Instructions for use



Oticon CROS





Model overview

This booklet is valid for Oticon CROS and covers both CROS and BiCROS.
□ CROS □ BiCROS
Oticon CROS is to be used with a compatible Oticon hearing aid that has either a single push button or a double push button for volume control.
□ Single push button □ Double push button
For an overview of which hearing aids Oticon CROS is compatible with,

For an overview of which hearing aids Oticon CROS is compatible with, please go to www.oticon.com/cros

Introduction to this booklet

This booklet gives you guidance on how to use and maintain your new transmitter. Please read the booklet carefully, including the **Warnings** section. This will help you get the full benefit of your new transmitter.

Your hearing care professional has adjusted the transmitter to meet your needs. If you have further questions, please contact your hearing care professional.

A hearing care professional* (hearing aid professional, audiologist, ENT (ear, nose and throat) doctor, and hearing aid dispenser) is a person who is appropriately educated and has proven competency in professionally assessing hearing, selecting, fitting, and delivering hearing instruments and rehabilitation care to persons with hearing loss.

*The job title may vary from country to country.

The education of the hearing care professional is in accordance with national or regional regulations.

For your convenience, this booklet contains a navigation bar to help you easily navigate through the different sections.

| About | Start-up | Handling | Warnings | More info |

IMPORTANT NOTICE

For details on the functionality of your specific hearing aid solution, refer to your hearing aids' instructions for use.

Intended use

Intended use	The transmitter is intended to transmit sound from the poorer ear to a hearing aid placed on the better ear.
Indications for use	Unaidable hearing loss on one ear (e.g. single-sided deafness (SSD), or very poor unilateral word recognition score).
Intended user	Person with hearing loss using a hearing aid and their caregivers. Hearing care professional responsible for adjusting the hearing aid.
Intended user group	Adults and children older than 5 years.
Use environment	Indoor and outdoor.
Contraindications	Not suitable for infants and children below 5 years of age. For children from 5 to 8 years of age, caution is advised. Users of active implants must pay special attention when using the device. For more information, read the Warnings section.
Clinical benefits	See clinical benefits of the hearing aid.

The CROS transmitter is an accessory to a medical device (wireless hearing instrument).

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Warnings

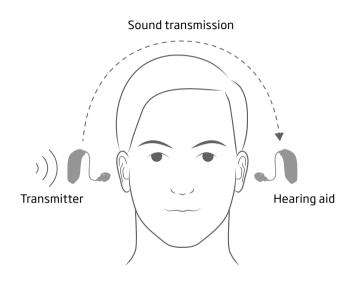
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CROS solution

A CROS or BiCROS solution consists of a transmitter and a hearing aid. The transmitter is placed on the poorer ear. It wirelessly sends sound from the poorer ear surroundings to the hearing aid placed on the better ear. The transmitter only works with certain Oticon hearing aids.

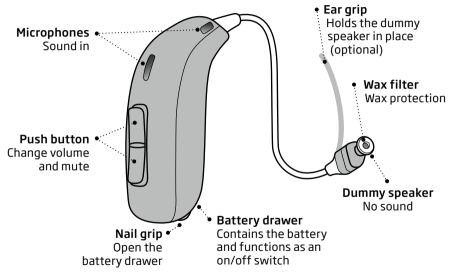
CROS (Contralateral Routing of Signals) is a solution for people with limited or no hearing in one ear combined with normal hearing in the opposite ear.

BiCROS (Bilateral Contralateral Routing of Signals) is a solution for people with limited or no hearing in one ear and hearing loss in the opposite ear.



Your transmitter

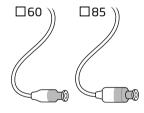
What it is and what it does



The dummy speaker has no acoustic purpose. The choice of size depends on what fits best in your ear.

The dummy speaker uses an open dome as shown below. This helps the transmitter stay in your ear.

