

OtoClear® Powered by Aquabot® Ear Irrigation Kit

INSTRUCTIONS FOR USE



OtoClear®, avec mécanisme
Aquabot® Mode d'emploi

OtoClear®, powered by Aquabot®
Instruções de Utilização

OtoClear® Powered by Aquabot®
setti Käyttöohjeet

POKYNY K POUŽITÍ systému
OtoClear® s technologií Aquabot®

Instrukcja użytkowania urządzenia
OtoClear® zasilanego przez Aquabot®

OtoClear®, powered by Aquabot®
Gebrauchsanweisung

OtoClear®, desarrollado por
Aquabot® Instrucciones de uso

OtoClear®, powered by Aquabot®
Gebruiksaanwijzing

„OtoClear®“, kurį pristato
„Aquabot®“, naudojimo instrukcijos

OtoClear®, drevet av Aquabot®
Bruksanvisning

OtoClear®, powered by Aquabot®
Istruzioni per l'uso

OtoClear® Powered by Aquabot®
Användningsinstruktioner

OtoClear®, powered by Aquabot®
Οδηγίες χρήσης

OtoClear®, drevet af Aquabot®
Brugsanvisning



INNOVATIVE SOLUTIONS FOR EVERYDAY PROBLEMS

CONTENTS

English	4
Français (French).....	14
Deutsch (German).....	24
Italiano (Italian).....	34
Português (Portuguese)....	44
Español (Spanish).....	54
Svenska (Swedish).....	64
Suomi (Finnish).....	74
Nederlands (Dutch).....	84
ελληνικά (Greek).....	94
Polski (Polish).....	104
Česky (Czech).....	114
Lietuvių k. (Lithuanian).....	124
Dansk (Danish).....	134
Norwegian (Norsk).....	144

PRODUCT OFFERING

#7270 - OtoClear/Aquabot, 20 tips, 1 Ear Basin

#7275 - OtoClear/Aquabot, 5 tips, 1 Ear Basin

Thank you for purchasing OtoClear®, powered by Aquabot®

OtoClear®, powered by Aquabot® provides a simple, yet effective, solution to patient safety, patient discomfort, and compacted cerumen removal. The key to this system is the OtoClear ear irrigation tips that are attached to the end of the wand. OtoClear ear irrigation tips direct water to the ear canal wall at 30 degree angles avoiding directly impacting the tympanic membrane.

This manual is designed to explain the proper assembly instructions for the entirety of the kit, including bottle assembly, cleaning, and tip placement.

Note: Any other use for the product outside of the intended use stated herein, Bionix shall not be held liable.

Getting Started:

Unpacking and Verifying Contents:

Before continuing, inspect the package for any damage during shipping.

If you find any damage notify your local distributor.

Next, check to ensure that your OtoClear®, powered by Aquabot® is complete.

Contents include:

- Aquabot® Bottle
- Adapter wand
- Either 20 OtoClear Tips or 5 OtoClear Tips
- Ear basin

If any item is missing please contact your distributor.

Intended use: The intended use of OtoClear powered by Aquabot is to flush cerumen and/or foreign bodies from a patient's ear canal without causing injury.

Indications for use: The OtoClear powered by Aquabot is indicated for use on patients 6 months or older with impacted cerumen and/or foreign bodies occluding the ear canal where no infection and/or eardrum perforation is known or suspected.

⚠ CAUTION: DO NOT perform irrigation if the tympanic membrane is perforated or if tympanostomy tubes are present. Discontinue irrigation immediately if bleeding, irritation or other trauma to the ear canal or tympanic membrane occurs.

WARNINGS:

- Use only warm water (98°F - 104°F / 37°C - 40°C) to reduce the risk of dizziness or vertigo
- If pain or discharge occurs see your physician
- Cross-contamination risk. Do not reuse the disposable OtoClear Tips as this may spread contamination from one patient to another patient.

Medical Device Reporting: Notice to Users and/or Patients in EU: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Clinical Benefits: Indicated in Intended Use.

