



## **URGENT: MEDICAL DEVICE RECALL**

**Product Field Action:** Voluntary Product Recall

**Description:** CP1000 Processing Unit Packed, Black, Platinum Detail

**Catalog No:** Z482005

**Serial Number:** 1010144926238, 1010145033607, 1010145074327, 1010145089635,  
1010145106516

**Dear Customer,**

We are writing to advise that Cochlear has recently become aware of an error that is impacting connectivity between a small number of Nucleus® 7 Sound Processors and Apple devices.

Patients who use Android devices are not impacted by this error. Our records indicate that you have received one or more of the Products. As the Authorized Representative in Malaysia, it is our duty to ensure that customers who may have received any of the Products also receive this important notification.

### **Background**

We have recently become aware of an error that is impacting connectivity between a small number of Nucleus 7 Sound Processors (manufactured during April and May 2022) and Apple devices. There is no safety risk, and the affected Nucleus 7 Sound Processors should function as normal in every other way. Patients will still be able to use their sound processor to hear.

The Nucleus 7 Sound Processors impacted by this error are unable to connect with Apple devices. Patients will see information on the screen flicker on and off as the devices attempt to pair with an Apple device and they will be unable to stream or use the Nucleus Smart App.

Android devices are not impacted by this error. Those who use an Android device or do not connect their sound processor with a smartphone can continue to use their Nucleus 7 Sound Processor; however, Cochlear will provide a replacement device if they choose, at any time in the future.

The error cannot be repaired remotely or in-clinic. To resolve this, Cochlear will make a replacement Nucleus 7 Sound Processor available to all patients who have received an impacted device.



We are taking a proactive approach to communicating this issue with our recipients and clinics/clinicians, to reassure them that we are aware of this issue, that there are no safety implications, and that we are working to address it as quickly as we can.

### **What Cochlear has done, and is doing**

The error has been resolved in manufacturing and we are already producing replacement sound processors. We will start replacing impacted sound processors and expect to complete replacements over the next four to six weeks.

### **Product and distribution information:**

<b>Product and Distribution Information Table</b>				
Manufacturer's Product number/ Catalog number	Lot/ Serial number	Manufacturing/ Distribution dates	Expiry date (MM/DD/YYYY)	Quantity
Z482005	1010144926238	14/04/2022	Not Applicable	1
Z482005	1010145033607	20/04/2022	Not Applicable	1
Z482005	1010145074327	12/04/2022	Not Applicable	1
Z482005	1010145089635	20/04/2022	Not Applicable	1
Z482005	1010145106516	20/04/2022	Not Applicable	1

### **Required actions**

1. Please examine your inventory to identify any CP1000 Processing Unit with Catalog Number and Serial Number referenced above. Immediately quarantine any affected product listed above.
2. Please inform product users of this notification and forward this notice to all those individuals who need to be aware within your organization.
3. Advise your patients that a replacement Nucleus 7 Sound Processor will be available (expected within 4 to 6 weeks)

4. Please assist us in meeting our regulatory obligation by completing the attached Business Reply Form. Then, please give the completed form and any affected products to Cochlear Representative who will return it to the product owner on your behalf and prepare the replacement unit.

We regret any inconvenience this action may cause you and if you have any questions, please feel free to contact the undersigned.

Sincerely,



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