
Instructions for Use – US

Aqua Stim

Caloric Irrigator

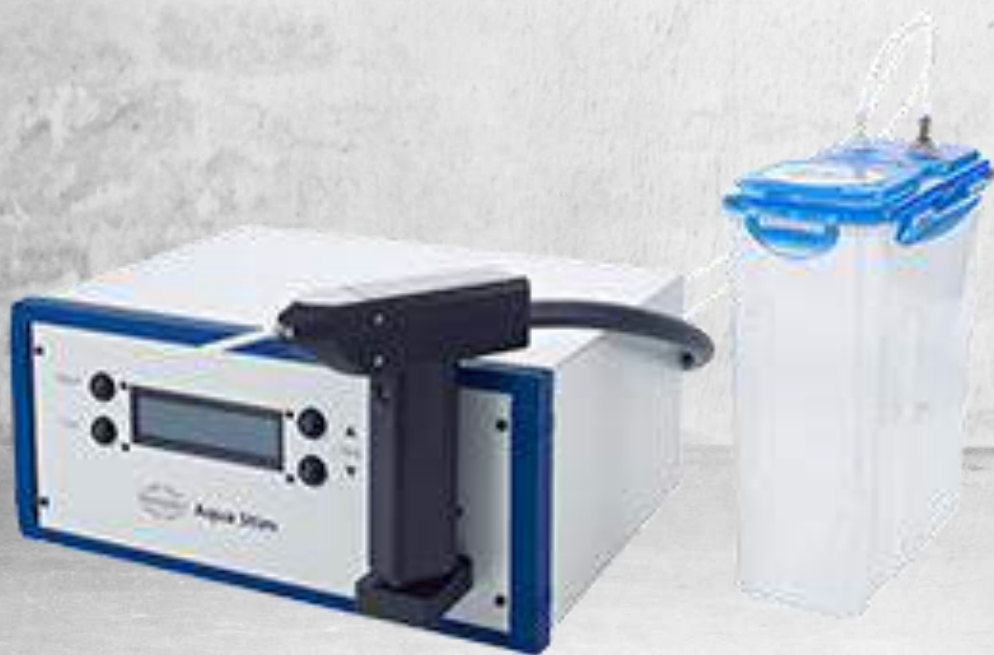


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1 Introduction

1.1 About this Manual

This manual is valid for the Aqua Stim Air 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 VNG system during caloric testing. The Aqua Stim will interface with VN415/VO425 when using InteracousticsVNG software version 7.0.6 or later via USB. The Aqua Stim USB driver is available on the Interacoustics Installation CD.



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 your local Interacoustics distributor. Do not attempt to repair the unit yourself.

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.



Do not perform irrigation on patients with tympanic membrane perforations.

1.3 Product Description




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. .

The systems consist of the following included and optional parts:

Qty	Designation
Included parts:	
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 Water Filter
Accessories:	

1.4 Warnings and Precautions

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

	WARNING indicates a hazardous situation which, if not avoided, could result in death or serious injury.
	CAUTION , used with the safety alert symbol, indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.
	NOTICE is used to address practices not related to personal injury.

Interacoustics – Steps marked with the Interacoustics logo are automatically performed by the USB interface with Interacoustics VNG software.

2 Unpacking and Installation

2.1 Unpacking and Inspection

Check box and contents for damage

When the instrument is received please check the shipping box for rough handling and damage. If the box is damaged it should be kept until the contents of the shipment have been checked mechanically and electrically. If the instrument is faulty please contact your local distributor. Keep the shipping material for the carrier's inspection and insurance claim.

Keep carton for future shipment

The Aqua Stim Water Irrigator comes in its own shipping carton, which is specially designed for the Aqua Stim Water Irrigator. Please keep this carton. It will be needed if the instrument has to be returned for service. If service is required please contact your local distributor.

Reporting Imperfections

Inspect before connection

Prior to connecting the product it should once more be inspected for damage. All of the cabinet and the accessories should be checked visually for scratches and missing parts.

Report immediately any faults

Any missing part or malfunction should be reported immediately to the supplier of the instrument together with the invoice, serial number, and a detailed report of the problem. In the back of this manual you will find a "Return Report" where you can describe the problem.


2.2 Storage

Environmental Conditions



The Aqua Stim may not be used in rooms where there are explosion risks. The equipment is not suitable for use in the presence of flammable anesthetic mixtures with air or oxygen or nitrous oxide.

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, you 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 Conditions	
Temperature of Room	20°C ~ 30°C 68°F ~ 86°F	Temperature of Room	1°C ~ 52°C 33°F ~ 125°F
Relative Humidity	Non-condensing	Relative Humidity	Non-condensing

The external water tank should be placed at the same level or up to 24 inches (60 cm) below the irrigator and water can still be drawn into the irrigator using the internal pump. 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 you 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:

Symbol	Explanation
	Type B applied parts. Patient applied parts that are not conductive and can be immediately released from the patient.
or	Refer to instruction manual
	WEEE (EU-directive) This symbol indicates that when the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling. Failing to do so may endanger the environment.
	Year of manufacture

