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Instructions for Use - US

Aqua Stim

Water Irrigator



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Table of Contents

- 1 INTRODUCTION 1**
 - 1.1 About this manual 1
 - 1.2 Intended use 1
 - 1.3 Product description 2
 - 1.4 Warnings and precautions 2

- 2 UNPACKING AND INSTALLATION..... 3**
 - 2.1 Unpacking and inspection 3
 - 2.2 Storage..... 3
 - 2.3 Marking 4
 - 2.4 Panel connections 5
 - 2.5 Installation 5
 - 2.6 Irrigator connections 6
 - 2.7 Drawing water from the tank 6

- 3 OPERATING INSTRUCTIONS 7**
 - 3.1 Using the Aqua Stim with VNG/ENG software 7
 - 3.2 Turn on the irrigator 7
 - 3.3 Attach the hose tip 7
 - 3.4 Maintain water level 7
 - 3.5 Select the irrigation temperature 8
 - 3.6 Set the irrigation time 8
 - 3.7 Perform the Irrigation 8
 - 3.8 Turn off the irrigator 9
 - 3.9 Draining the internal water 9
 - 3.10 Trouble shooting 10

- 4 MAINTENANCE 11**
 - 4.1 General cleaning procedure..... 11
 - 4.1.1 General Precautions 11
 - 4.1.2 Recommended cleaning agent and frequency 11
 - 4.2 After every patient use 12
 - 4.3 Daily 12
 - 4.4 Weekly 12
 - 4.5 Quarterly 13
 - 4.6 Annually 13
 - 4.7 Annual cleaning procedure 13
 - 4.7.1 Tools needed 13
 - 4.7.2 Prepare vinegar & water solution (mineral deposit removal)..... 13
 - 4.7.3 Prepare irrigator for use..... 14
 - 4.8 Replacing the water filters..... 14
 - 4.9 Warranty and service 15
 - 4.9.1 Product warranty..... 15
 - 4.9.2 Concerning product repair / service..... 15
 - 4.10 Component disposal 16
 - 4.11 Malfunction..... 16

- 5 GENERAL TECHNICAL SPECIFICATIONS..... 17**
 - 5.1 Device specifications 17
 - 5.2 Electromagnetic compatibility (EMC)..... 18



1 Introduction

1.1 About this manual

This manual is valid for the Aqua Stim Water Irrigator.

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1.2 Intended use

The Aqua Stim caloric irrigator is used for stimulating the motion sensors in the ear using warm or cool water pumped into the external ear canal. This standard clinical test is used to determine if the motion sensors are working properly in patients with dizziness or balance problems. Typically, four irrigations are performed, a cool and a warm for each ear. Responses to the irrigation are then compared to determine if one ear motion sensor is weaker than the other ear sensor.

The Aqua Stim can be used in conjunction with the Interacoustics VN415, VO425, VisualEyes 515, and VisualEyes 525 VNG/ENG software and Micromedical Spectrum VNG via USB. When integrated with one of the aforementioned software programs, use of the Aqua Stim irrigator will start the caloric test with the correct irrigation temperature.

All personnel who operate the Aqua Stim should familiarize themselves with the contents of this manual prior to using the irrigator with a patient. Additional training can be requested via Interacoustics or one of its representatives.

Aqua Stim should be used for irrigating the external ear canal only for the purposes of caloric stimulation as a part of VNG/ENG test protocol. The device is not intended for clearing ear wax.

If service is required, please contact Interacoustics or the local Interacoustics distributor.

The intended use of this product is for irrigation of the patient's external auditory canal with either warm or cool water for the purpose of assessing the peripheral vestibular system. The product is intended to be used by a trained professional in a clinic, hospital, or rehab setting. The appropriate patient population includes children and adults with normal external auditory canal and middle ear anatomy.

Contraindication:

Do not perform irrigation on patients with tympanic membrane perforations.



1.3 Product description

The Aqua Stim™ caloric irrigator is used for clinical testing of the head-motion sensors in the ear using warm 44°C or cool 30°C water delivered into the external ear canal. The Aqua Stim™ caloric irrigator has a lighted handle to illuminate the ear. The Aqua Stim™ caloric irrigator uses an external water tank so it may be used in offices without a sink. The Aqua Stim™ caloric irrigator can be operated as a standalone device or communicate with a VNG/ENG system directly via USB.

NOTICE: If the irrigator system is used along with VNG/ENG software, refer to the respective software user manual for computer specification and supported operating system related information.

The systems consist of the following included parts:

Qty	Designation
1	Aqua Stim Irrigator
1	External water tank with tubes
1	Power cord
1	User's Manual
1	Plastic kidney basin
1	Irrigator handle
1	Pack of silicone tubes (single-use)
1	USB Cable
1	Spare Filter Cone

1.4 Warnings and precautions

Throughout this manual the following meaning of warnings, cautions and notices are used:



WARNING

The **WARNING** label identifies conditions or practices that may present danger to the patient and/or user.



CAUTION

The **CAUTION** label identifies conditions or practices that could result in damage to the equipment.

NOTICE

NOTICE is used to address practices not related to personal injury.



2 Unpacking and installation

2.1 Unpacking and inspection

Check for damage

When the instrument is received, ensure that you have received all the components on the shipping checklist. All the components should be checked visually for scratches and missing parts before use. All the contents of the shipment have to be checked for their mechanical and electrical functioning. If the equipment is found faulty, please contact your local distributor immediately. Keep the shipping materials for the carrier's inspection and insurance claim.

Keep carton for future shipment

The instrument comes with shipping cartons, which are specifically designed for the components. It is recommended to keep the cartons for future shipments in case of any need for return or service.

