

ATLAS ROSA OTC Hearing Aids

User Instructional Brochure



FDA WARNINGS, CAUTIONS, NOTES

WARNING: If you are younger than 18, do not use this

You should go to a doctor, preferably an ear-nose-throat doctor (an ENT), because your condition needs specialized care. Over-the-counter (OTC) hearing aids are only for users who are age 18 or older.

This OTC hearing aid is for users who are 18 and older. People who are younger than 18 with hearing loss should see a doctor, preferably an ENT, because they may need medical testing and management. Hearing loss can affect speech and learning, so professional fitting and continuing care are also important.

WARNING: When to see a doctor

If you have any of the problems listed below, please see a doctor, preferably an ear-nose-throat doctor (an ENT).

- Your ear has a birth defect or unusual shape. Your ear was injured or deformed in an accident
- You saw blood, pus, or fluid coming out of your ear in the past 6 months
- Your ear feels painful or uncomfortable
- You have a lot of earwax, or think something could be in your ear

- You get really dizzy or have a feeling of spinning or swaying (called vertigo)
- Your hearing changed suddenly in the past 6 months
- Your hearing changes: it gets worse then gets better again
- You have worse hearing in one ear
- You hear ringing or buzzing in only one ear

WARNING: This hearing aid should not cause pain when inserting it

Remove this device from your ear if it causes pain or discomfort when you insert or place it. To try again, make sure to follow the instructions. If you feel pain or discomfort again, contact the manufacturer. If your pain or discomfort doesn't go away, contact your hearing healthcare professional. You can also report this to the FDA as an adverse event according to the instructions that appear later.

WARNING: Take these steps to prevent damage to hearing aid and accessories

- Do not modify shape of hearing aid, eartubes, eartips
- Do not wear hearing aids when sleeping
- Do not drop
- Do not expose to water, cleaning solutions, sprays
- Do not expose to fire or excessive heat including inside of hot car
- Remove before CT and MRI scans

Caution: This is not hearing protection

You should remove this device if you experience overly loud sounds, whether short or long-lasting. If you're in a loud place, you should use the right kind of hearing protection instead of wearing this device. In general, if you would use ear plugs in a loud place, you should remove this device and use ear plugs.

Caution: The sound output should not be uncomfortable or painful

You should turn down the volume or remove the device if the sound output is uncomfortably loud or painful. If you consistently need to turn the volume down, you may need to further adjust your device.

Caution: You might need medical help if a piece gets stuck in your ear

If any part of your hearing aid, like the eartip, gets stuck in your ear, and you can't easily remove it with your fingers, get medical help as soon as you can. You should not try to use tweezers or cotton swabs because they can push the part farther into your ear, injuring your eardrum or ear canal, possibly seriously.

Note: If you remain concerned, consult a professional

If you try this device and continue to struggle with or remain concerned about your hearing, you should consult with a hearing healthcare professional.

Note: What you might expect when you start using a hearing aid

A hearing aid can benefit many people with hearing loss. However, you should know it will not restore normal hearing, and you may still have some difficulty hearing over noise. Further, a hearing aid will not prevent or improve a medical condition that causes hearing loss. People who start using hearing aids sometimes need a few weeks to get used to them. Similarly, many people find that training or counseling can help them get more out of their devices.

If you have hearing loss in both ears, you might get more out of using hearing aids in both, especially in situations that make you tired from listening - for example, noisy environments.

Note: Tell FDA about injuries, malfunctions, or other adverse events

To report a problem involving your hearing aid, you should submit information to FDA as soon as possible after the problem. FDA calls them "adverse events," and they might include: skin irritation in your ear, injury from the device (like cuts or scratches, or burns from an overheated battery), pieces of the device getting stuck in your ear, suddenly worsening hearing loss from using the device etc. Instructions for reporting are available at https://www.fda.gov/Safety/MedWatch or call 1-800-FDA-1088. You can also download a form to mail to FDA.

