

Welch Allyn® Ear Wash System



Directions for use

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For patent information, please visit www.welchallyn.com/patents.

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Welch Allyn, Inc.
4341 State Street Road
Skaneateles Falls, NY 13153 USA

Regulatory Affairs Representative
Welch Allyn Limited
Navan Business Park
Dublin Road
Navan, County Meath,
Republic of Ireland

www.welchallyn.com



WelchAllyn[®]
Advancing Frontline Care™

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Introduction

Thank you for purchasing the Welch Allyn Ear Wash System.

The Welch Allyn Ear Wash System provides a safer and more effective way to remove cerumen. This method of irrigation is much cleaner and safer than other irrigation methods currently on the market. The Welch Allyn Ear Wash System provides the following features:

- Patient Comfort - Hydrovac action
- Patient Safety- High temperature water shut-off
- Water pressure regulation inside chamber
- User Friendly - Visual temperature feedback sensor
- Superior Engineering - Fully functional at variable water pressures as well as different faucets

This manual describes how to operate and maintain the Welch Allyn Ear Wash System. Please follow these instructions to ensure many years of accurate and reliable service. Carefully read the instructions regarding the method on "Using the Ear Wash System" on page 8 to minimize patient discomfort and to avoid the risk of perforating a patient's tympanic membrane. For additional information on cerumen types and the irrigation process, see the "Types of Cerumen" section.

About this Manual

This manual serves as guide for ear irrigation using the Welch Allyn Ear Wash System. The Welch Allyn Ear Wash System is intended for use by Healthcare Professionals. Any use other than the intended use invalidates the manufacturer's warranty.

Warnings and Symbols

This manual uses the icons and symbols described below.



WARNING The warning statements in this manual identify conditions or practices that could lead to illness, injury, or death. Warning statements appear with a grey background in a black and white document.



CAUTION The caution statements in this manual identify conditions or practices that could result in damage to the equipment or other property, or loss of data. This definition applies to both yellow and black and white symbols.



The CE mark on this device indicates that it has been tested and conforms to the provisions noted within the 93/42/EEC Medical Device Directive.

Miscellaneous symbols



Reorder Number



Do Not Reuse



Consult Directions for use



Manufacturer



WARNING Only a licensed health care professional or a properly trained person under the direction of such a professional should perform the irrigation procedure. Always inspect the ear before attempting any irrigation. Do not irrigate with this device: a) if a perforated tympanic membrane is documented in the patient's chart or observed on inspection, b) if a perforated tympanic membrane is suspected, or c) if the tympanic membrane cannot be visualized on inspection. Note that sometimes small perforations are evident only as an immobile tympanic membrane. Irrigation is not advised if the patient presents with severe pain, vertigo (especially with nystagmus), sensorineural hearing loss, active and significant bleeding or severe tinnitus. Irrigation in a patient with a perforated tympanic membrane may result in contaminating the middle ear with debris from the ear canal. Use clinical discretion if the patient has acute otitis media, chronic or complicated otitis media, PE Tubes or is immunocompromised.



WARNING If the water is too cold, the patient may experience vertigo or light-headedness. Please verify that the thermal indicator is white before proceeding with the irrigation.

Reimbursement Information

- Coverage -** Use of the Ear Wash System in the physician office is usually covered by payers when medically necessary.
- Coding -** 69210, removal of impacted cerumen (separate procedure), one or both ears.
- Payment -** payment for use of the Ear Wash System varies by payer, plan, and provider contract and may be separately payable in the physician's office setting.

Getting Started

Unpacking and Verifying Contents

Inspect the packaging for any damage incurred during shipping. If you find any damage, notify the carrier.

Complete and return the warranty registration card. It validates the warranty and allows Welch Allyn to send announcements of product enhancements.

When you unpack your new Welch Allyn Ear Wash System, verify that the following items are included:

- Water chamber
- One snap-aerator
- Chamber Aerator
- Storage Tray
- Quick Reference Guide
- Handle/Tubing assembly*
- Three different faucet adapters
- One box of ear tips (25 ct)
- Operating Instructional Manual
- Warranty Card

If any items are missing, please contact your Welch Allyn distributor.

