

ENGLISH



# **Cochlear™ Osia® 2 Aqua+** **User manual**

## **About this user manual**

This manual is intended for recipients and carers that use the Osia® 2 Aqua+ (referred to as the *Aqua+*). The Aqua+ is compatible with:

- the Cochlear™ Osia® 2 Sound Processor
- the Cochlear™ Osia® 2(I) Sound Processor

referred to as the *Osia 2 Sound Processor* or simply the *sound processor*.

## **Intended use**

The Cochlear™ Osia® System uses bone conduction to transmit sounds to the cochlea (inner ear) with the purpose of enhancing hearing. The Cochlear Osia 2 Aqua+ is intended to be used as an accessory to the Cochlear Osia 2 Sound Processor. To maintain reasonable hearing above water in situations when there is a risk of water immersion of the sound processor, it creates a water tight and dust proof seal.

## **Indications**

The Cochlear Osia System is indicated for patients with conductive, mixed hearing loss and single-sided sensorineural deafness (SSD).

Patients should have sufficient bone quality and quantity to support successful implant placement.

The Osia System is indicated for patients with up to 55 dB SNHL.

## Clinical benefit

Most recipients of a bone conduction hearing solution will experience improved hearing performance and quality of life compared to unaided listening.

## Serious incidents

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

## Symbols used in this guide



### NOTE

Important information or advice.



### CAUTION (NO HARM)

Special care to be taken to ensure safety and effectiveness. Could cause damage to equipment.



### WARNING (HARMFUL)

Potential safety hazards and serious adverse reactions. Could cause harm to person.

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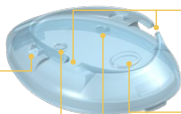
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# Osia<sup>®</sup> 2 Aqua+

## Aqua+ cover

*Hole for retention line*

*Microphone ports*



*Clips for goggle strap*

*Access to sound processor button*

## Osia 2/2(I) Sound Processor



## Aqua+ base

*Alignment track for Osia battery door*



*Alignment track for Aqua+ cover*

## Battery use with Aqua+

The standard zinc-air type batteries used in the sound processor require airflow to function, and therefore cannot be used when sealed inside the Aqua+.

You must use other disposable batteries such as alkaline, nickel metal hydride or silver oxide\* batteries when using the sound processor with the Aqua+.

Battery type	Use with Aqua+	Estimated battery life
Zinc air - p675 - PR44	No	22 to 35 hours
Alkaline (LR44)	Yes	3 hours 30 minutes**
Nickel metal hydride (P675)	Yes	2 hours 20 minutes**
Silver oxide (SR44)	Yes	2 hours 50 minutes**

\* (USA) Silver oxide batteries are contraindicated by the FDA.

\*\* Battery time may vary up to one hour above or below the stated values.

# Before you get wet...

## Replace batteries

Replace batteries with approved types.



### CAUTION

The sound processor will not work if incorrect battery is used.

If you have a Safety Line or a Cochlear SoftWear™ pad on your sound processor, remove them.

## Place sound processor in Aqua+

1. Open the Aqua+ by pushing the base towards the top cover. (Fig. 1)  
OR  
Pull the two parts apart with your fingers with the support of the grooves. (Fig. 2)
2. Place the sound processor in the base with the button and the battery door aligned with the cut out in the base. (Fig. 3)
3. Align and place the cover on top of the base and press the two pieces together evenly. (Fig. 4)



### NOTE

Ensure that as little air as possible is trapped in the Aqua+. Excess air will create feedback and attenuation.



### CAUTION

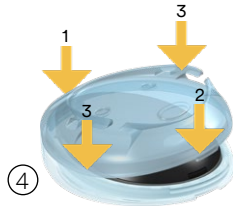
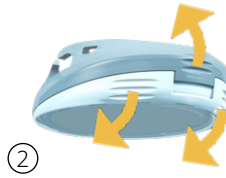
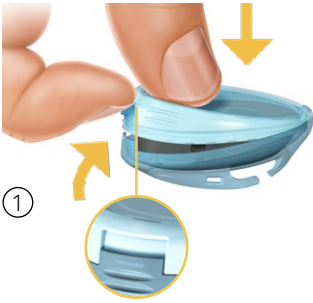
Make sure the Aqua+ is properly sealed so that water does not leak in and damage the sound processor.