Reporting and returning procedure

Any missing part or malfunction or any damaged components (due to shipment) should be reported immediately to the supplier/local distributor along with the invoice, serial number and a detailed report of the issue. For any on-site service-related information, please contact your local distributor. If the system/ components are to be returned for service, please fill all the details related to product issues in the 'Return Report', which is attached to this manual. It is very important that you describe all the known facts about the issue in the return report, as this will help the engineer to understand and solve the problem to your satisfaction. Your local distributor holds the responsibility for coordinating any service/return procedure and related formalities.

2.2 Storage

Environmental conditions



The Aqua Stim is not suitable for use in the presence of flammable anesthetic mixtures with air or oxygen or nitrous oxide as there may be an explosion risk.

Standards Compliance

- Class I device for protection against electric shock
- Type B Applied Part for degree of protection against electric shock
- IPX0 rating for degree of protection against the ingress of water
(I. e. the system will be damaged if any water is absorbed by the electronic equipment)

The Aqua Stim was tested according to IEC60601-1-2 regarding EMC. Thus, one can install and use the Aqua Stim in a clinical exam room where other medical equipment is located.

Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided.

- Portable and mobile radio frequency (RF) communications equipment (e. g. cell phones, personal data assistants, etc.) can affect medical electrical equipment. This equipment should not be used at close distances to the equipment
- Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

	Performance Conditions	Storage	Transport
Temperature	20°C ~ 30°C 68°F ~ 86°F	1°C ~ 50°C 34°F ~ 122°F	-15°C ~ 50°C 5°F ~ 122°F
Relative Humidity	10% ~ 90%	10% ~ 90%	10% ~ 95%
	Non-condensing	Non-condensing	Non-condensing



The external water tank should be placed at the same level as the irrigator. Do not place the external water tank higher than the irrigator.



Do not place the water tank at a position above the irrigator as this may affect water fill and overflow functions.

Water is drawn from the external water tank into the irrigator for heating to 30°C or 44°C prior to each irrigation. Water will remain in the irrigator until it has been emptied by following the draining instructions.



Prior to transport, follow the water draining instructions in this manual. Do not ship the irrigator without draining it as the internal water may damage components due to freezing and this will void the warranty.

2.3 Marking

The following marking can be found on the instrument:

	Name in brackets of the keyboard key to press
	An applied part that includes a patient connection that is intended to deliver electrical energy or an electrophysiological signal to or from the patient shall be a Type BF part. An EOG amplifier is considered a Type BF part.
	An applied part that includes a patient connection which can be disconnected from the patient immediately is a Type B part. The [Subject] is a Type B part.
	Refer to the Instructions for Use
	Observe precautions for handling electrostatic sensitive devices
	It is against the law to dispose of electronic devices in the trash. The crossed-out wheeled bin symbol shows that the components cannot simply be tossed into the trash but must be recycled or disposed in accordance to local environmental regulations.
	Chinese RoHS compliance standard where the product contains less than the maximum concentration value of lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, and polybrominated diphenyl ethers.
	Electrical ground
	ETL 5003648 - This device has met Electronic Testing Laboratories standards
	The CE-mark indicates that the manufacturer meets the requirements of Annex II of the Medical Device Directive 93/42/EEC for the quality system.
	Medical Device



2.4 Panel connections



Figure 1 Front Panel Diagram

- A Selects Warm Irrigation (2nd press to cancel)
- B Selects Cool Irrigation (2nd press to cancel)
- C Increase irrigation time by 1 sec per press (30 seconds max.)
- D Decrease irrigation time by 1 sec per press (15 seconds min.)
- E Handle Rest
- F Irrigator status display



Figure 2 Rear Panel Diagram

- | | | | |
|---|------------------------------|---|-------------------------|
| A | Exhaust fan and filter | F | Power Switch |
| B | Handle electronics connector | G | Fuse Holder |
| C | USB B connector | H | AC Power Cord Connector |
| D | Handle Blue tube disconnect | I | Water Inlet Disconnect |
| E | Handle Red tube disconnect | J | Water Outlet Disconnect |
| | | K | Ground lug |

2.5 Installation

The Aqua Stim consumes 600 watts from a standard AC wall outlet. Do not connect other high current devices into the same outlet as it may exceed the current limits of the AC outlet and trip a mains circuit breaker. Contact a local electrician if there are questions about the capabilities of the building circuits.

The Aqua Stim is ventilated by a fan at the back of the device. Do not place the Aqua Stim near a radiator or other heating source. Provide at least 10 cm (4 in) of free space behind the unit to provide adequate circulation.



2.6 Irrigator connections



Do not plug in the handle electrical connector when the irrigator is powered on. If the handle does not operate, power down the irrigator and check the handle electrical cable is plugged in securely into the back of the irrigator.

The Aqua Stim is shipped from Interacoustics without any water in the tank. Please fill the external tank with 3½ L of good quality water (preferably distilled or demineralized) that is not considered “hard water” due to high mineral content. Do not fill above the 3½ L mark. Connect the color coded Inlet (white) / Outlet (grey) tubes between irrigator and the external water tank. Push the tubes into the connectors until they “snap” in. To remove the tubes, push on the small ring next to the tube using two finger tips while pulling gently on the tube. Connect the red and blue tubes from the handle to the back of the irrigator. Verify that the arrow [→] on the red tube’s water filter is pointing away from the irrigator. The electrical connector from the handle plugs into the back of the irrigator. Note that the electrical connector is keyed for orientation. Rotate the connector between the fingers while gently pressing in on the connector until it seats and makes connection. A ground lug is provided on the rear panel for electrical testing by BMETs. Plug in the 240 VAC power cable into the AC power cord connector. If the Aqua Stim is used in conjunction with video nystagmography (VNG) software then connect the USB cable to the VNG computer, otherwise leave the USB cable disconnected.