* This water chamber is designed for use with handle/tubing assemblies dated after March 2002 only. The date code is located on the face of the handle interface at the bottom of the crescent pocket.

Date Code

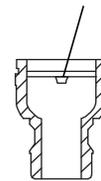
02

03



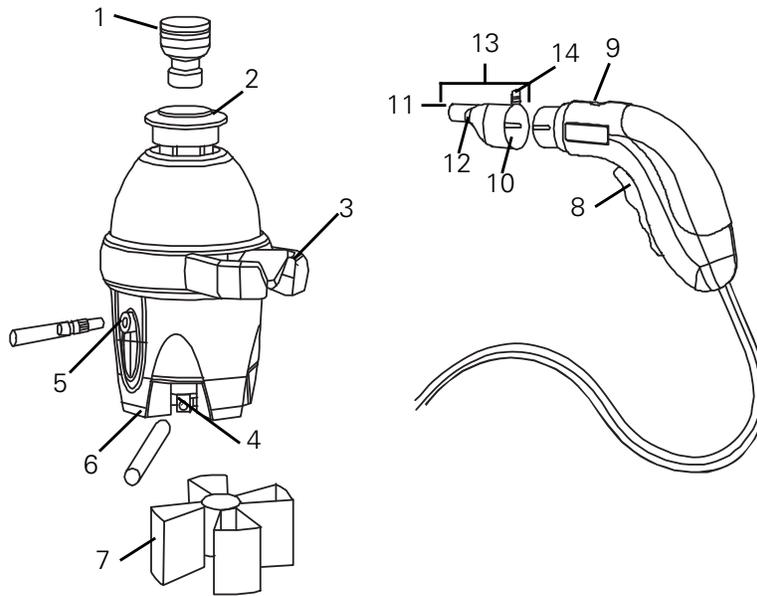
For safe use, verify the plastic flow limiter is in ALL aerators. If your facility has multiple exam rooms with snap aerators, you MUST inspect each one to verify the plastic flow limiter is inside. Replace all aerators that have missing components. Call Welch Allyn Technical Support if assistance is needed. (Aerator Flow = 4.0 gpm)

Plastic Flow Limiter



Use the figure shown to familiarize yourself with the features of the Welch Allyn Ear Wash System.

Diagram of the Welch Allyn Ear Wash System



1	Snap Aerator	8	Water Flow Actuator
2	Snap Connector with white ring	9	Water Temperature Sensor
3	Handle Rest Grip Ring	10	Cerumen Trapping Screen in ear tip
4	Irrigation Port - Irrigation water to ear (blue)	11	Water Jet Output
5	Return Port - Return water from ear (black)	12	Water Suction Input
6	Return Water Exit Port	13	Disposable ear tip
7	Chamber Aerator	14	Ear Tip Removal Tab

Faucet Aerator Installation

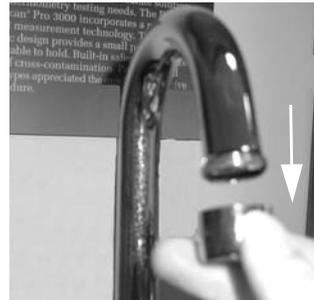


Caution This system is designed for use on faucets where line pressure does not exceed 100 PSI or flow rate of 5.7 gallons / minute. If you suspect the line pressure or flow rate is greater, have it tested prior to use of the Ear Wash System or contact Welch Allyn Technical Service Department.

1. Remove your current aerator from your faucet, including any original washers. You may need to use a pair of pliers to remove your aerator. If you still have difficulty in removing it, soak your current aerator in distilled vinegar for about twenty minutes and try again.



Caution Failure to remove all parts of the aerator from the faucet will affect the Ear Wash System performance.



2. Ensure all snap aerator parts are intact and attach the assembly to your faucet by turning it counter-clockwise. If it does not fit, locate the appropriate adapter from the kit included with the unit. Attempt to match the adapter to your faucet and then attach the snap aerator. Verify the rubber washer on the snap aerator and adapter matches to the old washer on your faucet. If you need to use the threadless universal adapter (only available in certain regions), you may need to remove the inner rubber o-ring if it is too small for your faucet.
3. Once the snap aerator is attached to the faucet, the ear cleaning chamber is easily attached or removed. You can still use your sink normally when the Ear Wash System is not attached.