### CAUTION

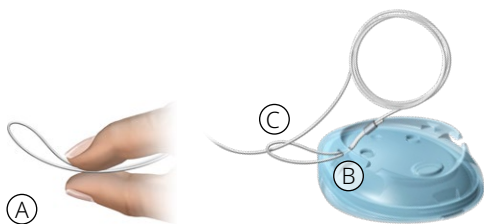
Make sure you have clean hands before open and closing the Aqua+. Sunscreen or other items may hinder the seal ring from closing properly.





## Attach Safety Line

1. Pinch the loop on the end of the line between your fingers and thumb. (A)
2. Pass the loop through the attachment hole in the Aqua+ from front to back. (B)
3. Pass the clip through the loop (C) and pull the line tight.
4. Attach the clip to your clothing or hair depending on the Safety Line design.



### WARNING

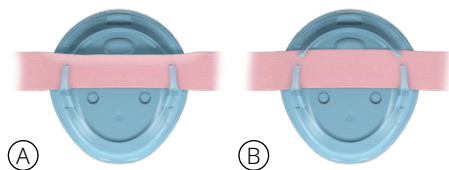
Retention lines longer than the Safety Line (standard length) are not recommended for use by children as they may present a risk of strangulation.

## Attach goggles

To help retain your Aqua+, use goggle straps or the Cochlear Headband.

To find the correct spot on the goggle straps for your sound processor, put the goggles on first without the sound processor and find the point on the straps where they pass over the implant site.

When you have found the correct spot on the goggle straps for the sound processor, slide the band under the long clips (A) and then under the short clips (B).



### NOTE

There is a wide variety of goggles on the market and you may have to find a model that fits the Aqua+.

## Using your Aqua+

Using the Everyday-program with the Aqua+ will feedback when diving underwater due to the increased pressure on the highly sensitive microphones.

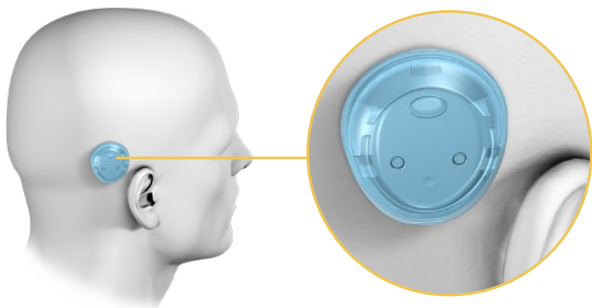
### To avoid feedback:

- Switch to the Aqua+ Underwater program. This will decrease the risk of feedback but the hearing performance will decrease.
- If wearing goggles you can reposition your sound processor so it doesn't sit over the implant. When above water, reposition it again over the implant.
- Or simply remove the sound processor.

# Wear

Place the Aqua+ with the sound processor over the implant site.

Ensure that the LED is facing upward.



Finally, do the Aqua+ checklist to make sure you're ready to get wet!

- Using correct batteries (not zinc air)
- Aqua+ tightly sealed
- Safety Line attached if required
- Retention aid adapted for type of activity
- Have fun!



## CAUTION

Don't forget you can't go deeper than 3 metres!

## After you get wet... care and storage

1. Rinse Aqua+ with clean water and dry with a soft cloth.
2. Open the Aqua+ top cover and remove your sound processor.
3. Allow your Aqua+ to dry overnight.
4. Once it's thoroughly dry, put the two halves together and test the seal by pressing down on the bottom.



### CAUTION

If any air leaks out, you should not use it again but replace the Aqua+ with a functioning one.

5. If the seal is ok, separate the two halves again and place your Aqua+ in your Osia Activity Kit's waterproof case until you want to use it again.

# **Cautions**

- When possible, avoid pressing the processor button with your fingernail as this can damage Aqua+.