Contraindications:

- The person has previously had complications following ear irrigation procedures
- There is a history of a middle ear infection in the last six weeks
- There is discharge from the ear canal or ear pain or tenderness
- The person has or suspects an ear drum perforation
- The person has had ANY form of ear surgery
- The person has cleft palate, repaired or not
- The person has tympanostomy tubes
- There is a history of inner ear problems (especially vertigo)
- Button or hearing aid batteries are indications for emergent ENT consultation

Residual Risk: Risk associated with the use of this product has been reduced as far as possible, but the product cannot completely eliminate potential patient or user harm arising from the following:

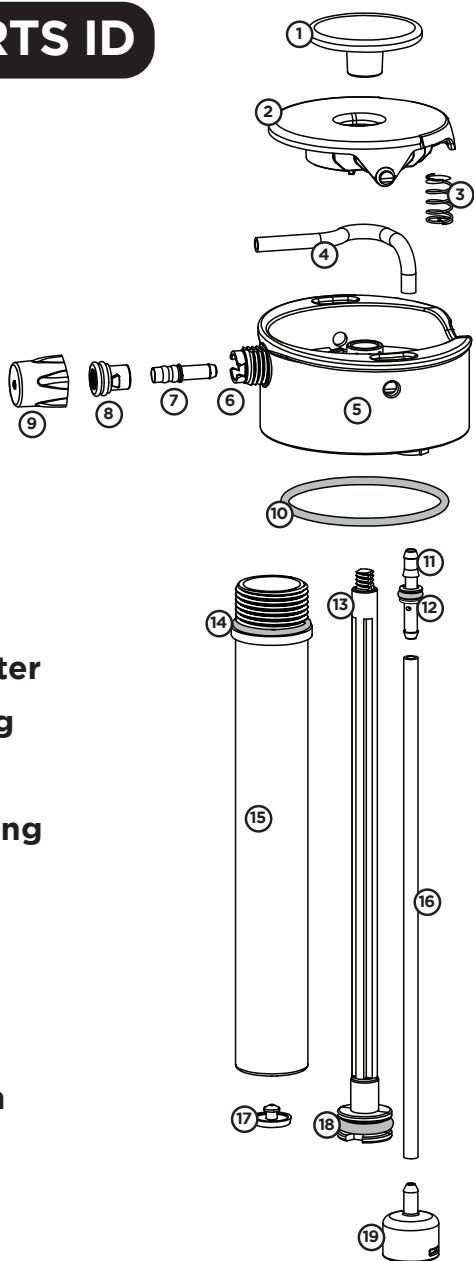
- Harm from mechanical hazards
- Harm from misuse, or use error
- Harm from unanticipated origins

Before you begin:

Exam the ear canal and tympanic membrane with an otoscope noting the type and location of any cerumen. Hard or impacted wax may require a cerumenolytic agent.

Aquabot® PARTS ID

- 1 Pump Handle
- 2 Trigger
- 3 Spring
- 4 Pinch Tube
- 5 Lid
- 6 Lid Nozzle
- 7 Nozzle Adapter
- 8 Soft Nozzle
- 9 Nozzle Cap
- 10 Lid O-ring
- 11 Draw Tube Adapter
- 12 Draw Tube O-ring
- 13 Piston Rod
- 14 Pump Barrel O-ring
- 15 Pump Barrel
- 16 Draw Tube
- 17 Umbrella Valve
- 18 Piston O-ring
- 19 Weighted Screen



! Aquabot® WARNINGS

- Do not over-pressurize the unit.
- Do not use liquids with temperatures above 120°F / 49°C.
- **CHOKING HAZARD** Unit contains small parts. Not suitable for children under 3 years.
- Only use lid with Aquabot bases.
- Do not use lid on any metal or glass bases.

