AUDICUS

The Clara

Hearing Aid Instruction Manual

312 Battery

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 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 an 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 ear wax, or you 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 the 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 FDA as an adverse event according to the instructions that appear later.

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.

Welcome!

We're thrilled to be part of your hearing journey

This guide is an important resource, please set aside a few minutes to review in order to get the most out of your custom tailored

Audicus Clara hearing aid

Audicus is with you every step of the way.
Find more info and help at
audicus.com/support

And remember, you're never on your own.
Reach out anytime, for anything at all.
(720) 669-7186 • accounts@audicus.com

What's inside?

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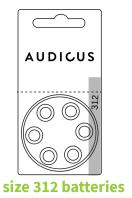
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dome variety pack









Getting Started

Using the Clara

Device Information

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Your hearing aid at a glance



volume control - changes volume up and down

mics/microphones – where sound enters your hearing aid

battery door - on/off switch and battery access point

receiver wire - connects receiver (speaker) unit to hearing aid

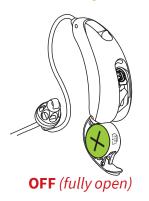
receiver – amplifies the sound directly into the ear canal and contains the earwax guard in the tip

dome – grey hypoallergenic silicone cover on the receiver to hold the unit in the ear canal

retention guard – (not shown) keeps the receiver in place

Turning on / off

The **battery door** acts as the on & off switch





ON (fully closed)

Battery size



312 zinc-air
– brown tab

IEC: PR41 | ANSI: 7002ZD

Low battery warning

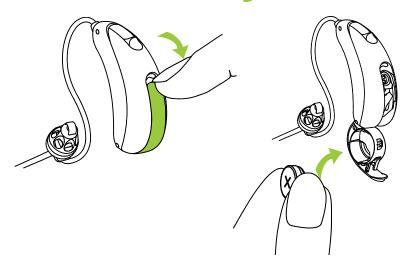


2 beeps30 mins remaining

Do not dispose of batteries in household trash

- Do not recharge batteries as this could result in injury
- Keep batteries away from high temperature
- Keep batteries away from children and pets
- Do not carry batteries loose in your pocket or purse
- Do not place batteries in your mouth; if swallowed, consult a physician

Inserting a new battery

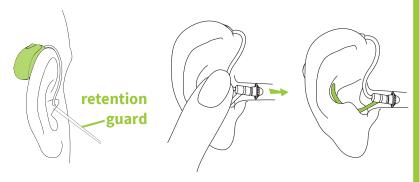


To insert or replace the battery:

- **1.** Gently swing open the battery door with your fingernail and push out the old battery
- Remove the plastic tab from the new battery, wait
 minute for the battery to activate
- **3.** Line up the battery's plus "+" sign so that it is facing up inside the battery door
- 4. Close the battery door gently
- 5. The hearing aid will play a melody as it turns on 🎶

Putting on your hearing aid

Hearing aids are color-coded with a marking on the back of the device: **blue = left red = right**



- 1. Clean your ear and hearing aid before every use
- 2. We recommend using a mirror to practice. First, place the hearing aid body over the top of your ear
- 3. Hold the wire near the dome and gently push the dome into your ear canal. Pull up and back on the cartilage of the ear to ease insertion
- 4. Rest the retention guard in the bowl of your ear. You can trim the retention guard to a comfortable length or remove it altogether

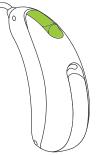
Handle your hearing aid with care when placing in your ear Do not pull or bend the receiver wire as this may cause damage

Adjusting to your new hearing aid

Your hearing aid is programmed to you individually Adjusting to hearing aids fully may take up to 6 weeks

- 1. You may hear sounds you haven't heard in years
 - Sounds will be amplified and more distinguished, e.g., leaves rustling, running water, your own voice
 - This is normal and will go away with regular use
- 2. Find the right dome for your ear
 - Your hearing aid ships with a size medium dome attached, with an additional variety pack of domes
 - Use the "Finding the right dome" guide if you have discomfort or hear a whistling sound
- 3. It may take a few weeks to get used to the feel of your hearing aid. Contact Audicus any time for guidance and tips for adjusting comfortably to your device
- **4.** Your aid is programmed to your specific hearing test; it may take some time to become accustomed. After a few weeks of daily use - if you'd like an adjustment -Audicus offers free reprogrammings for the life of the device, just contact us

Volume level



The device button controls volume. Hearing aids are paired and adjusted simultaneously. Turning off the device resets to the default volume

Increase: press button on the **RIGHT** hearing aid **Decrease:** press button on the **LEFT** hearing aid



From the default volume you can adjust 5 steps up or down. When you hear a double tone, that means you've reached the max / min volume

For single Clara customers: volume cycles from **default to +5**

The Clara will automatically adjust sound quality based on the environment with the standard Autoadapt/Universal program