## **NOTE**

- If your Aqua+ appears damaged or worn, replace it with a new one. The Aqua+ has been tested for 50 times use (open and closed). There is a risk it may wear out before 50 uses. Always inspect the Aqua+ thoroughly to ensure that the water seal is intact.
- If your sound processor does get wet, remove the battery, dry it with a soft dry cloth and allow it to dry for a few hours.

# Warnings

- Removable parts of the system (batteries, magnets, battery door, and safety line) can be lost or may be a choking or strangulation hazard. Keep out of reach of children or lock the battery door.
- Users and caregivers must routinely check the device for signs of overheating and for signs of discomfort or skin irritation at the implant site. Remove the processor immediately if there is any discomfort or pain (e.g. if device becomes hot or sound is uncomfortably loud) and inform your hearing care professional.
- Users and caregivers must monitor for signs of discomfort or skin irritation if a retention aid (e.g. headband) is used that applies pressure to the sound processor. Remove the aid immediately if there is any discomfort or pain, and inform your hearing care professional.
- If you experience tightness or pain from your retention aid (e.g. Headband, goggles), either loosen it or replace it with a larger retention aid.
- Dispose of used batteries promptly and carefully, in accordance with local regulations. Keep the battery away from children.
- Do not allow children to replace batteries without adult supervision.
- Use your Osia System only with approved devices and accessories.



- Your processor and other parts of the system contain complex electronic parts. These parts are durable but must be treated with care.
- No modification of this equipment is allowed. Warranty will be void if modified.
- If you experience tightness or pain at the implant site, or develop significant skin irritation, stop using your sound processor and contact your hearing care professional.
- Do not apply continued pressure to the processor when in contact with the skin (e.g. sleeping while lying on processor, or using tight fitting headwear).

# Other information

## Environmental conditions

Condition	Minimum	Maximum
Storage & transport temperature	-10 °C (14 °F)	+55 °C (131 °F)
Storage & transport humidity	0 % RH	90 % RH
Operating temperature	+5 °C (41 °F)	+40 °C (104 °F)

## Product dimensions (Typical values)

Component	Length	Width	Depth
Osia 2 Aqua+ unit	42 mm (1.65 in)	38 mm (1.5 in)	13.9 mm (0.55 in)

## Product weight

Component	Weight
Osia 2 Aqua+ unit	4.5 g
Osia 2 Aqua+ unit including an Osia 2 Sound Processor with magnet (strength 1) and battery	13.9 g
Osia 2 Aqua+ unit including an Osia 2(I) Sound Processor with magnet (strength 1(I)) and battery	16 g

## Material

- Plastic: Grilamid TR90 PA12
- Silicone: SHINETSU LSR, KE-2090 40A

## **Privacy and the collection of personal information**

During the process of receiving a Cochlear device, personal information about the user/recipient or their parent, guardian, carer and hearing health professional will be collected for use by Cochlear and others involved in care with regard to the device.

For more information please read Cochlear's Privacy Policy on **[www.cochlear.com](http://www.cochlear.com)** or request a copy from Cochlear at the address nearest you.

## **Warranty**

An undamaged and correctly assembled Aqua+ allows you to swim with your Aqua+ in fresh, salty or chloride water and dive to a maximum depth of 3 meters for a maximum of 2 hours. This is according to the IP68 classification of the product. It is tested to be used at a maximum of 50 occasions.

# Labelling symbols

The following symbols may appear on Aqua+ components and/or packaging:



Consult instruction for use



Specific warnings or precautions associated with the device, which are not otherwise found on the label



Manufacturer



Authorised representative in the European Community



Catalogue number



Serial number



Batch number



Date of manufacture



Recyclable material

Rx Only

By prescription

**IP68**

Ingress Protection Rating

- Protected against failure from dust penetration
- Protected against failure from continuous immersion in water up to 3 metres depth for up to 2 hours



CE mark and Notified Body number



UK Conformity mark with approved body number



Medical device



Unique device identifier

Store at room  
temperature

Store at room temperature





Temperature limits







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