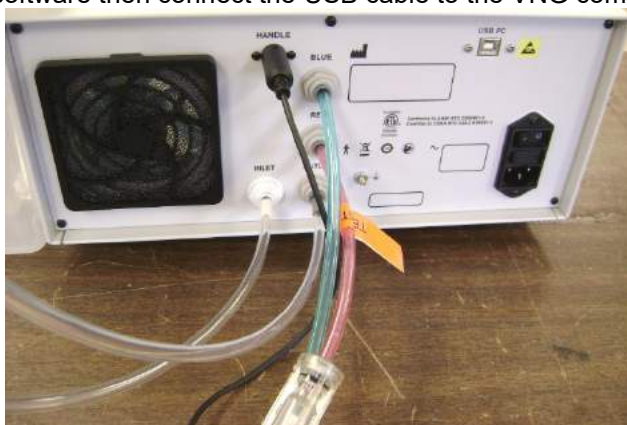


Figure 3 Tubes and Electrical Connection



Figure 4 External tank with pick up filter

2.7 Drawing water from the tank

The external water tank should be placed on the same table as the irrigator. For the first operation, turn on the irrigator using the power switch on the back of the irrigator at the power entry. Once the irrigator has power and the front panel display shows **Select Cool/Warm**, press the “Cool” button on the front panel. The irrigator will draw water from the external water tank and fill the internal heater tank. There will be a change in pitch of the irrigation pump as it self-primed. Some water will flow from the irrigator back into the external tank from the overflow tube. Read the front panel display to confirm the current water temperature is displayed and that the irrigator is heating to the preset 30°C temperature.

The Aqua Stim uses two filters to catch any contaminants in the water. A pickup filter is attached to the end of the inlet tube in the external tank. An inline filter is placed within the handle’s red tube. Inspect these filters periodically to make sure they are not blocked.



Always use fresh water in the external tank. **Tap water** may be used in the Aqua Stim provided that the water is not “hard water” due to excess mineral content. Build up and / or damage from mineral deposits is not covered under warranty. **Demineralized or distilled water** is always recommended and should be used if the tap water is “hard” due to mineral content or if there is any question about water purity. The user should follow the appropriate cleaning and disinfectant procedure (Refer section 4 for the detailed procedure for maintenance).



3 Operating instructions

3.1 Using the Aqua Stim with VNG/ENG software

The Aqua Stim water irrigator can be configured with compatible¹ VNG/ENG software. The caloric test settings or system settings must be configured to communicate with the Aqua Stim irrigator. When the caloric test is prepared, the irrigator will prepare the irrigator for a warm or cool irrigation based on the test selected. The test will not be able to start until the irrigator has reached the desired temperature. The VNG/ENG software will reflect the status of the irrigator as the irrigator prepares for the desired irrigation.

3.2 Turn on the irrigator

Turn on the power switch on the back panel. The Aqua Stim will initialize and go into the standby state.

Select Cool / Warm

3.3 Attach the hose tip



Use Interacoustics provided soft silicone hose tips placed on the end of the delivery handle. The silicone tips are *single-use-only* to prevent transmission of disease between patients. *Only use silicone tips from Interacoustics.*

To assemble the silicone tip on the delivery handle, slide the tube over the short stainless steel tip as shown. Confirm the silicone tube is on straight and that it tightly grips the tip.



Figure 5 Place silicone tip on irrigation handle.

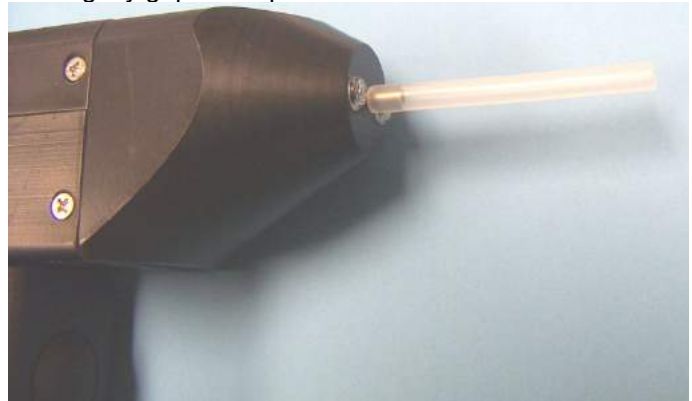


Figure 6 Pull lightly on silicone tip to verify it is secure.

3.4 Maintain water level

As a good practice, verify the external water tank is filled completely with water at the start of the day. A full water tank holds enough water for approximately 14 irrigations. The irrigator will display “**No water in tank**” if there is not enough water in the tank to perform the next irrigation.

For optimal operation, the water in the external tank should be kept up to 10°C (18°F) cooler than the desired testing temperature. If the tank water is too warm for the 30°C irrigation, add cool water or a few ice cubes to the external tank. Power down, power up and press the “Cool” button to flush the internal tank with cooled water.

If the irrigator will not be used for 30 days, drain the irrigator according to section 3. 9 Draining the internal water, then empty the external tank.

¹ Compatible VNG/ENG software includes Spectrum, VN415, VO425, VisualEyes 515, and VisualEyes 525.



3.5 Select the irrigation temperature

If the Aqua Stim is used as a stand-alone device, press the front panel “Cool” button to select the Cool Irrigation or press the front panel “Warm” button to select the Warm Irrigation. The irrigator display will show when the irrigator is ready for irrigation.

Select Cool / Warm

Cool:	30°C	30s
Temp:	25.	
	5°	

3.6 Set the irrigation time

The Aqua Stim default irrigation time is 30 seconds. Using the Aqua Stim default flow setting (500 ml/min) the irrigation volume is 250ml. For the current irrigation, the duration can be reduced from 30 seconds to a minimum of 15 seconds using the front panel up & down “TIME” push buttons. Changing the irrigation duration will also change the irrigation volume.