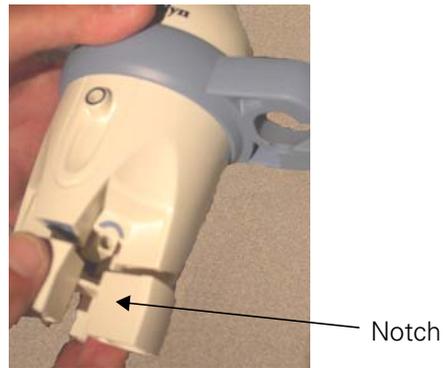


Chamber Aerator Installation

The chamber aerator is an optional attachment that is necessary if you are experiencing a significant amount of water splash around your sink.

1. Find the notch located on the top of the chamber aerator and line it up with the blue irrigation port on the chamber.
2. Gently press the chamber aerator against the chamber until it is snug.

Note The chamber aerator is only capable of attaching to the chamber if it is aligned correctly. It should go on relatively smoothly and there is no need to force it onto the chamber.



Using the Ear Wash System

Steps for Irrigation

It is essential to follow the technique described in this section for using the Ear Wash System to minimize patient discomfort and avoid the risk of perforating the tympanic membrane.

The factors determining the risk of perforating the tympanic membrane while irrigating the ear canal are the water pressure at the point of discharge and whether the discharged flow of water directly impinges on the tympanic membrane.

The typical range of water pressure at the point of discharge in the ear tip of the Ear Wash System is 10 - 13 PSI. There is great variability among patients regarding susceptibility to perforation of healthy tympanic membranes by pressure. Present evidence suggests that a water pressure of 13 PSI may be capable of perforating healthy tympanic membranes in a very small percentage of patients, estimated to be less than .05%, if the water flow directly impacts the tympanic membrane. This small risk is avoidable if the water flow is directed to impact the wall of the ear canal, so that only indirect turbulent flow reaches the tympanic membrane. This technique will also minimize patient discomfort.

Pre-Treatment Procedure

Carefully grasp the pinna and administer the ear wax softener, which will enhance performance.



Attaching the Tubing and Chamber

1. Connect the tubing to the chamber. Match the black connector to the black return port on the side of the chamber. Match the blue connector to the blue irrigation port on the lower side of the chamber.



2. To attach the chamber to the faucet, pull down the white plastic ring on the top of the chamber, and then insert the chamber over the snap aerator on the faucet. When the chamber is positioned, release the white plastic ring. The chamber is now secure.



Attaching an Ear Tip

1. Line up the grooves on the side of the ear tip with the corresponding indentations on the handle interface. Verify that you are attaching the ear tip with the tab facing upwards.
2. Press firmly on the ear tip until it is flush against the handle interface. You will feel a slight snap when the ear tip is in place.



Irrigation

1. Initially, you may cover the patient with a cloth drape to eliminate splashing onto his or her clothes. Once the technique of sealing the ear canal is mastered, this is not necessary.
2. Begin to run water through the unit by turning the hot and cold water on full power. Adjust the water exiting the bottom of the chamber until it feels close to body temperature.

Note Reducing the hot or cold water will impact the pressure.

3. Check the temperature of the irrigating water by looking at the thermal sensor while depressing the water flow actuator. If the thermal sensor is blue, the irrigating water is not warm enough. If the thermal sensor is white, the water temperature is at least 90° F and the procedure may begin. You must depress the actuator on the handle for the temperature sensor to function correctly.



WARNING If the water is too cold, the patient may experience vertigo and/or light-headedness. Please verify that the thermal indicator is white before proceeding with the irrigation.

4. To irrigate the ear, grasp the patient's pinna. Pull gently back to straighten a child's ear canal or up and back for an adult. While maintaining tension on the pinna, insert the tip of the handle into the ear to create a seal. Tilt the handle so the ear tip is directed away from the longitudinal axis of the ear canal and toward any point on the wall of the ear canal. Squeeze the actuator on the handle and slowly rotate the tip. By adjusting how much force you push on the actuator, some control over the flow rate is attained.