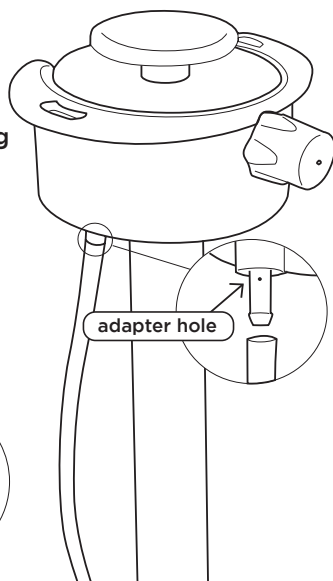
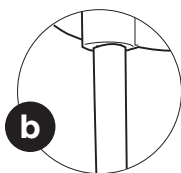
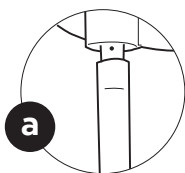
FAILURE TO READ AND FOLLOW THE ABOVE WARNINGS AND OPERATING INSTRUCTIONS COULD LEAD TO SERIOUS BODILY INJURY.

Aquabot® SPRAY MODES

Aquabot has two operating modes called Stealth and Pulse.

Stealth is ideal for drinking, misting and conserving pressure. Pulse is ideal for cleaning and conserving water.

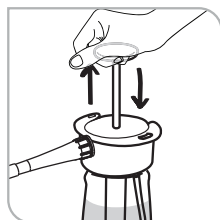
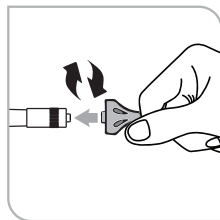
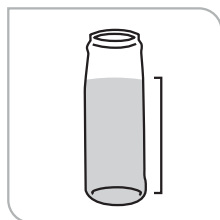
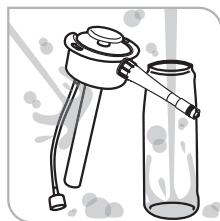
- Expose adapter hole to use in **Pulse** mode.
- Cover adapter hole to use in **Stealth** mode.



OtoClear[®], powered by Aquabot[®]

USE INSTRUCTIONS:

1. Clean by filling base half full with soapy water, twist on the lid, shake to clean and then spray soapy water through the unit. Repeat with fresh water.
2. Fill base to 32 oz. mark on 1000mL bottle and 19 oz. on 650mL bottle. Fill the water reservoir of the delivery device with warm water (approximate body temperature). **DO NOT** use cold or hot water as it may cause dizziness in some patients.
3. Attach Aquabot to top of bottle and close firmly by rotating clockwise.
4. Grasp the OtoClear Tip and twist onto the luer lock fitting of the adapter until it stops.
5. Pump no more than 6 times. This will pressurize the unit to approximately 35 psi. Take note of the force required on the last pump and use this as a guide for when to stop pumping on future charges so that you do not over-pressurize the unit.



6. Insert OtoClear tip fully into the ear canal. The flared design of the OtoClear tip protects against over-insertion. Tip: Fully inserting OtoClear Tip will help eliminate backslash.
7. Place a basin beneath the outer ear to capture draining effluent. Note: The OtoClear tip directs the water towards the walls of the ear canal creating a turbulent lavage that effectively dislodges the cerumen. The exit portals control backslash and deliver the effluent into the basin.

8. To release water, and irrigate the ear canal firmly press the colored circle on the back of the trigger.



9. Reexamine the ear canal. Repeat the irrigation procedure as needed. Sometimes a large plug of wax will not exit through the portal. In these cases, we recommend the use of a Safe Ear Curette™ to extract any remaining cerumen.
10. Remove any remaining water in the ear canal with an absorbent sponge. When procedure is complete, remove and dispose of the single-use OtoClear tip.
11. The safest method to depressurize the unit is to hold it upside down, while keeping the weighted screen above the water line. Then press the trigger to spray out compressed air.



WARNING: Failure to remove the OtoClear Tip runs the risk of cross contamination between patients. The tip is designed to be a single-use product.