CONGRATULATIONS

You are now part of the ATLAS OTC Hearing Aid Program

Be in charge of your Hearing and your Quality of Life with:

OTC Hearing Aids and Accessories

ATLAS OTC ePortal

Safe Listen Tools

ATLAS OTC Library

Go to ATLAS OTC Marketplace to easily get:

Earcare products

Extra accessories for hearing aid maintenance

This brochure is for the OTC Hearing Aids and Accessories.

You also get step-by-step guidances and tips from the ATLAS OTC ePortal and ATLAS OTC Library.

Information and access to the other products and services are provided separately with purchase of hearing aids.

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Know your ATLAS ROSA Hearing Aids and Accessories





Accessories

Storage case
Battery Pack (312, 6 batteries)
Eartube with Receiver (1, Size 2B attached to hearing aid)
Closed Eartip (3 pairs, S,M,L, Large pair attached to hearing aid)
Oval Eartip (3 pairs, S,M,L)

Waxguards (4)
Cleaning Brush with magnet
Cleaning Cloth
Earplugs with Case
NOTE Serial Number on back of hearing aid

Power On/Off



Top

Bottom

Insert Battery to turn on/off

Open battery door carefully (do not go past 90°).

Orient battery so that flat side with orange tab is facing up.

Remove tab, place battery on battery door with raised side in first. Gently close door.

You can use the magnet at end of cleaning brush to pick up battery from flat side (no tab) and placing in holder. Battery should last for 3-5 days depending on hearing aid use.

ON: Insert battery, close door OFF: Open door, remove battery LOW BATTERY: Rapid beeps

Select Settings, Control Volume

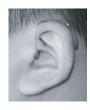
Press and hold top of switch to go through different settings

- 1. Low volume, Low noise: Indoor, daily home activities, one-on-one conversations 'Quiet'
- 2. Mid volume, Mid noise: Indoor group conversations, restaurants 'Group' (Default)
- 3. High volume. High noise: Outdoor situations such as traffic, outdoor events 'Noisy'
- 4. High volume, No/Low noise: Listening to music when there is low background noise 'TV'
- **5.** Telecoil: For use with phones and in places with hearing loops 'Phone'

Male voice prompts: Quiet (1), Group (2), Noisy (3), TV (4), Phone (5)

Raise Volume: Press and quickly release top of switch Lower Volume: Press bottom of switch Beeps indicate change in volume. Female voice prompts: Maximum and Minimum volumes

Wear Hearing Aid



Place hearing aid body behind ear with one hand - eartube will be in front of ear.

Use other hand to gently position eartip into earcanal so that eartube is flat on skin.

Check for a snug fit - select a smaller eartip if it feels too tight, or larger if it feels loose.

Pull top of ear to open up earcanal to help positioning eartip.

If you wear glasses, place your hearing aid between stem of glasses and ear.

Select Eartip for Proper Fit





Hold stem at end of eartube and gently twist out attached eartip. Select new eartip and twist to push in on stem.

Tug it slightly and to ensure it does not come off.

Suggested Settings and Volume for Self-Detected Symptoms

- Trouble hearing speech in noisy places: Setting 3
- Hard to follow speech in groups: Setting 2
- Trouble hearing on the phone: Setting 5
- Listening make you tired: Setting 1, Wear all-day even in quiet places
- Turn up volume on TV: Setting 4

Sign for locations with hearing loops: Setting 5

Keep **volume** to middle level. Avoid frequent use of highest volume level.

Remove, Clean, Store after each use

Remove hearing aid by holding the eartube near your earcanal and gently pulling eartip out. Remove hearing aid body from behind your ear.

Brush away earwax debris on outside, including any debris blocking microphone, with cleaning brush.

Gently wipe all surfaces with cleaning cloth.

Open battery door, remove battery, place open hearing aid and battery in storage case.

Place open storage case in a cool, dry place and out of reach of young children and pets.