Dummy speakers

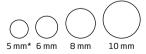


Earpiece



🔲 Open dome

Dome sizes



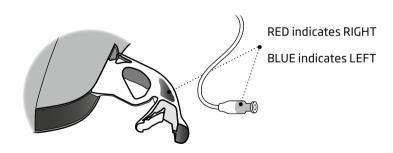
* Only for dummy speaker 60

Please see details for replacing the dome in section: Replace the earpiece.

Left/right identification

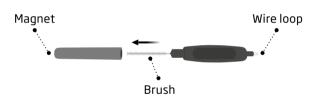
It is important to distinguish between the transmitter and the hearing aid. The left/right color indicator helps you distinguish between left and right.

On the transmitter, you can find left/right color indicators in the battery drawer. On the dummy speaker it is located as shown.



MultiTool for handling batteries and cleaning

The MultiTool contains a magnet that makes it easier to replace the battery in the transmitter. It also contains a brush and wire loop for cleaning and removing earwax. If you need a new MultiTool, please contact your hearing care professional.



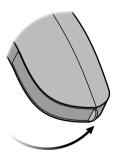
IMPORTANT NOTICE

The MultiTool has a built-in magnet. Keep the MultiTool at least 30 centimeters (1 foot) away from credit cards and other magnetically sensitive devices.

Turn the transmitter ON and OFF

The battery drawer is used to switch your transmitter on and off. To save battery life, make sure the transmitter is switched off when you are not wearing it. If you wish to return to the standard settings, simply open and close the battery drawer.

Turn ON Close the battery drawer with the battery in place.



Turn OFF Open the battery drawer.



When to replace the battery

When it is time to replace the battery in the transmitter, you will hear three alternate high pitch tones in the hearing aid. They will be repeated in moderate intervals until the battery runs out.



Battery tip

Keep a spare battery on you at all times to ensure your transmitter always works.

How to replace the battery (size 312)

1. Remove



Fully open the battery drawer. Remove the battery.

2. Uncover



Remove the sticky label from the + side of the new battery.

Tip:

Wait 2 minutes for the battery to draw air to ensure optimal functioning.

3. Insert



Insert the new battery into the battery drawer. Make sure the + side is facing up.

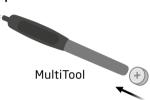
Insert it from above, NOT from the side.

4. Close



Close the battery drawer.

Tip



The MultiTool can be used to change the battery. Use the magnetic end to remove and insert batteries.

The MultiTool is provided by your hearing care professional.

Put on the transmitter

Step 1



Place the transmitter behind your ear.

Step 2



Hold the bend of the dummy speaker wire between your thumb and index finger. The earpiece should point towards opening of the ear canal.

Step 3



Gently push the earpiece into your ear canal until the dummy speaker wire sits close to your head. If the dummy speaker has an ear grip, place it in the ear so it follows the contour of the ear.

Caring for the transmitter

When handling your transmitter, hold it over a soft surface to avoid damage if you drop it.

Clean the microphone openings

Use the brush of the MultiTool to carefully brush debris away from the openings. Carefully brush the surface around the openings.

Make sure that no parts of the MultiTool are squeezed into the microphone openings by force. This may damage the transmitter.



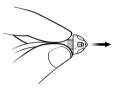
IMPORTANT NOTICE

Use a soft, dry cloth to clean the transmitter. The transmitter must never be washed or immersed in water or other liquids.

Replace the earpiece

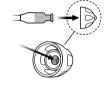
The earpiece should not be cleaned. If it is filled with wax, replace it with a new one.

Step 1



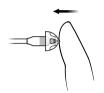
Hold on to the dummy speaker and then pull off the earpiece.

Step 2



Insert the dummy speaker into the exact center of the earpiece for a secure attachment.

Step 3



Push firmly to ensure that the earpiece is securely fastened.

IMPORTANT NOTICE

If the earpiece is not on the dummy speaker when removed from the ear, the earpiece may still be in the ear canal. Consult your hearing care professional for further instructions.