3.7 Perform the Irrigation



An audiologist or physician should inspect the patient’s ear with an otoscope prior to testing, looking for infection, open wounds, wax impaction, or a perforated eardrum. If any of these are observed, DO NOT use the Aqua Stim.



The purpose of a caloric irrigation is to cause a temperature imbalance between the left and right ear. The irrigation of a functional ear will result in the patient feeling like the patient is spinning for a minute or two after the irrigation is over. This is normal. However, some motion sensitive patients may experience nausea. The examiner should be prepared for some patients who vomit as a result of the irrigation. Do not perform any more irrigations during this visit if the patient vomits.

Prior to irrigation, the patient should be supine with their head elevated 30 degrees. The patient’s head should be at an elevation within 12 inches / 30 cm (higher or lower) relative to the irrigator height. Irrigating with the patient elevation too high or too low could adversely affect the irrigation flow rate.

NOTICE

Irrigation using the handle button is done by the “press and hold” method or the “push and release” method. The irrigation will continue for the predefined duration even if the button is released from “press and hold”.

Once the selected irrigation temperature has been reached, the irrigator will beep and say “Ready”. The LEDs in the handle will also light up. Place the irrigator tip gently into the ear canal, then click the button on the irrigator handle to begin water flow and the VNG/ENG software will begin recording. Direct the water at the ear drum. Catch the water in an emesis basin placed below the ear as it drains from the ear canal. After each irrigation, properly dispose of this contaminated water.

If the irrigation needs to be suddenly aborted, remove the tip from the ear and direct flow into the emesis basin. Press and hold the button on the irrigator handle for 2 seconds. The irrigator will beep, stop the water flow, and display the standby idle screen.

Ten seconds after the irrigation is complete, water will be pumped from the external tank to get ready for the next irrigation. The display will read “Filling...” during this operation.

Once the final irrigations have been completed, remove the silicone tip and clean the handle tip with Sani-Cloth wipes.



3.8 Turn off the irrigator

The Aqua Stim caloric irrigator will go into standby mode from the ready state after ten minutes has elapsed or the irrigation temperature selection button is pressed twice. If the Aqua Stim is used in conjunction with the VNG software, then the software will send the Aqua Stim into standby mode at the end of the test. When the Aqua Stim is in the standby mode, it is safe to turn off the power switch on the back panel.

Select Cool / Warm

3.9 Draining the internal water

The Aqua Stim holds 300 ml of water internally. Some water will remain inside the irrigator and its tubes after irrigations. This water must be drained prior to shipment of the irrigator.

NOTICE To remove the tubes, push on the small ring next to the tube using two finger tips and pull gently on the tube.

1. When the irrigator is in standby mode press the Time Up/Down buttons simultaneously. This will put the irrigator in Drain mode.

Use Handle Drain

2. Point the handle into an empty bucket (with at least 500ml capacity) and click the handle button to initiate a flush of the internal tank.

Draining... 40s

3. At the end of the drain cycle, power off the irrigator.

**Drain Complete
Turn Off Power**

4. Disconnect all the tubes (red, blue, grey and white), the handle electrical connector and the USB cable. Some water will come out of the handle tubes. Some water will come out of the Red / Grey outlet connector. Please have a towel handy to clean up drips. Hang the handle assembly up and put the tubes in a bucket to drain manually.

The Aqua Stim should now be drained of water and ready for shipping. Drain the external tank, disconnect remaining tubes / cables and pack the irrigator components with proper packing material in the provided shipping container.



3.10 Trouble shooting

LCD Display or Problem Observed	Cause	Solution
No Water in Tank	External water tank empty	Refill water tank with water at less than 75°F (24°C). Check hose connections. Select Cool / Warm to retry operation
Fill Cool Water	Water in external tank is warmer than the desired irrigation temperature	Add cooler water to the external water tank then select Cool / Warm to retry operation
Irrig. Timeout	Irrigator left on for 10 minutes without performing another irrigation, will return to Standby screen	Press Cool or Warm to initiate irrigation procedure, otherwise none Select Cool / Warm to retry operation
No water comes out of the irrigator handle after irrigator displays “Ready” and pressing the irrigation button.	Possible blockage in the irrigator handle.	Disconnect the handle from the irrigator. Push air with a syringe into the blue tube to flush out water and impurities. Discard water coming out of the red tube.
Water dribbles out of the irrigation handle when the irrigator is running in Cool or Warm mode. This happens before “Ready” state is reached.	Fault in the electronics power module for the handle.	Check the handle’s electrical connector on the back panel is properly connected.
Too Warm	Residual warm water in the irrigator preventing reaching the desired temperature	Stop current operation by pressing Cool / Warm. Then retry desired temperature Cool / Warm. Aqua Stim will purge the internal water by filling from the external water tank.
Handle does not light or respond to button press.	Electrical connector not making good contact.	Power-down irrigator then check connections on back.
Call TechSupport (note additional error message)	Internal problem requiring technical support for assistance	Call Interacoustics Technical Support with the additional error message on the display (e. g. “Level Sense Error” etc).

Prior to calling Interacoustics Technical Support note the firmware version of the Aqua Stim irrigator. This is shown on the display briefly when the Aqua Stim first starts.

**Select Cool / Warm
Aqua Stim v1. 6**



4 Maintenance

4.1 General cleaning procedure

4.1.1 General Precautions

- Before cleaning always switch off and disconnect from the power supply
- Do not autoclave, sterilize, or immerse the instrument or accessory in any fluid
- Do not use hard or pointed objects to clean any part of the instrument or accessory
- Do not let parts that have been in contact with fluids dry before cleaning
- Disinfectant. The use of organic solvents and aromatic oils must be avoided.
- Ensure that isopropyl alcohol does not have contact with, any screens on the instruments
- Ensure that isopropyl alcohol does not have contact with, any silicone tubes or rubber parts
- To prevent a degradation of the material by the Isopropanol it is recommended to irrigate the water system with distilled water after disinfecting with 70-85% v/v Isopropyl alcohol.
- It is recommended that the operator use gloves during the operation of the AquaStim™ Caloric Irrigator and the accessories. The gloves are to be changed after each patient, to minimize the contact points and cross contamination.
- Use **distilled or demineralised water** if the local tap water available is of poor quality. It is also recommended to use **distilled or demineralised water** if the system usage frequency is low. This will prevent bacterial and algae growth and deposit of minerals on critical internal components. When the Aqua Stim is not in use, the hose should be coiled using the hose management tape.
- Single use components should be replaced after every patient use to avoid potential cross contamination from patient to patient.