Change Waxguards

Remove eartip.

Removal

Take the Waxguard stick and check (i) removal end - looks like a small hook or point and (ii) replacement end - has a new wax guard on it.

Insert the removal end into the old waxguard.

Gently pull it out. It should come out attached to the stick.

Replacement

Flip the stick and align replacement end with opening in hearing aid.

Push in new guard firmly, then pull stick away. The new guard should stay in place. Attach eartip.

Wear Earplugs in Loud Places



See FDA Caution that hearing aids do not provide hearing protection and earplugs should be worn in loud places.

Curve right hand around back of head to pull left ear up and back.

Use left hand to gently slide earplug into ear canal - rock plug back and forth to help.

Push into place with finger on left hand.

Repeat with opposite hands for right ear.

S.M.A.R.T Way to Listen Well

Small steps everyday

Manage correct hearing aid fit, use & care

Aim to improve hearing

Relate to everyday living

Track your progress

Get step-by-step guidance and support from ATLAS services:

- OTC ePortal
- Safe Listen Tools
- OTC Library
- OTC Marketplace

Maintain Hearing Aid Performance



Keep away from heat



Remove before MRI. CT or any other electromagnetic procedures



Remove if you are in the rain, swimming, showering. No hairsprays.





Check hats, headwear for stuck hearing aids





Do not make modifications to the device, do not share with others



Choking hazard, keep out of reach of children, pets



Clean regularly with provided accessories. store properly



Do not discard in trash, use appropriate recycling

Troubleshoot

Whistling/Feedback Remove obstructions (like finger) from microphones. Decrease volume and increase it

slowly. Check eartip fit and place correctly in ear. Clean wax from ears and eartube. Check

if hearing aid shell is damaged.

Not powering on Check that battery is inserted properly. Change battery.

Poor sound quality Replace eartips and/or waxguard. Make sure hearing aids are fully charged.

Try other eartip design and check for snug fit. Ears should be clean of wax.

Not loud enough Increase volume. Replace eartips and/or waxguard if you notice wax buildup.

Per FDA requirement, all OTC hearing aids have a maximum output limit to protect from

further hearing damage.

Sound of own voice is too loud. Familiar sounds are different.

See FDA Note that hearing aids do not restore normal hearing.
Practice listening to your voice in a quiet environment to get used to it.
Start talking to others in a familiar environment e.g. your home.
Gradually start using them in conversations outside familiar places.

Troubleshoot

Hearing	aids	falling	out
of ears			

Make sure eartips placed properly in ears. Insert eartip into ear canal until eartube is flat against your ear and the eartip feels secure. Choose another eartip size. Note that you may need different sizes for each ear.

Eartips falling off, discolored, stiff

Securely fasten eartips to eartube end; check this every time you put on hearing aids. Check that the eartip is attached to the eartube after removing hearing aids. Replace eartips if stiff.

Eartip stuck in ear

See FDA caution. Try removing with fingers; do not use sharp objects to remove. Get medical help if you cannot remove it.

Eartube feels too loose or too tight

If you have tried all eartips and the eartube feels too loose or too tight, contact Audition Technology.

Go to ATLAS ePortal for step-by-step directions on use, adjusting and wear success. Take steps to improve Quality of Life. Go to ATLAS Marketplace for extra Accessories (like batteries, eartips, waxguards) and Earcare products (like earwax removal drops, otoscope for checking inside of ear).

Technical Specifications

Maximum output (OSPL90)109 dBTotal Harmonic Distortion0.70%Full-on Gain36 dBSelf-generated noise18 dBLatency7 msUpper and lower cutoff frequencies for bandwidth200, 5600 Hz

Warranty, Returns

Warranty: 1 year warranty. **Returns:** 45-day return period.

Terms and conditions apply. See 'Warranty and Returns' document on website.

Contact Audition Technology

Call: 1-844-576-1110, Email: contact@auditiontech.com