ProWax miniFit filter

The dummy speaker has a white wax filter attached to the end with the earpiece. The wax filter keeps wax and debris out of the dummy speaker. It has no acoustic purpose. Replace the filter for hygienic reasons when clogged.

Remove the earpiece from the dummy speaker before replacing the wax filter.

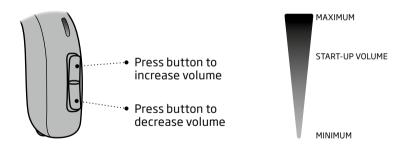


IMPORTANT NOTICE

Always use the same type of wax filter as was originally supplied with the transmitter. If you are in any doubt about the use or replacement of wax filters, contact your hearing care professional.

Change volume on the transmitter

The push button on the transmitter allows you to adjust the volume of the transmitted sound. You will hear a high pitch beep in the hearing aid when you increase or decrease the volume.



CROS users only

The microphones on the hearing aid are deactivated. This means that there is no sound coming from the hearing aid.

Hearing aid with single push button

The push button on the hearing aid has no volume functionality. To adjust the transmitted sound, you need a ConnectClip, Oticon ON app, Remote Control or iPhone®.

Hearing aid with double push button

If your hearing care professional has activated the volume control, the push button on the hearing aid will adjust the transmitted sound.

Apple, the Apple logo, iPhone, iPad, and iPod touch are trademarks of Apple Inc., registered in the U.S. and other countries.

BiCROS users only

The sound from the hearing aid remains the same when you adjust the volume of the transmitted sound.

Hearing aid with single push button

The push button on the hearing aid has no volume functionality. To adjust the combined sound from the transmitter and hearing aid, you need a ConnectClip, Oticon ON app, Remote Control or iPhone.

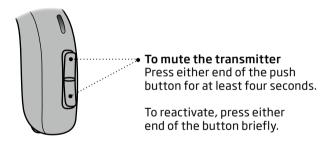
Hearing aid with double push button

If your hearing care professional has activated the volume control, the push button on the hearing aid will adjust the combined sound from the transmitter and the hearing aid.

Contact your hearing care professional for more information.

Mute

Use the mute function if you need to temporarily turn off the transmission of sound to the hearing aid. The mute function mutes the microphones on the transmitter.



IMPORTANT NOTICE

Do not use the mute function as an off switch, as the transmitter is still using battery power in this mode.

Sound indicators

Different sound indicators help to communicate the status of your transmitter. The sounds will be transmitted to your hearing aid.

Volume	Sound
Start-up volume	2 high pitch beeps
Minimum / maximum volume	3 high pitch beeps
Volume up / down	1 high pitch beep

Warnings	Sound
Battery low indication	3 high pitch alternate tones
Battery shut down	4 high pitch descending tones
Microphone service check needed	8 high pitch beeps repeated 4 times

⚠ General warnings

For your personal safety and to ensure correct usage, you should familiarize yourself fully with the following general warnings before using your transmitter. Consult your hearing care professional if you experience unexpected operations or serious incidents with your transmitter during use or because of its use. Your hearing care professional will support you with issue handling and, if relevant, reporting to the manufacturer and/or the national authorities.

Note that transmitter does not restore normal hearing and does not prevent or improve a hearing impairment resulting from organic conditions.

Furthermore, note that in most cases, infrequent use of a transmitter does not permit a user to attain full benefit from it.

Choking hazards & risk of swallowing batteries and other small parts

The transmitter, its parts and the battery should be kept out of reach of children and anyone who might swallow these items or otherwise cause injury to themselves.

Batteries have occasionally been mistaken for pills. Therefore, check your medicine carefully before swallowing any pills.

If a battery, transmitter or small part is swallowed, see a doctor immediately and contact the National Poison Center at 1-800-222-1222 or National Battery Ingestion Hotline at 1-800-498-8666.

Battery use

Always use batteries recommended by your hearing care professional. Low quality batteries may leak and cause bodily harm.

Never attempt to recharge your batteries, and never dispose of batteries by burning them. There is a risk that the batteries will explode.