4.1.2 Recommended cleaning agent and frequency

The AquaStim™ caloric irrigator and the temperature-controlled water is intended for contact with intact skin only. According to the Spaulding classification used by WHO¹, it is therefore regarded a non-critical low risk product in regard to contamination control. The WHO's recommended level of decontamination for non-critical devices is cleaning. Disinfection and sterilization are not recommended. However, in case of an epidemic outbreak, disinfection of both the surface of the device and the entire water system can be performed.

1. [WHO "Decontamination and Reprocessing of Medical Devices for Health-care Facilities"](#)

Cleaning Agent

The AquaStim™ Caloric Irrigator is recommended to undergo the regular cleaning procedure with appropriate cleaning agent. The cleaning agent must be able to remove any foreign material (e. g. , soil, organic, in-organic, and microbial contaminants) from the system. It is recommended to use nonabrasive cleaning solution like pH neutral detergent as cleaning agent.

Disinfectant

Though the AquaStim™ Caloric Irrigator is categorized as non-critical device, it is also recommended to disinfect the system on a regular interval with an appropriate disinfectant to reduce biofilm development.

It is recommended to use **70-85% v/v Isopropyl alcohol** as disinfectant agent for the AquaStim™ Caloric Irrigator which is also approved by WHO¹¹¹ as standard disinfectant agent. Isopropyl alcohol 70-85% v/v will also have a mild effect on the materials. The user can also alternatively use **chlorine solution** according to their local standards as disinfectant agent.

Frequency

The minimum requirement for cleaning and disinfection frequencies are discussed below in detail. However, if the user can decide to improve their cleaning standards with additional cleaning/disinfection especially during any epidemic outbreaks as per local clinic standards & requirements and WHO recommendations.



4.2 After every patient use

Maintain the water level in the Aqua Stim external water tank. After each examination of a patient, it should be ensured that there is no contamination on the parts in connection with the patient.

4.3 Daily

External surface of the device which is generally used by the healthcare professional is to be cleaned daily with recommended cleaning solution (refer section 4. 1. 2).

Cleaning procedure: Wipe off the external surface with a disposable, clean, non-linting cloth which is damped in the cleaning solution until all visible soil is removed. Ensure that moisture doesn't enter the critical areas of device. Cleaning solution should be changed at each cleaning session and when visibly soiled.

4.4 Weekly

Internal & external water tube system, external water tank, pickup filter in the external water tank and in-line filter shall be disinfected every week.

The user shall choose Isopropyl alcohol (70-80% v/v) or chlorine solution to disinfect the system. The instructions for disinfection procedure are discussed below.

Disinfection with Isopropyl alcohol (70-80% v/v):

Before starting the disinfection procedure, the user should drain the irrigator by pressing the two buttons on the right side of the irrigator display. Clean the external water tank with dish soap and warm water before you start the disinfection procedure. Then fill the external water tank with 600 ml of **Isopropyl alcohol (70-80% v/v)**. Run one complete cycle of cool irrigation. Then drain the irrigator appropriately. Discard the excess solution carefully in the sink from the external water tank.

Clean the external water tank again with dish soap and warm water. Also, rinse external water tank with distilled water to remove alcohol residues. Refill the external water tank with 600 ml of distilled water and run couple of cool irrigation cycles to rinse off the alcohol residues from the system.

As a final step, check both the external pickup and in-line filters for any visual debris, if no debris seen you can continue using the filters for the normal use. If you see any debris, the filter to be replaced appropriately. Refer section 4. 8 for filter replacement procedure.

Disinfection with Chlorine solution:



Interacoustics recommends using appropriate safety precautions such as protective goggles, apron, and gloves when working with chlorine. Leaving the chlorine solution in the irrigator for longer than 4 hours could cause permanent damage to irrigator components.

Clean the external water tank with dish soap and warm water before you start the disinfection procedure. Then fill the external water tank with 60 ml of chlorine solution make up the volume with water to 2 L. Run three consecutive cool irrigation cycles. Drain the irrigator appropriately. Discard the excess solution carefully in the sink from the external water tank.

Clean the external water tank again with dish soap and warm water. Also, rinse external water tank with distilled water to remove disinfectant residues. Refill the external water tank with 900 ml of distilled water and document the water pH in the external tank. Run three cool irrigation cycles to rinse off the chlorine residues from the system. At the end of 3rd irrigation cycle, check the pH level of irrigated water. If the pH level of irrigated water doesn't match with the water pH in the external tank, repeat the cool irrigation cycle until the target water pH is achieved.



As a final step, check the both external pickup and in-line filters for any visual debris, if no debris seen you can continue using the filters for the normal use. If you see any debris, the filter to be replaced appropriately. Refer section 4. 8 for filter replacement procedure.

4.5 Quarterly

Verification of the irrigation flow rate can be performed by the clinician with the use of a graduated cylinder of 500ml capacity with 5ml marks. The clinician should perform a cool irrigation and measure the output water amount. If the volume of water is in excess of 265ml, then contact Interacoustics for irrigator calibration.