Aquabot® MAINTENANCE

- Clean with soap and water as needed.
The base is dishwasher safe for top rack only.
The lid is **NOT** dishwasher safe.
- Do not put the unit in the freezer.
- Store out of direct sunlight.
- Do not store pressurized for more than 36 hours.
- Spray air through the unit to dry out the silicone tube before storing for long periods.
- It's a good idea to lock the trigger in the ON position when storing for long periods to keep the Pinch Tube from kinking.
- Spare parts are available on lunatecgear.com.
- Instructional videos are available on product pages at lunatecgear.com.
- For help, contact us at support@lunatecgear.com

High Level Disinfection of OtoClear®, powered by Aquabot®:

It is recommended to high level disinfect OtoClear®, powered by Aquabot® after any use where there was contact with blood, infectious material, or non-intact skin.

01. Use one of the following high level disinfecting (HLD) solutions that are compatible with OtoClear®, powered by Aquabot®:
 - Ortho-Phthalaldehyde Solution (0.55% maximum)
 - Accelerated Hydrogen Peroxide Solution (2% maximum)
 - Glutaraldehyde Solution (3.0% maximum)
02. Prepare the HLD solution per the manufacturer's instructions.
03. Remove the spray head from the bottle.
04. Ensure all water has been drained from the bottle and the spray head.
05. Fill OtoClear®, powered by Aquabot® with the HLD solution and reattach the spray head.
06. Pump OtoClear®, powered by Aquabot® until HLD solution discharges.
07. Remove the spray head and completely fill the bottle with HLD solution.
08. Reattach the spray head.
09. Allow the HLD solution to soak in OtoClear®, powered by Aquabot® per the HLD manufacturer's instructions for use.
10. After the manufacturer's recommended soak, remove the spray head from the bottle and empty the HLD solution from the bottle.
11. Thoroughly rinse the outer surfaces of the bottle and spray head with water.
12. Fill the bottle with clean rinse water and reattach the spray head.
13. Pump until half of the bottle is discharged.
14. Repeat steps 11 – 13 until the bottle has been rinsed three times.
15. Remove the spray head from the bottle.
16. Drain all water from the bottle.
17. Pump the spray head until all water is discharged.
18. Dry the outer surfaces of the bottle and spray head and leave them separated to allow complete drying.
19. To high level disinfect the ear basin, repeat steps 1 & 2 and follow the manufacturer's instructions.

Aquabot® TROUBLESHOOTING CHART

PROBLEM	REASON	SOLUTION
Unit does not build or hold pressure	Lid O-ring is missing	Replacement parts available at lunategear.com
	Pump Barrel is too loose	Tighten Pump Barrel
	Something else	Email support@lunategear.com or call 858.653.0401
Builds pressure but does not spray	Pinch Tube is kinked	Remove trigger and unkink Pinch Tube
	Something else	Email support@lunategear.com or call 858.653.0401
Water is getting inside of pump barrel	Umbrella Valve is not sealing	Replacement parts available at lunategear.com
	Pump Barrel is too loose	Tighten Pump Barrel
Water is leaking from under trigger	Pinch Tube is damaged	Replacement parts available at lunategear.com
	Something else	Email support@lunategear.com or call 858.653.0401
Water is leaking from under trigger	Soft Nozzle is missing	Replacement parts available at lunategear.com
	Wear and tear on Soft Nozzle	Replacement parts available at lunategear.com
	Something else	Email support@lunategear.com or call 858.653.0401
Mist is not fine	Wear and tear	Try sanding 0.5mm off the open side of the Nozzle Cap. If that doesn't work, order a new Nozzle Cap.
	Operating mode is in Pulse	Switch to Stealth mode
	Something else	Email support@lunategear.com or call 858.653.0401
Spray is too noisy	Operating mode is in Pulse	Switch to Stealth mode

	Medical Device		Do Not Use if Package is Damaged
	Manufacturer		Do Not Reuse Single-Use Device
	Date of manufacture		Single patient-multiple use
	Use-By Date		Consult Instructions For Use (IFU)
	Lot Code		Caution
	Reorder Number		Warning
	Serial number		Authorized representative in the European Community
	Sterilized using irradiation		European Conformity
	Do Not Resterilize		Prescription Only or "For Use by or on the order of a licensed medical professional"
	Non-sterile		Temperature limitation