Dysfunction

Be aware of the possibility that your transmitter may stop working without notice. Keep this in mind when you depend on warning sounds (e.g. when you are in traffic). The transmitter may stop functioning, for instance if the batteries have expired.

Active implants

The transmitter has been thoroughly tested and characterized for human health according to international standards for human exposure (Specific Absorption Ratio – SAR), induced electromagnetic power and voltages into the human body.

The exposure values are well below international accepted safety limits for SAR, induced electromagnetic power and voltages into the human body defined in the standards for human health and coexistence with active medical implants, such as pacemakers and heart defibrillators.

If you have an active brain implant, please contact the manufacturer of your implantable device for information about the risk of disturbance.

The MultiTool (which has a built-in magnet) should be kept more than 30 centimeters (1 foot) away from the implant, e.g. do not carry it in your breast pocket.

Follow the guidelines recommended by the manufacturers of implantable defibrillators and pacemakers on use with magnets.

X-ray/CT/MR/PET scanning, electrotherapy and surgery

Remove your transmitter before X-ray examinations and CT/MR/PET scans, electrotherapy, surgery, etc. as your transmitter may be damaged when exposed to strong electromagnetic fields.

$oldsymbol{\Lambda}$ General warnings

Heat and chemicals

The transmitter must never be exposed to extreme heat, e.g. left inside a parked car in the sun.

The transmitter must not be dried in microwave ovens or other ovens.

The chemicals in cosmetics, hairspray, perfume, aftershave lotion, sunscreen lotion, and insect repellent can damage the transmitter. Always remove your transmitter before applying such products and allow time to dry before use.

Possible side effects

The transmitter and earpiece may cause an accelerated accumulation of earwax.

The non-allergenic materials used in the transmitter may in rare cases cause a skin irritation or other side effects.

Please consult a physician if these conditions occur.



Interference

The transmitter has been thoroughly tested for interference according to the most stringent international standards.

Electromagnetic interference may occur in the vicinity of equipment with the symbol to the left. Portable and mobile RF (radio frequency) communications equipment can affect the performance of your transmitter. If your transmitter is affected by electromagnetic interference, move away from the source to reduce the interference.

Use of third-party accessories

Only use accessories, transducers or cables supplied by the manufacturer.

Non-original accessories may result in reduced electromagnetic compatibility (EMC) of your hearing aids.

Modification of the transmitter is not allowed

Changes or modifications not expressly approved by the manufacturer will void the warranty of the equipment.

Detached earpiece in ear canal

If the earpiece is not on the dummy speaker when removed from the ear, the earpiece may still be in the ear canal. For further instructions, consult your hearing care professional.

Transmitter use in complex listening environments

The use of a transmitter may have an impact on speech discrimination in complex listening situations. Special caution is advised for children from five to eight years of age. Children may be unable to manage interfering, non-speech sound transmitted to their better ear by the device.

⚠ General warnings

Warnings to hearing care professional

A hearing care professional should advise a prospective hearing aid user to consult immediately with a licensed physician (preferably an ear specialist) before dispensing a hearing aid if the hearing care professional determines through inquiry, actual observation, or review of any other available information concerning the prospective user, that the prospective user has any of the following conditions:

- (i) Visible congenital or traumatic deformity of the ear.
- (ii) History of active drainage from the ear within the previous 90 days.

- (iii) History of sudden or rapidly progressive hearing loss within the previous 90 days.
- (iv) Acute or chronic dizziness.
- (v) Unilateral hearing loss of sudden or recent onset within the previous 90 days.
- (vi) Audiometric air-bone gap equal to or greater than 15 decibels at 500 Hertz (Hz), 1,000 Hz, and 2,000 Hz.
- (vii) Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
- (viii) Pain or discomfort in the ear.

Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure capability exceeds 132 dB SPL as there may be risk of impairing the remaining hearing of the hearing aid user.