5. It is important to aim the stream of water away from the longitudinal axis of the ear canal and toward the ear canal walls by tilting and rotating the handle during the irrigation. Flood the ear with water. The suction return system will return the discharge away from the ear.
6. During the irrigation, provide inquiries about patient comfort to provide confidence. Periodically stop irrigation. View the ear canal (using an otoscope) to check on progress. (Wax evacuation is not always evident watching the ear tip/suction tubing.)
7. If the temperature of the irrigating water becomes too hot, the unit will restrict the flow to the handle, while continuing to discharge out the bottom of the unit. For the unit to reset, bring the water temperature down to a safe level by adjusting the knobs on the faucet until the water cools sufficiently.
8. Release the actuator and keep the ear tip in the canal for 5 to 10 seconds to vacuum any residual irrigating water.

Note The procedure typically takes 30 seconds to 5 minutes depending on the type of cerumen and whether or not a wax softening agent is used. In severe cases, the process could take longer.

9. When the irrigation is complete, grasp the tab located on the disposable ear tip and pull the ear tip off of the handle with a downward motion. Please place in an appropriate receptacle.



 **WARNING** If there is no water flow out of the ear tip and the actuator is depressed, check to see if the hot water shut-off has tripped by running cold water through the unit. This should restore water flow to the handle.



WARNING Patient injury risk. To avoid cross contamination, use ear tips for a single patient. Discard after use.

WARNING If the application of non-sterile tap water in a patient's ear is a concern, administer a few drops of the following solutions to the ear canal after the procedure is completed as a preventative measure:

- **70% Isopropyl Alcohol**
- **Hydrogen Peroxide**
- **Solution of 1 part Vinegar/1 part Isopropyl Alcohol**

Note Discoloration or staining of the tubing can occur over time due to local water conditions and/or introduction of other ear cleaning solutions.

Disassembly

1. Turn off the faucet and disconnect the tubing from the chamber. (Twist the fitting when removing the hose from the chamber.)
2. Detach the chamber from the faucet. Press down the white ring on top of the chamber and then pull the chamber from the snap aerator. The chamber will drain through the open hose ports at the front and bottom.
3. To remove any stagnant water from the tubing, place the open end of the tubing over the sink. Hold the handle higher than the tubing and squeeze the actuator (A). Roll the tubing up into a coil, holding the handle higher than the tubing (B). The water should run out of the open end into the sink basin.



(A)



(B)



Maintenance

Cleaning and Disinfecting the System

Clean or **Disinfect** Ear Wash System daily. **High Level Disinfect** each time the unit is used on a patient with compromised skin.

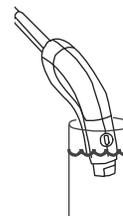
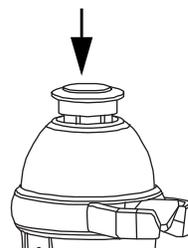
Cleaning the unit eliminates any debris and reduces the number of microorganisms in the tubing. Disinfecting the unit eliminates most bacteria and fungi growth.

To Prepare the Unit

- Remove the ear tip and discard.
- Clean the outside of the chamber, handle and hose with a soft cloth saturated with a mild solution of soap and water
- Detach the chamber from the faucet. Leave the hoses attached to the unit.

To Clean the Unit

- Prepare a 4 cup solution of soapy water.
- Pour 1/2 cup of the solution into the top opening of the coupler. (Save the remainder of the solution for later steps in this procedure.)
- Replace the chamber on the faucet and submerge the handle interface surface (where the tip attaches) into the solution. Turn on the water. Squeeze the actuator to allow the solution to flow from the handle into the container.
- The suction line will remove the solution. Continue this process for 5 minutes. Remember to keep the exposed tip of the handle submerged in the solution.
- Remove both tubes from the chamber and allow the chamber to drain.
- Remove the chamber from the faucet.



- To remove any stagnant solution in the tubing, place the open end in the sink. Squeeze the actuator and the solution will run out into the sink basin.
- Allow the chamber to drip dry. Place the unit in its holding container.
- To facilitate a recommended thorough flush and faster drying time, pour isopropyl rubbing alcohol inside the chamber and hoses.

To Disinfect the Unit

Follow Cleaning instructions, except replace the soapy water with a 2 cup solution of isopropyl rubbing alcohol or a 10% bleach/90% water solution. Rinse handle thoroughly with water after cleaning solution is used.