Finding the right dome

The dome is the small, grey silicone tip on the end of the hearing aid that is inserted into your ear

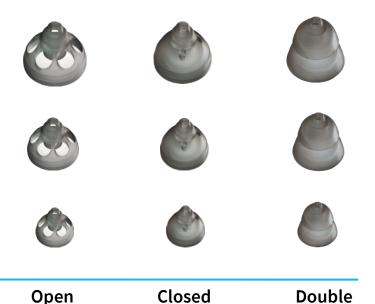
Domes come in a variety of shapes and sizes. The proper choice of dome style and size can help with comfort and sound quality

New hearing aids come pre-fit with a medium size dome in your recommended dome style

New orders include a variety of dome sizes and styles. Depending on your specific hearing loss, your order may not include all dome styles

Take some time to find which size dome is right for you. The dome should fit snugly in your ear canal. If missized or the wrong style, you may hear feedback: a squealing or whistling sound that can be resolved with a different dome size or style

Dome styles and sizes





- Clean your domes regularly
- Replace old, brittle, discolored or damaged domes or if they pull off the hearing aid easily
- Earwax production is different for each person.
 Replace domes as needed, at least every 2–3 months
- Always ensure that a new dome is firmly attached to the receiver before inserting into your ear

Medium

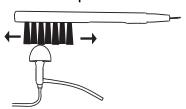
Small

Caring for your hearing aid

With regular maintenance your devices will sound great for years to come

<u>Daily:</u> Clean with a lint-free cloth or nonalcoholic Audiowipe. Allow earwax to dry and harden before brushing off

Weekly: Remove earwax and debris from device and dome using supplied cleaning brush. Replace batteries if needed



Quarterly: Domes and earwax guards should be replaced at least every 2-3 months

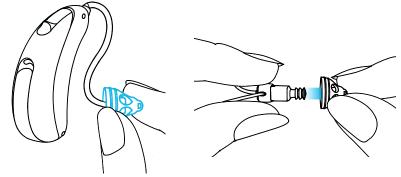
- Everybody's ears are different: you may need to clean your devices or replace components more frequently
- Never use cleaning agents such as detergent, soap, alcohol or bleach to clean your hearing aid
- Do not submerge your hearing aid or rinse your hearing aid under water

Protecting your aid

- Open the battery door when not in use. Remove the battery when storing for extended periods
- Always store your hearing aid in its case, in a clean and dry environment. The UV Dry Box can also be used for safe storage
- Never wear your hearing aid in the shower, bath, sauna or swimming. Keep protected from rain
- If the hearing aid becomes wet, remove battery and ensure the aid is dry before using. Do not dry in an oven or microwave
- We recommend regularly drying your hearing aid. You can purchase a sanitizing UV Dry Box from audicus.com/accessories Remove battery before placing in the UV Dry Box
- Keep your hearing aid away from high temperatures. Do not leave your hearing aid in direct sunlight or wear while using a hair dryer
- Keep hearing aids away from children and pets

Replacing the dome and earwax guard

A. To remove the dome: hold the receiver with one hand and gently pull off the dome

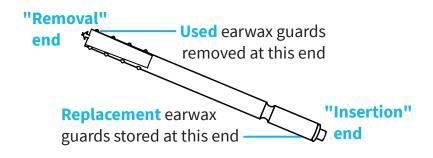


B. You now have access to change the earwax guard

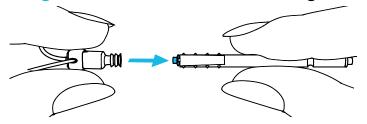
The earwax guard is a very small, white plastic filter inserted into the receiver tip. The earwax guard collects and prevents earwax from entering the receiver, which may impair or damage the device

Replace your earwax guard every 2-3 months or more frequently if you have more earwax production. Additionally, replace the earwax guard any time the sound quality is diminished

Your order comes with a small case containing 8 earwax guard sticks to remove and replace the guards



C. To dispose of the used earwax guard, insert the removal end of the tool into the tip of the receiver. Carefully pull straight out to remove the earwax guard. Do not twist when removing



D.Ensure the receiver is empty and a new earwax guard is visible at the insertion end of the tool. Gently push the new earwax guard into the tip of the empty receiver until the outer ring is aligned

E. Reattach the silicone dome onto the receiver and dispose of the old earwax guard and stick

Returns and warranty

FDA information

The Audicus 100% happiness guarantee

If for any reason you are not satisfied with your Audicus hearing aids, you may return it within 45 days after delivery date for a full refund of the original purchase price

This guarantee is only possible if the hearing aid has not been modified, tampered with, damaged or repaired by the user. Please see return instructions at audicus.com/returns

Manufacturer warranty

All Audicus hearing aids come with a 24 month guarantee that covers manufacturing defects. This guarantee will not be valid if the hearing aid has been modified, tampered with, damaged or repaired by the user. Hearing aids must be cleaned prior to any repairs, otherwise a cleaning fee will apply

If your device stops functioning correctly reach out to accounts@audicus.com or (720) 669-7186

Use your hearing aid all day long

The best way to ensure better hearing is to practice listening with your hearing aid until you are able to wear it comfortably all day. Generally, infrequent use of the hearing aid does not provide you with the full benefit of amplification.