If the volume is less than 235ml, then disconnect the water filter assembly from the handle and connect the handle's red tube directly to the irrigator bypassing the water filter assembly entirely. Perform a cool irrigation and measure the output water amount. If the volume is 250ml, then follow the instructions in 4. 9 Replacing the water filters section. If the volume is still low, then contact Interacoustics for further troubleshooting.

4.6 Annually

Replace the cone filter /in-line filter in the internal water tube system every year as a part of maintenance. And, clean out or replace the pick-up filter in the external water tank. The irrigator system is to be cleaned with acetic acid every year as a part of demineralization procedure (mineral deposit removal).

Laboratory verification of the irrigation temperatures and flow rates should be performed annually by a trained service technician. If the irrigator fails temperature or flow rate verification, contact Interacoustics to send back the irrigator for factory calibration. Note: the irrigator must be drained of water prior to shipment.

4.7 Annual cleaning procedure



Leaving acetic acid & water solution in the irrigator for longer than 4 hours could cause permanent damage to irrigator components.

4.7.1 Tools needed

Measuring container, pH strips, 5% acetic acid, graduated cylinder and two in-line filter cones, protective goggles, rubber gloves, and protective apron.

4.7.2 Prepare vinegar & water solution (mineral deposit removal)

Clean the external water tank with dish soap and warm water before you start the demineralization procedure.

Fill the external water tank with 2 liters of water and add 8tsp (40ml) 5% acetic acid. Stir the solution gently. The acetic acid solution is used to remove mineral deposits which is detected by looking at the blue tube and seeing the blue tube opaque or filled with small particulate. Start cool irrigation cycle and this will draw and circulate the solution into the internal tank. Wait until the cycle is completed which will take approximately 10 minutes. After 10 minutes of holding the solution inside the system, drain the irrigator appropriately. Discard the excess solution carefully in the sink from the external water tank.

Clean the external water tank again with dish soap and warm water. Also, rinse external water tank with distilled water to remove vinegar residues. Refill the external water tank with 600 mL of distilled water and document the water pH in the external tank. Run three cool irrigation cycles to rinse off the chlorine residues from the system. At the end of 3rd irrigation cycle, check the pH level of irrigated water. If the pH level of irrigated water doesn't match with the water pH in the external tank, repeat the cool irrigation cycle until the target water pH is achieved.



4.7.3 Prepare irrigator for use

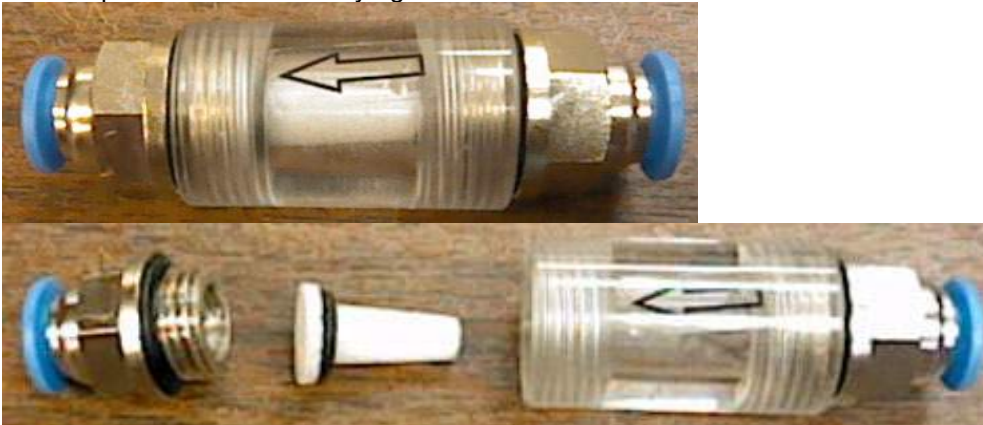
1. Drain the irrigator by pushing the Time Up/Down arrows and following instructions on the irrigator.
2. Remove handle and drain water from the handle.
3. Inspect filter on the red tube of the handle assembly. Replace the cone insert if dirty.
4. Fill the external water tank with fresh water.

4.8 Replacing the water filters

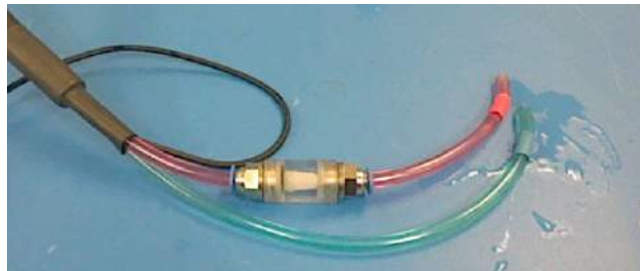
This pick-up filter can be rinsed off if it gets clogged. However, if the filter needs replaced, it can be pulled off the end of the clear intake tube inside the external tank.



If the water filter assembly is not damaged, then the water filter assembly can be disconnected from the red tube and the filter cone replaced. To remove the tubes, push on the small ring next to the tube using two finger tips and pull gently on the tube. The caps can be removed with a 9/16" socket wrench or crescent wrench. The water filter assembly should have an arrow sticker that shows the direction of the water flow – the water will flow from the tapered end of the filter to the larger end for maximum filtration. Use the wrench to open the side where the arrow points. The filter can be removed with a tap of the filter assembly against the table.



After replacing the filter, close the water filter assembly and tighten just past finger tight using the socket wrench or crescent wrench. Check direction of the filter cone in the water filter assembly. The tapered end should point towards the irrigator as water is pushed into this tube from the irrigator. Add the new water filter assembly to the Red line. Trim the red tube on filter assembly to the same length as the blue tube before connecting to the irrigator.