To High Level Disinfect the Unit

- Prepare at least 2 cups of .55% Ortho-Phthalaldehyde solution (Welch Allyn recommends the use of Cidex OPA).
- Pour at least 2 cups of the solution into the top opening of the coupler.
- Replace the chamber on the faucet and submerge the handle interface surface (where the tip attaches) into the solution. Turn on the water. Do not squeeze the actuator. After half of the solution is removed, turn the water off.
- Remove handle from solution and rest it in the handle rest/grip ring. This will trap the solution in the return line and allow effective disinfection. Follow the manufacturers recommendations on soak times for maximum benefit.
- Remove the chamber from the faucet.
- To remove any residual disinfecting solution in the tubing, place the open end in the sink, squeeze the actuator and the solution will run out into the sink basin.



Caution If hard water/ calcium buildup is a concern, a solution of 100% vinegar can be substituted. Allow the vinegar to soak in the chamber for no more than 2-3 minutes. A final flush of isopropyl alcohol is required.

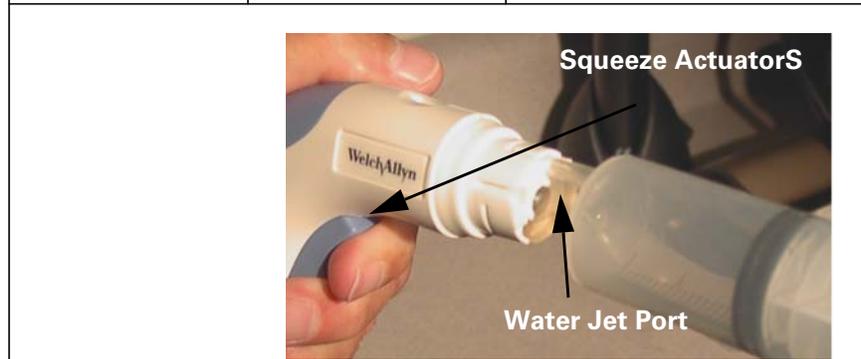
Caution Do not use solutions that contain chlorhexidene.

Caution Do not sterilize the unit with other methods such as ETO or autoclave. These methods may damage the unit.

Troubleshooting

If your Welch Allyn Ear Wash System is experiencing problems, consult the following table to find the symptom and the likely cause and the solution. If the information in this table does not describe or solve the problem you are having, contact the Welch Allyn Technical Service Department at 1-800-535-6663 / 1-315-685-4653 or an authorized Welch Allyn Distributor to help you. See Service and Warranty Information Card for more information.

Problem	Possible Cause	Solution
No water is coming out of the handle even though I am pulling the actuator.	The temperature shut-off safety feature has activated due to the hot water temperature.	Run COLD water through the system for 10-30 seconds. This will reset the temperature shut off safety feature and allow water to flow again.
	There is a kink in the tubing.	Make sure there are no bends in the tubing restricting the flow of water.
	The tubing on the INSIDE of the handle is restricting water flow.	Remove the ear tip. Turn off the faucet and disconnect the tubing from the chamber. with the ends of the tubing in the sink and the actuator squeezed, inject air with a syringe into the water jet port of the handle.



Problem	Possible Cause	Solution
Excessive water leaking from the ear.	The water is not turned on high enough.	Turn the cold water on full in order for the suction system to work properly (but still within the right temperature range).
	Ear tip attachment problem.	Replace the ear tip with the tab side pointing upwards.
	Tubing connection problem.	Ensure that both tube fittings are fit snugly into the chamber.
	Incorrect technique.	Check the Quick Reference Guide to verify you are aiming the water correctly.
	Suction not adequate.	Check suction by immersing tip only into a graduated cup. Verify the suction is at least 180 ml per 20 seconds. **
Difficulty removing ear wax.	Water too cold	Slowly increase water temperature until desired results occur.
	Water flow inadequate	With an ear tip attached, spray water from the handle into a graduated cylinder or measuring cup for exactly 20 seconds. If there was less than 100 mL or more than 134mL of measured water, replace the tip and repeat. If the results are the same, contact your Welch Allyn Technical Service Department.
	Patient has very hard ear wax.	Apply ear drops for about 5 - 10 minutes then retry. If unsuccessful, have patient apply ear drops overnight then retry. Rotate tip within the ear canal (to direct stream of water to different areas rather than the same spot).
Lack of a clean water stream coming from ear tip.	Installation of ear tip has caused a problem.	Apply a new ear tip with the tab side pointing upwards.