Important notice for prospective hearing aid users

Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. Licensed physicians who specialize in diseases of the ear are often referred to as Otolaryngologists, Otologists or

Otorhinolaryngologists. The purpose of medical evaluation is to ensure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased. Following the medical evaluation, the physician will give you a written statement that states that your hearing loss has been medically evaluated and that you may be considered a candidate for a hearing aid. The physician will refer you to an audiologist or a hearing aid dispenser, as appropriate, for a hearing aid evaluation.

⚠ General warnings

The audiologist or hearing aid dispenser will conduct a hearing aid evaluation to assess your ability to hear with and without a hearing aid. The hearing aid evaluation will enable the audiologist or dispenser to select and fit a hearing aid to your individual needs. If you have reservations about your ability to adapt to amplification, you should inquire about the availability of a trial, rental or purchase-option program. Many hearing care professionals now offer programs that permit you to wear a hearing aid for a period of time for a nominal fee, after which you may decide if you want to purchase the hearing aid.

Federal law restricts this device to sale by or on the order of a doctor, audiologist or other hearing care practitioner licensed to dispense hearing aids in your state-in accordance with all applicable rules and regulations.

Children with hearing loss

In addition to seeing a physician for medical evaluation, a child with a hearing loss should be directed to an audiologist for evaluation and rehabilitation, since hearing loss may cause problems in language development and educational and social growth of a child. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of a child with a hearing loss. If the user is an infant, small child, or person with cognitive impairment, it is recommended that the hearing aid be modified with a tamper-resistant battery compartment.

Troubleshooting

Symptom	Possible causes
	Dead battery
	Transmitter microphone muted
No sound from the transmitter	Transmitter turned OFF
	Receiving hearing aid turned OFF
	Receiving hearing aid muted
Intermittent or reduced sound	Moisture on either the transmitter or hearing aid battery
Beeping	If your transmitter plays 8 beeps, 4 times consecutively, it needs a microphone service check

If none of the above solutions work, consult your hearing care professional.

Solutions
Replace the battery
Unmute the transmitter microphone
Turn transmitter ON
Turn hearing aid ON
Unmute hearing aid
Wipe batteries with a dry cloth
Contact your hearing care professional

Water & dust resistant (IP68)

Your transmitter is dust tight and protected against ingress of water, which means it is designed to be worn in all daily life situations. Therefore, you do not have to worry about sweat or getting wet in the rain. Should your transmitter come into contact with water and stop working, please follow these guidelines:

- 1. Gently wipe off any water.
- Open the battery drawer and remove the battery and gently wipe off any water in the battery drawer.
- 3. Let the transmitter dry with the battery drawer left open for approximately 30 minutes.
- 4. Insert a new battery.

IMPORTANT NOTICE

Do not wear your transmitter while showering or participating in water activities. Do not immerse transmitter in water or other liquids.

Conditions of use

Operating conditions	Temperature: +1°C to +40°C (34°F to 104°F) Humidity: 5% - 93% relative humidity, non-condensing Atmospheric pressure: 700 hPa to 1060 hPa
Transportation and storage conditions	Temperature and humidity shall not exceed the below limits for extended periods during transportation and storage: Transportation:
	Temperature: -25°C to +60°C (-13°F to 140°F) Humidity: 5% - 93% relative humidity, non-condensing Atmospheric pressure: 700 hPa to 1060 hPa Storage:
	Temperature: -25°C to + 60°C (-13°F to 140°F) Humidity: 5% - 93% relative humidity, non-condensing Atmospheric pressure: 700 hPa to 1060 hPa

Warranty

Certificate

Name of owner:			
Hearing care professional:			
Hearing care professional's address:			
Hearing care professional's phone:			
Purchase date:			
Month:			
Serial no.:			

International warranty

Your device is covered by an international limited warranty issued by the manufacturer for a period of 12 months from the date of delivery to you. This limited warranty covers manufacturing and material defects in the device itself. but not in accessories such as batteries, cables, power supplies, etc. Problems arising from improper/incorrect handling or care, excessive use, accidents, repairs made by an unauthorized party, exposure to corrosive conditions, damage due to foreign objects entering the device, or incorrect adjustments are NOT covered by the limited warranty and may void it. Under this warranty, the manufacturer will choose, at its sole discretion, whether to repair the device, or replace it with an equivalent model. The above warranty does not affect any legal rights that you might have under

applicable national legislation governing the sale of consumer goods. Your hearing care professional may have issued a warranty that goes beyond the clauses of this limited warranty. Consult him/her for further information.