4.9 Warranty and service

4.9.1 Product warranty

Interacoustics warrants that:

- The AquaStim™ system is free from defects in material and workmanship under normal use and service for a period of 12 **months from the date of delivery** by Interacoustics to the first purchaser
- Accessories are free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of delivery by Interacoustics to the first purchaser

If any component requires service during the applicable warranty period, the purchaser should communicate directly to the local distributor to determine the appropriate repair facility. Repair or replacement will be carried out at Interacoustics' expense, subject to the terms of this warranty. The product requiring service should be returned promptly with proper packing, and postage prepaid. Loss or damage in return shipment to Interacoustics shall be at purchaser's risk. In no event shall Interacoustics be liable for any incidental, indirect or consequential damages in connection with the purchase or use of any Interacoustics product. This shall apply solely to the original purchaser.

This warranty shall not apply to any subsequent owner or holder of the product. Furthermore, this warranty shall not apply to, and Interacoustics shall not be responsible for, any loss arising in connection with the purchase or use of any Interacoustics product that has been:

- repaired by anyone other than an authorized Interacoustics service representative;
- altered in any way so as, in Interacoustics judgement, to affect its stability or reliability;
- subject to misuse or negligence or accident, or which has had the serial or lot number altered, effaced or removed; or
- improperly maintained or used in any manner other than in accordance with the instructions furnished by Interacoustics.

This warranty is in lieu of all other warranties, express or implied, and of all other obligations or liabilities of Interacoustics. Directly or indirectly, Interacoustics does not give/grant the authority to any representative or other person to assume on behalf of Interacoustics for any other liability in connection with the sale of Interacoustics products.

INTERACOUSTICS DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FOR FUNCTION OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION.

4.9.2 Concerning product repair / service

Interacoustics is responsible for the validity of the CE marking, effects on safety, reliability and performance of the equipment if:

- Assembly operations, extensions, readjustments, modifications or repairs are carried out by authorized persons
- A 1-year service interval is maintained
- The electrical installation of the relevant room complies with the appropriate requirements, and
- The equipment is used by authorized personnel in accordance with the documentation supplied by Interacoustics

The customer shall reach out to the local distributor to determine the service/repair possibilities including onsite service/repair. It is important that the customer (through local distributor) fills out the **RETURN REPORT** every time when the component/product is sent for service/repair to Interacoustics.



4.10 Component disposal

NOTICE

In case of a conflict, all information contained herein is superseded by National, State or Local regulations. If there is any question, contact the local area authorities for compliance.

Hazardous material

There are no hazardous materials in the system.

Packing material

If storage space allows, packing material for the irrigator should be retained. This original packing material affords the maximum protection in case any of these items must be returned for service. All cardboard or paper should be recycled with a local disposal company if possible. If storage space for the foam packaging material is not available, visit the Alliance of Foam Packaging Recyclers website, <http://www.epspackaging.org/>, for suggestions and locations for recycling.

Electronic parts

Some electronic parts can be recycled. The following web site lists the states within the USA and identifies their programs: <http://www.nrc-recycle.org/resources/electronics/policy.htm>.

Disposal of product



It is against the law to dispose of electronic devices in the trash. The crossed-out wheellie bin symbol appears on the irrigator showing that the components cannot simply be tossed into the trash. Those electronic devices must be recycled or disposed in accordance to local environmental regulations.

4.11 Malfunction

In the event of a product malfunction, it is important to protect patients, users, and other persons against harm. Therefore, if the product has caused, or potentially could cause such harm, it must be quarantined immediately.

Both harmful and harmless malfunctions, related to the product itself or to its use, must immediately be reported to the distributor where the product was acquired. Please remember to include as many details as possible e. g. the type of harm, serial number of the product, software version, connected accessories and any other relevant information.

In case of death or serious incident in relation to the use of the device, the incident must immediately be reported to Interacoustics and the local national competent authority.



5 General technical specifications

5.1 Device specifications

Water Flow Rate:	250ml / 30 seconds (fixed)
Flow accuracy:	+/- 15ml / 30 seconds
Duration of irrigation:	30 seconds (Adjustable from 30 to 15 seconds)
Irrigation Temperature:	30°C Cool irrigation 44°C Warm irrigation
Accuracy at tip:	+/- 1°C
Stability of temperature:	+/- 1°C
External water container:	~ 3. 5 liters (approx. 14 irrigations)
VNG computer interface:	USB 1,1 or faster
Dimensions w/ handle:	35(w) x 32(d) x 22(h) cm / 13. 8(w) x 12. 6(d) x 8. 7(h) in.
Water hose (detachable):	3m (9. 8ft) length with a rubber protective cover
Weight of hose and handle:	0. 9 kg (2 lbs)
Weight of cabinet (drained):	5. 4 kg (11. 9 lbs)
Voltage:	110-130 VAC or 220-240 VAC
Power:	600 watts
External Fuse size:	110 -130VAC: 2x T8AH 250V Fuses 220 - 240VAC: 2x T4AH 250V Fuses
Internal Fuse:	220 – 240VAC: T2. 5AL 250V

The CE-mark indicates that Interacoustics A/S meets the requirements of Annex II of the Medical Device Directive 93/42/EEC.

Approval of the quality system is made by TÜV – identification no0123

The DEVICE is an active, diagnostic medical product according to the class IIa of the EU medical directive 93/42/EEC.

Compliance

Standards: IEC 60601-1:2005 + AMD1:2012- Basic safety & Essential Performance
IEC 60601-1-2:2012 - EMC



5.2 Electromagnetic compatibility (EMC)

This section is valid for the AquaStim system including all variants.

This equipment is suitable in hospital and clinical environments except for near-active HF surgical equipment and RF-shielded rooms of systems for magnetic resonance imaging, where the intensity of electromagnetic disturbance is high.

NOTICE: ESSENTIAL PERFORMANCE for this equipment is defined by the manufacturer as:
This equipment does not have an ESSENTIAL PERFORMANCE Absence or loss of ESSENTIAL PERFORMANCE cannot lead to any unacceptable immediate risk.
Final diagnosis shall always be based on clinical knowledge.