Problem	Possible Cause	Solution
The water splash is making a mess or splashing onto adjacent electrical units.	Excess water pressure from the water line.	Ensure that the chamber aerator is attached to the bottom of the chamber.
The water pressure from the ear tip seems too high or too low.	Installation of ear tip has caused a problem.	Apply a new ear tip with the tab side pointing upwards.
	There is leakage from the chamber aerator and/or adapter	Tighten the aerator and/or adapter with a pair of pliers.
	The return water exit port is clogged on the bottom of the chamber.	Remove the chamber from the faucet and dislodge any foreign materials from the exit port. Proceed with the normal cleaning procedure.
	There is an internal malfunction. Check water pressure from the sink.	With an ear tip attached, spray water from the handle into a graduated cylinder or measuring cup for exactly 20 seconds. If there was less than 100 mL or more than 134mL of measured water, replace the tip and repeat. If the flow is still above 125 ml / 20 seconds, either add regulation to the faucet or move to a faucet with adequate water pressure and flow. Otherwise, contact your Welch Allyn Technical Service Department.
Sensor not turning white even though water feels warm coming out of the bottom of the unit.	The sensor is defective.	Replace handle/hose assembly.
	Delay in change of color	Keep water flowing from handle so that warm water reaches the sensor to change its color.
Algae, fungus, or other growth in hose.	Hose is not being properly disinfected.	See "Cleaning and Disinfecting the System" on page 14. Use a germicidal or anti-bacterial soap or Cidex.

*** To properly test suction, follow the steps below:**

1. If suction is too low, replace the ear tip. If suction does not improve go to step 2.
2. Remove ear tip and place handle interface into water. If suction improves replace handle/hose assembly. If suction does not improve go to step 3.
3. Make sure hose from handle to black fitting is not kinked and is free of obstruction. Replace hose if it is kinked. Clean it out if it is obstructed. If the hose is not kinked or obstructed go to step 4.
4. Check to see if water is flowing freely out of the bottom of the chamber. If no water is flowing from the chamber replace it. If there is water flowing go to step 5.
5. Check water faucet pressure/flow rate. Water flow out of the faucet should be at least 1 gallon per 30 seconds. If the water flow is adequate there is a blockage in the chamber. Replace chamber. If the flow is less than 1 gallon per 30 seconds, the water pressure/flow is inadequate. Move to a faucet with adequate water pressure/flow.

**** To properly test water flow, there are a few stages**

1. If water flow is too low, replace the disposable ear tip. Make sure the tab side points upwards. If water flow does not improve go to step 2.
2. Check hose from blue fitting on chamber to handle. Make sure there are no kinks or obstructions. If hose is kinked, replace hose. If there are obstructions, remove hose and clean out. If there are no kinks or obstructions go to step 3.
3. Follow steps 4 and 5 above. Take action as required.

Types of Cerumen

Cerumen is the natural by-product of the ear canal. It lubricates the skin lining in the ear canal, acts as a water repellent, and entraps dust, hair follicles, and foreign bodies. Cerumen can take many different forms which affect the process and time to remove. There are generally two different types of cerumen found in the ear canal: dry and wet. The following are subtypes of cerumen that you will commonly encounter and how they may affect the irrigation procedure.

White/Flaky Cerumen

This form of cerumen will easily dissolve in the irrigation water. The irrigation procedure is relatively short, and a cerumenolytic agent is not always necessary. Often you will not see solids trapped in the ear tip with this form of cerumen; rather, you will see some of the dissolved cerumen trapped in the ear tip screen. The rest of the dissolved cerumen will leave through the exit port of the chamber.

Light Brown/"Jelly-Like" Cerumen

This cerumen resembles the consistency of petroleum jelly and does not completely dissolve in the irrigation water. Some solids may be present in the ear tip, and the procedure time is slightly longer than for the white/flaky variety. A cerumenolytic agent is recommended to shorten the time of irrigation.

