup>1</sup>. Results are then sent remotely to the recipient's clinic for review by their clinician.

Cochlear will begin a controlled release of Remote Check in the US and intends to accelerate the release of Remote Check in many countries where regulatory clearance has already been received, including Canada, the United Kingdom, and select countries in Western Europe.

Remote Check was developed to conduct routine cochlear implant checks outside the hearing clinic. The technology has been tested in previous pilots in five countries worldwide. Following increased demand for remote care due to the COVID-19 pandemic, the FDA expedited its approval. Remote Check will enable hearing healthcare providers and hospitals to quickly identify those most in need of audiological care during the COVID-19 pandemic, as well as those who would benefit from Remote Check as part of their routine care over the longer-term.

Cochlear's CEO & President, Dig Howitt said, "Remote care has been a core pillar of Cochlear's long-term innovation strategy, with access to care crucial to people who rely on a cochlear implant. With many people around the world now practising social distancing, Remote Check provides recipients with the ability to continue to access a level of care at a time when many clinics are closed to in-person visits. The FDA's expedited approval of Remote Check during the COVID-19 crisis underscores the importance of remote hearing care solutions – now more than ever – with many healthcare authorities already recognising the value in reimbursing Remote Care consultations for clinicians."

For recipients with a Cochlear™ Nucleus® 7 Sound Processor, Remote Check can provide significant cost savings by offering a convenient, time-saving option for care that does not require travel to a clinic. Using this technology, clinicians will not only be able to provide a more convenient care option, post the COVID-19 pandemic disruption, they can also free up time to manage the anticipated growth in the number of people needing cochlear implants, and re-direct in-clinic time to manage patients with the greatest need.

A clinician can choose to assign any of the following activities for their patient to complete as part of their Remote Check:

- Photographing the implant site and the area behind the ear;
- Completing questionnaires to gather information about general health and hearing;
- Taking an audiogram test to precisely measure the softest levels heard across a range of frequencies;
- Taking a listening-in-noise test to objectively assess hearing ability by identifying three-digit numbers presented in background noise; and
- Impedance check to assess the performance of the implant electrodes.

Remote Check is designed for both adults and carers of children. The clinician can review the results by logging securely into their myCochlear.com Professional Portal. Remote Check is designed to provide a snapshot of a patient's hearing health so a clinician can quickly determine whether a patient is progressing well, or whether further clinical intervention is required<sup>2</sup>.

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Authorised for lodgement by Cochlear Continuous Disclosure Committee.

**References**

1. To use Remote Check, a patient requires: latest version of the Nucleus Smart App (Remote Check is part of this App) running on a compatible Apple device (iPhone or iPod Touch); Nucleus 7 Sound Processors with implant models: CI24RE, CI512, CI513, CI522, CI532, CI612, CI622 and CI632; compatible firmware on the Nucleus 7 Sound Processor (4.1.3.3 or later). A clinician requires access to Cochlear's secure web-based myCochlear.com Professional Portal to access and review patient results. The recommended browser for accessing the Professional Portal is Google Chrome. A clinician also requires Custom Sound 5.1 or later software to upgrade the patient's firmware to enable access to Remote Check. For sound processor and app compatibility information, visit [www.cochlear.com/compatibility](http://www.cochlear.com/compatibility).

2. Remote Check does not replace clinical care and does not involve remote programming of the sound processor.

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