

Cochlear[™] Osia[®] Smart App User manual

Welcome

With the Cochlear[™] Osia[®] Smart App, you can discreetly change programs, customise the sound on your sound processor, and activate streaming from your compatible wireless audio sources.

The Osia Smart App uses Bluetooth® to communicate with the sound processor via a compatible* Apple or Android smartphone.

To download** the Osia Smart App, and to use some of its features, a stable WiFi or 4G internet connection is required.





^{*} For an up-to-date list of compatible devices, please visit www.cochlear.com/compatibility.

^{**} The Osia Smart App is available for download via App Store or Google Play.

Intended purpose

The Osia Smart App is a software application intended to remotely control and monitor the Osia 2 Sound Processor or the Osia 2(I) Sound Processor directly from a compatible smartphone. The Osia Smart App is intended to be used in any scenario where the recipient's compatible smartphone can be used and be connected to the sound processor via Bluetooth®.

Intended users

Intended users of the Osia Smart App are:

- 1. Recipients of a compatible Cochlear Osia Sound Processor.
- 2. Carers of recipients, who carry out recipient functions as needed. Carers could include parents of paediatric recipients, nurses or other caregivers of dependant recipients.
- 3. Clinicians/audiologists.

Indications

The Osia Smart App is indicated for use with a compatible Cochlear Osia Sound Processor.

Compatible Osia Sound Processors are: Osia 2 Sound Processor and Osia 2(I) Sound Processor.

Contraindications

The Osia Smart App is not indicated for use with sound processors other than the Osia 2 Sound Processor and the Osia 2(I) Sound Processor.

Intended clinical benefits

The Osia Smart App functions as part of a Cochlear Osia bone conduction system. Most recipients of a bone conduction hearing solution will experience an improved hearing performance and quality of life compared to unaided listening.

Intended patient population

The Osia Smart App is intended for patients with a compatible Cochlear Osia Sound Processor and a compatible smartphone who are comfortable using smartphones and apps. There are no restrictions for the intended patient population of the Osia Smart App in terms of age, weight, health, or other condition.

Performance characteristics

The Osia Smart App can be used to temporarily modify a subset of parameters available within a compatible Cochlear Osia Sound Processor and is limited to the performance characteristics of the sound processor. The subset of parameters includes: adjusting overall volume, adjusting volume in three separate frequency bands (bass, mid, treble), and mimicking the sound processor hard button functionality to change listening program and activate streaming from Cochlear True Wireless™ devices.

Summary of safety and clinical performance

A summary of the safety and clinical performance of the Osia Smart App can be found at https://ec.europa.eu/tools/eudamed.

Before you start

Consider security when connecting your 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.

To use the app, you will need to accept the Terms & Conditions and log in to the app using your Cochlear account. Follow the instructions on the screen.

Pair and connect

Android

- 1. Download and install the Osia Smart App on your compatible smartphone.
- Start the Osia Smart App and follow the instructions on the screen to log in, pair and connect the app to your sound processor.

To un-pair your sound processor, open the app, navigate to Settings and select 'Unpair'.

iPhone

- Go to Settings/Accessibility/MFi Hearing Devices on your iPhone
- 2. Restart your sound processor.
- 3. When your sound processor appears in the list, tap to select it.
- 4. Accept the pairing request on your iPhone. You will hear an audio signal in your sound processor as a confirmation of a successful pairing.
- 5. Download and install the Osia Smart App.
- Start the Osia Smart App and follow the instructions on the screen to log in and connect the app to your sound processor.

To un-pair your sound processor, go to Settings/Accessibility/MFi Hearing Devices on your iPhone. Select your sound processor in the list, then tap on 'Forget device'.

Using the App

Controlling your sound processor

Program and streaming

The app automatically displays all your sound processor programs and paired Cochlear Wireless Accessories. Simply select the corresponding icon to change program or activate streaming.

Volume

To adjust the volume of your sound processor, use the volume slider. Use the mute function to mute or un-mute the sound that is delivered

You can adjust the ratio between the audio that is picked up by your sound processor microphone and the audio that is streamed from your wireless accessories.

If you have a bilateral configuration, you can adjust the balance between your right and left sound processor.

Bass/Mid/Treble

The app allows you to select presets for specific situations or environments, or fine-tune bass, middle and treble. These adjustments do not alter the programs your hearing care professional has created and can be stored in your app for easy access.

If changes are made to the program configuration, e.g. at a fitting, it can be necessary to adjust or remove the presets. Follow the in-app instructions.

Monitoring your sound processor

The app monitors the battery level of your sound processor and tells you when the battery is almost empty.

Navigate to 'Hearing Mentor' from the app main menu to see how many hours you have used the sound processor and the programs.

If you cannot find your sound processor, use the 'Locate sound processor' feature in the app main menu.

Troubleshooting

I can't pair or connect my sound processor to the Osia Smart App.

Make sure that your smartphone is compatible (refer to www.cochlear.com/compatibility). Always make sure that your sound processor is ON, is nearby and has a fresh battery. Follow the instructions in the sound processor user manual on how to restart your sound processor.

Issue is not resolved

- 1. Completely close the app
- 2. Restart the app

Issue is not resolved

- 1. Un-pair the sound processor from your smartphone
- 2. Un-install the app from the smartphone
- 3. Install the app
- 4. Pair the sound processor to your smartphone (refer to the instructions in the section "Pair and connect" on page 7)

Issue is not resolved

Contact Cochlear Customer Service (www.cochlear.com/customer-service)

Reporting a serious incident

Whilst serious incidents in relation to medical devices are rare, it is acknowledged that incidents may happen. As an organisation, Cochlear recognises the potential for harm and will respond to any reported serious incident. A 'serious incident' means any event that directly or indirectly has caused or could have caused an unexpected or unwanted event including any of the following:

- a. The death of a patient, user, or other person,
- The temporary or permanent serious deterioration of a patient's, user's or other person's state of health,
- c. A serious public health threat

Serious incidents in relation to your device should be reported to your Cochlear representative and to the medical device authority in your country, if available.

- Your local Cochlear office: https://www.cochlear.com
- · Therapeutic Goods Administration: https://www.tga.gov.au

Key to symbols

w

Manufacturer and date of manufacturing

REF

Catalogue number



Refer to instruction for use (IFU)

EC REP

Authorised representative in the European

Community

UDI

Unique device identifier

Rx Only

By prescription

MD

Medical device



CE registration mark with notified body number



UK Conformity mark with approved body

number

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For information regarding the compatibility of Cochlear's Sound Processors with Apple or Android devices, visit www.cochlear.com/compatibility. Cochlear's range of Smart Apps and Support Apps are available on App Store and/or Google Play. For information regarding the sound processors, operating systems and devices that are compatible with the Cochlear's range of Smart Apps and Support Apps, visit www.cochlear.com/compatibility.

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