If you need service

Take your device to your hearing care professional, who may be able to solve minor problems and make adjustments immediately. Your hearing care professional can assist you in obtaining warranty service from the manufacturer. Your hearing care professional may charge a fee for their services.

Technical information

The transmitter contains a radio transceiver that uses short-range magnetic induction technology working at 3.84 MHz. The magnetic field strength of the transmitter is very weak and is always below 15 nW [typically below -40 dBµA/m at a distance of 10 meters (-12.20 dBµA/ft at a distance of 33 feet)]. Only use your transmitter in areas where wireless transmission is permitted.

The transmitter complies with international standards concerning radio transmitters, electromagnetic compatibility and human exposure.

Due to the limited space available on the transmitter, relevant approval markings can be found in this booklet.

Additional information can be found in the "Technical Data sheets" on www.oticon.com

USA and Canada

This device contains a radio module with the following certification ID numbers:

FCC ID: 2ACAH-AUMRTE IC: ID: 11936A-AUMRTE

Radio frequency radiation exposure information

For body-worn operation, this device meets FCC and Innovation, Science and Economic Development Canada's RF exposure limits and has been tested while in contact with the human body. Use of other accessories not verified by the manufacturer may not ensure compliance with FCC and Innovation, Science and Economic Development Canada's RF exposure guidelines. the device must not be co-located or used in conjunction with any other antenna or transmitter.

Note:

The device complies with Part 15 of the FCC rules and with Innovation, Science and Economic Development Canada's license-exempt RSSs standards. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Note:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications However, there is no quarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

Changes or modifications not expressly approved by party responsible for compliance could void the user's authority to operate the equipment.

The manufacturer declares that this transmitter is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU.

This medical device complies with Medical Device Regulation (EU) 2017/745.

Declaration of Conformity is available at the headquarters.

Oticon A/S Kongebakken 9 DK-2765 Smørum Denmark www.oticon.global/doc

C € 0123









Description of symbols used in this booklet



Warnings

Text marked with a warning symbol must be read before using the device.

Manufacturer



The device is produced by the manufacturer whose name and address are stated next to the symbol. Indicates the medical device manufacturer, as defined in EU Regulation 2017/745.

CF mark



C € 0123 The device complies with all required EU regulations and directives. The four digit number indicates the identification of the notified body.

Electronic waste (WEEE)



Recycle hearing aids, accessories or batteries according to local regulations. Hearing aid users can also return electronic waste to their hearing care professional for disposal. Electronic equipment covered by Directive 2012/19/EU on waste and electrical equipment (WEEE).

Regulatory Compliance Mark (RCM)

The device complies with electrical safety, EMC and radio spectrum requirements for devices supplied to the Australian or New Zealand market.

IP code



Class of protection against harmful ingress of water and particulate matter according to FN 60529...

IP6X indicates total dust protection. IPX8 indicates the protection against the effects of continuous immersion in water.



Radio Frequency (RF) transmitter

Your hearing aid contains an RF transmitter.

Description of symbols used on the regulatory packaging label



Keep dry

Indicates a medical device that needs to be protected from moisture.



Catalog number

Indicates the manufacturer's catalog number so that the medical device can be identified.



Serial number

Indicates the manufacturer's serial number so that a specific medical device can be identified.



Medical Device

The device is a medical device.



GTIN

A globally unique 14-digit number used to identify medical device products including medical device software. GTIN on regulatory packaging label is related to medical device hardware.



Unique device identifier

Indicates a carrier that contains unique device identifier information.