Dark/Hard Cerumen

This cerumen is often found lining the walls of the canal and forms a plug in the patient that can cause significant hearing loss. Large solids of cerumen are seen trapped in the ear tip and the procedure time is often longer than the wet/"jelly-like" cerumen. A cerumenolytic agent is often necessary to shorten the time of irrigation.

Anatomy And Physiology

- Cerumen is produced in the outer third of the ear canal and naturally moves to the outer ear as new tissue grows from the area around the tympanic membrane.
- Normal cerumen routinely becomes a medical issue when it impedes the physicians ability to visualize the tympanic membrane. Less frequently, cerumen can accumulate and harden, in the canal causing occlusion of the ear canal. In the

most severe cases cerumen can become 'impacted' in the deep (bony) canal causing pain and temporary loss of hearing.

Cerumenolytic Agents

- Cerumenolytic agents are those agents designed specifically to dissolve or soften cerumen.
- Most softening agents, particularly over-the-counter products contain carbamide peroxide which is the only agent the FDA considers safe for loosening or softening cerumen.
- In some instances, it is necessary to soften cerumen prior to removal or instead of removal.

Cross Contamination / Backflow Prevention

- At the time of this printing, ear wax (cerumen) is not considered a biohazard. However individual municipalities may place a higher level of concern where water is sucked back into the line (from the Ear Wash) when a negative line pressure condition exists. You can order a back flow prevention adapter that meets all current national and international requirements by calling Welch Allyn or obtaining one from your local hardware store (watts model 8C). To determine if this type of device is necessary, contact your local water authority.

Warranty and Service Information

Warranty

Welch Allyn, Inc. warrants the Ear Wash System to be free of original defects in material and workmanship and to perform in accordance with manufacturer's specifications for a period of one year from the date of purchase. If this instrument or any other component thereof is found to be defective or at variance from the manufacturer's specifications during the warranty period, Welch Allyn will repair or replace the Ear Wash System or component(s) at no cost to the purchaser.

This warranty only applies to products purchased new from Welch Allyn or its authorized distributors or representatives. The purchaser must return the product directly to Welch Allyn or an authorized Ear Wash System distributor or representative and bear the cost of shipping.

This warranty does not cover breakage or failure due to tampering, misuse, neglect, accidents, modification or shipping, and is void if the instrument is not used in accordance with Welch Allyn's recommendations or if repaired or serviced by other than Welch Allyn or a Welch Allyn authorized representative.

Note Return of the instrument registration card is required for proof of purchase and warranty validation.

Replacement Parts and Accessories

Ordering Information

To order replacement parts or accessories, contact your Welch Allyn Service Representative or call the Welch Allyn Customer Service Department in Skaneateles Falls, NY (USA) directly at:
1-800-535-6663 Monday through Friday, 8:00AM to 8:00 PM EST

Part	Part Number
Ear tips (Case of Ear Tips)	29360
Tubing (Hose Assembly)	29330
Aerator Adapter Kit (4.0 gpm): Domestic (snap aerator and 3 adapters) Domestic / International adapters	29373 29381
Back flow Prevention Adapter	29399
Aerator (4.0 gpm)	29372

Specifications

General Specifications

The specifications common to all of the major components of Welch Allyn Ear Wash System are listed the following table.

Operating Temperature:	50° - +104° F(10° - +40° C)
Storage Temperature:	-40° - +120° F(-40° - +49° C)
Flow Rate from Ear Tip:	100-134 mL (0.0264 gal) of water per 20 seconds at operating pressure.
Source (faucet) Water Pressure Range:	40 - 100 Psi (275kPa - 690 kPa)
Minimum Source Water Flow Rate:	7.5 l/min (2 gal/min)
Maximum Source Water Flow Rate:	21.5 l/min (5.7 gal/min)
Water Pressure from Ear Tip:	Typical range 10-13 Psi (69kPa - 90kPa)

Ear Tips

- Bio-compatible, latex-free, insert type
- One size fits patients from pediatric to adult
- Single-use only
- Fits most round ear canals

WelchAllyn[®]

Advancing Frontline Care[™]

Welch Allyn, Inc.
4341 State Street Road
Skaneateles Falls, NY 13153

Material No. 726920 Ver. A