Your hearing aid will not restore normal hearing. Hearing aids will not prevent or improve hearing impairment resulting from a physiological condition. Hearing aids will help you to make better use of your residual hearing.

The use of hearing aids is only part of hearing rehabilitation; auditory training and lip reading instruction may be required as well.

Possible side effects

If you are experiencing discomfort, contact Audicus or your hearing care professional for modification of the hearing aid at the point of irritation. A hearing aid may cause an accelerated accumulation of cerumen (earwax). Also in rare cases, the otherwise nonallergenic material may cause a discharge from the ear, allergic reaction, or any other unusual condition. Please seek immediate consultation with a physician if these conditions occur.

Technical information

The Clara is manufactured by Unitron Hearing, Canada and distributed by Audicus.

FCC ID: VMY-UWNB2

IC: 2756A-UWNB2

Hereby, Unitron Hearing declares that this product meets the requirements of the Medical Device Directive 93/42/EEC and complies with Radio Equipment Directive 2014/53/EU.

Changes or modifications not expressly approved by Audicus may void the FCC authorization to operate this device.

This device complies with Part 15 of the FCC Rules and with RSS-210 of Industry Canada. 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.

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 and ICES-003 of Industry Canada. 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 guarantee 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 device into an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help

Operating conditions:

This device is designed such that it functions without problems or restrictions if used as intended, unless otherwise noted in these user guides.

Transport conditions:

Temperature: Lower Limit = -20° C (-4° F),

Upper Limit = $+60^{\circ}$ C ($+140^{\circ}$ F)

Humidity: Lower Limit = 0%, Upper Limit = 75% Pressure: Lower Limit = 50kPA, Upper Limit = 106kPA





Keep dry

The symbol with the crossed-out garbage bin is to make you aware that this device may not be thrown away as normal household waste. Please dispose of old or unused devices at waste disposal sites intended for electronic waste, or give your device to your hearing care professional for disposal. Proper disposal protects the environment and health.

	Standard Receiver	<u>Power</u> <u>Receiver</u>
Output Sound Pressure Level 90 (OSPL90) (dB SPL)	111	117
Full on gain (input 50 dB SPL)	47	57
Total harmonic distortion at 500Hz/800Hz/1600Hz (%)	1.0/1.0/1.0	1.5/1.0/0.5
Equivalent input noise at Reference Test Setting (dB SPL)	19	18
Frequency range (Hz)	<100-8500	<100-7300
Battery life (h)	160	140

Warning to hearing care professionals (to comply with the U.S. Food and Drug Administration (FDA) regulations)

Hearing care professionals should advise a prospective hearing aid user to consult promptly 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 or 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.
- 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), 1000 Hz and 2000 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 level exceeds 132 decibels because 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 assure 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 care professional, as appropriate, for a hearing aid evaluation.

The audiologist or hearing care professional will conduct a hearing aid evaluation to assess your degree of hearing. 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 the sale of hearing aids to those individuals who have not obtained a medical evaluation from a licensed physician. Federal law permits a fully informed adult to sign a waiver statement declining the nominal fee after which you may decide if you want to purchase the hearing aid or medical evaluation for religious or personal beliefs that preclude consultation with a physician. The exercise of such waiver is not in your best interest and its use is strongly discouraged.

Children with hearing loss

In addition to seeing a physician for a medical evaluation, a child with hearing loss should be directed to an audiologist for evaluation and rehabilitation since hearing loss may cause problems in language development and the 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 hearing loss.

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Troubleshooting

Cause	Remedy	
No sound or intermittent sound		
Not turned on	Ensure battery is inserted and battery door is fully closed, see page "Turning on / off"	
Low / dead battery	Replace battery	
Battery upside down	Insert battery according to battery symbol. See page "Inserting a new battery"	
Dirty battery contact	Wipe battery compartment or reach out to Audicus	

Cause	Remedy
Two long beeps	
Low battery	Replace battery

Feedback / whistling

Hand or clothing near device	Move hand / clothing away from device
Poorly fitting dome	See "Finding the right dome"
Dome not inserted properly	See "Putting on your hearing aid"

Poor quality sound

Dome blocked with debris / earwax	Replace dome and replace earwax guard. See "Replacing the dome and earwax guard"
Plugged microphone	Clean device with cleaning brush. If issue persists, contact Audicus
Receiver not inserted properly	See page "Putting on your hearing aid"

For more help please visit **audicus.com/support**

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audicus.com •

(720) 669-7186 •

accounts@audicus.com