Use of this equipment adjacent to other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Use of accessories and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. The list of accessories and cables can be found in this section.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result in improper operation.

This equipment complies with IEC60601-1-2:2014, emission class B group 1.

NOTICE: There are no deviations from the collateral standard and allowances uses.

NOTICE: All necessary instructions for maintenance comply with EMC and can be found in the general maintenance section in this instruction. No further steps required.
To ensure compliance with the EMC requirements as specified in IEC 60601-1-2, it is essential to use only the accessories as specified in this instruction.

Anyone connecting additional equipment is responsible for making sure the system complies with the IEC 60601-1-2 standard.

Conformance to the EMC requirements as specified in IEC 60601-1-2 is ensured if the cable types and cable lengths are as specified below:

Description	Length (meters)	Screened (Yes/No)
Power leads	<3	No
USB	<3	Yes



Guidance and manufacturer's declaration - electromagnetic emissions

The <i>AquaStim</i> is intended for use in the electromagnetic environment specified below. The customer or the user of the <i>AquaStim</i> should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The <i>AquaStim</i> uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The <i>AquaStim</i> is suitable for use in all commercial, industrial, business, and residential environments.
Harmonic emissions IEC 61000-3-2	Complies Class A Category	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Recommended separation distances between portable and mobile RF communications equipment and the *AquaStim*.

The <i>AquaStim</i> is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the <i>AquaStim</i> can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the <i>AquaStim</i> as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.23\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30
For transmitters rated at a maximum output power not listed above, the recommended separation distance <i>d</i> in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
Note 2 These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			



Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The **AquaStim** is intended for use in the electromagnetic environment specified below. The customer or the user of the **AquaStim** should assure that it is used in such an environment.


Immunity Test	IEC 60601 Test level	Compliance	Electromagnetic environment - guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	+8 kV contact +15 kV air	+8 kV contact +15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be greater than 30%.
Electrical fast transient/burst IEC61000-4-4	+2 kV for power supply lines +1 kV for input/output lines	+2 kV for power supply lines +1 kV for input/output lines	Mains power quality should be that of a typical commercial or residential environment.
Surge IEC 61000-4-5	+1 kV differential mode +2 kV common mode	+1 kV differential mode +2 kV common mode	Mains power quality should be that of a typical commercial or residential environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	< 5% <i>UT</i> (>95% dip in <i>UT</i>) for 0. 5 cycle 40% <i>UT</i> (60% dip in <i>UT</i>) for 5 cycles 70% <i>UT</i> (30% dip in <i>UT</i>) for 25 cycles <5% <i>UT</i> (>95% dip in <i>UT</i>) for 5 sec	< 5% <i>UT</i> (>95% dip in <i>UT</i>) for 0. 5 cycle 40% <i>UT</i> (60% dip in <i>UT</i>) for 5 cycles 70% <i>UT</i> (30% dip in <i>UT</i>) for 25 cycles <5% <i>UT</i> for 5 sec	Mains power quality should be that of a typical commercial or residential environment. If the user of the AquaStim requires continued operation during power mains interruptions, it is recommended that the AquaStim be powered from an uninterruptable power supply or its battery.
Power frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or residential environment.

Note: *UT* is the A. C. mains voltage prior to application of the test level.



Guidance and manufacturer's declaration — electromagnetic immunity

The **AquaStim** is intended for use in the electromagnetic environment specified below. The customer or the user of the **AquaStim** should assure that it is used in such an environment,

Immunity test	IEC / EN 60601 test level	Compliance level	Electromagnetic environment – guidance
<p>Conducted RF IEC / EN 61000-4-6</p> <p>Radiated RF IEC / EN 61000-4-3</p>	<p>3 Vrms 150kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2,7 GHz</p>	<p>3 Vrms</p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any parts of the AquaStim, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:</p> $d = 1,2\sqrt{P}$ <p>$d = 1,2\sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d = 2,3\sqrt{P}$ 800 MHz to 2,7 GHz</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range. ^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies
 NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^{a)} Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **AquaStim** is used exceeds the applicable RF compliance level above, the **AquaStim** should be observed to verify normal operation, If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the **AquaStim**.

^{b)} Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Return Report – Form 001



Opr. dato: 2014-03-07 af: EC Rev. dato: af: MSt Rev. nr.: 4

Company: _____

Address: _____

Phone: _____

Fax or e-mail: _____

Address

10393 West 70th Street
Prairie
MN 55344
USA

Phone

(+1) 800 947 6334

Fax

(+1) 952 903 4200

E-mail

rmd@interacoustics-us.com

Contact person: _____ Date: _____

Following item is reported to be:

- returned to INTERACOUSTICS for: repair, exchange, other: _____
- defective as described below with request of assistance
- repaired locally as described below
- showing general problems as described below

Item: _____ **Type:** _____ **Quantity:** _____
Serial No.: _____ Supplied by: _____
Included parts: _____

Important! - Accessories used together with the item must be included if returned (e.g. external power supply, headsets, transducers and couplers).

Description of problem or the performed local repair:

Returned according to agreement with: Interacoustics, Other : _____

Date : _____ Person : _____

Please provide e-mail address or fax No. to whom Interacoustics may confirm reception of the returned goods:

The above mentioned item is reported to be dangerous to patient or user ¹

In order to ensure instant and effective treatment of returned goods, it is important that this form is filled in and placed together with the item.
Please note that the goods must be carefully packed, preferably in original packing, in order to avoid damage during transport. (Packing material may be ordered from Interacoustics)

¹ EC Medical Device Directive rules require immediate report to be sent, if the device by malfunction deterioration of performance or characteristics and/or by inadequacy in labelling or instructions for use, has caused or could have caused death or serious deterioration of health to patient or user. Page 1 of 1