2.4 Connection Panel Dictionary

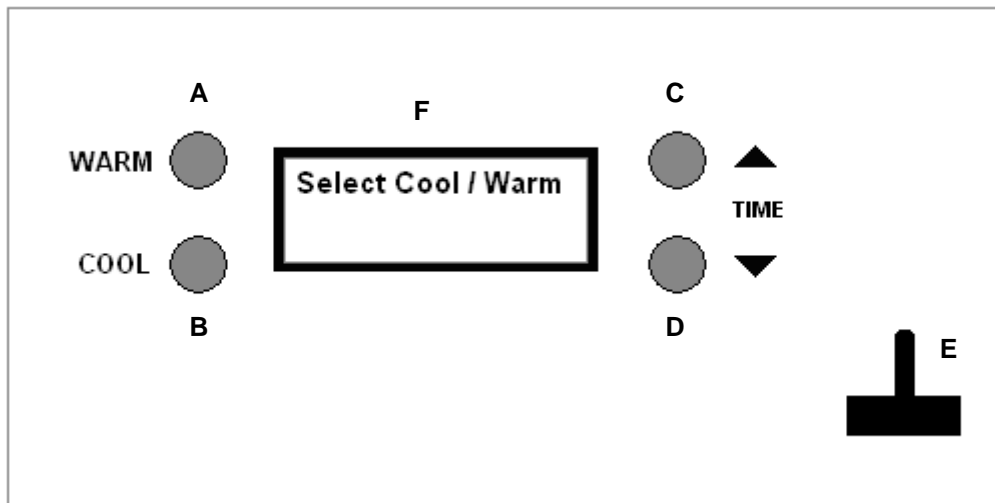


Figure 1 Front Panel Diagram

- 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

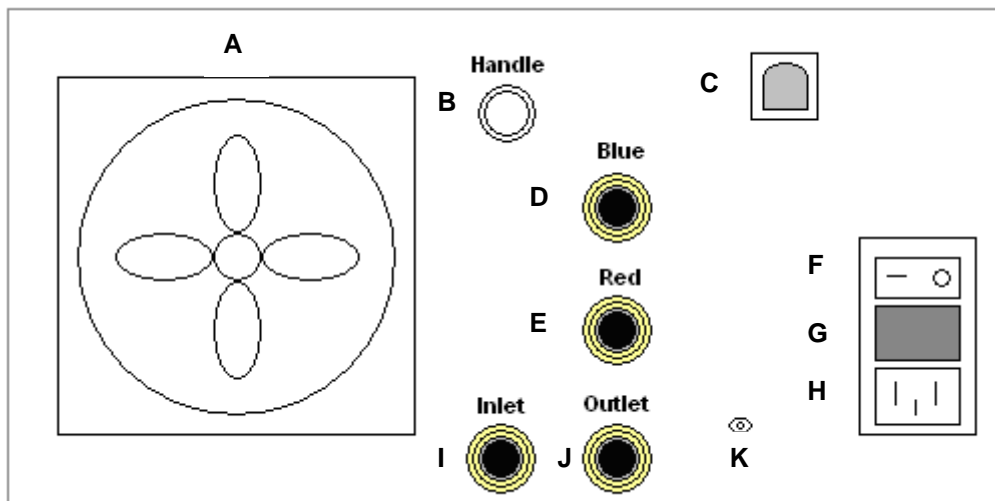


Figure 2 Rear Panel Diagram

- | | |
|-------------------------------|--------------------------------|
| A Exhaust fan and filter | F Power Switch |
| B Handle electrical connector | G Fuse Holder |
| C USB (B-size) connector | H AC Power Cord Connector |
| D Handle Blue tube disconnect | I Water Tank Inlet Disconnect |
| E Handle Red tube disconnect | J Water Tank 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 your local electrician if you have questions about the capabilities of your 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 Connectors



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 a gallon 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 you feel them “snap” in. To remove the tubes you will need to 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 your fingers while gently pressing in on the connector until it seats and makes connection. A ground lug is provided on the rear panel for hospital grade wiring. Lastly, plug in the appropriate 120 VAC or 240 VAC power cable into the AC power cord connector.



Figure 3 Tubes and Electrical Connection



Figure 4 External tank with pick up filter

2.7 Draining Water from the Tank

The external water tank should be placed on the same table as the irrigator or up to 24 inches (60 cm) below 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. You will hear 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 being displayed and that the irrigator is heating to a preset 30°C temperature. If you do not plan to perform irrigations right away you can return the irrigator to standby mode (**Select Cool/Warm**) by pressing the “Cool” button again.

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. If you have any questions, contact our service department.



You should 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 in your mind about water purity. Unclip and remove the top of the external water tank. Wash the container weekly using mild dish soap. Rinse the tank after washing to remove soap residue. Replace cover and check hose connections. Fill with fresh, clean water.

3 Operating instructions

3.1 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 nipple as shown in Figures 4 and 5. Confirm the silicone tube is on straight and that it tightly grips the nipple.



Figure 5 Place silicone tip on irrigation handle nipple. Use silicone Tips provided by Interacoustics that are calibrated for flow rate and heat transfer.

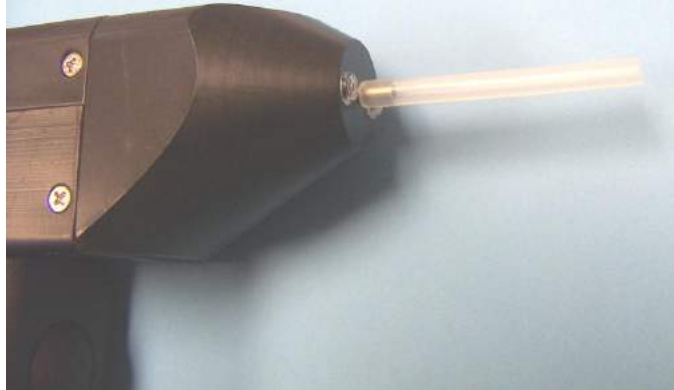


Figure 6 Pull lightly on silicone tip to verify it is secure.

3.2 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 alert you if there is not enough water in the tank to perform the next irrigation by displaying “No water in tank”.

For optimal operation, the water in the external tank should be kept between 68°F (20°C) and 75°F (24°C). Warm water in the tank above 27°C will prevent 30°C irrigations. If the tank water is too warm for the 30°C irrigation, you may 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.

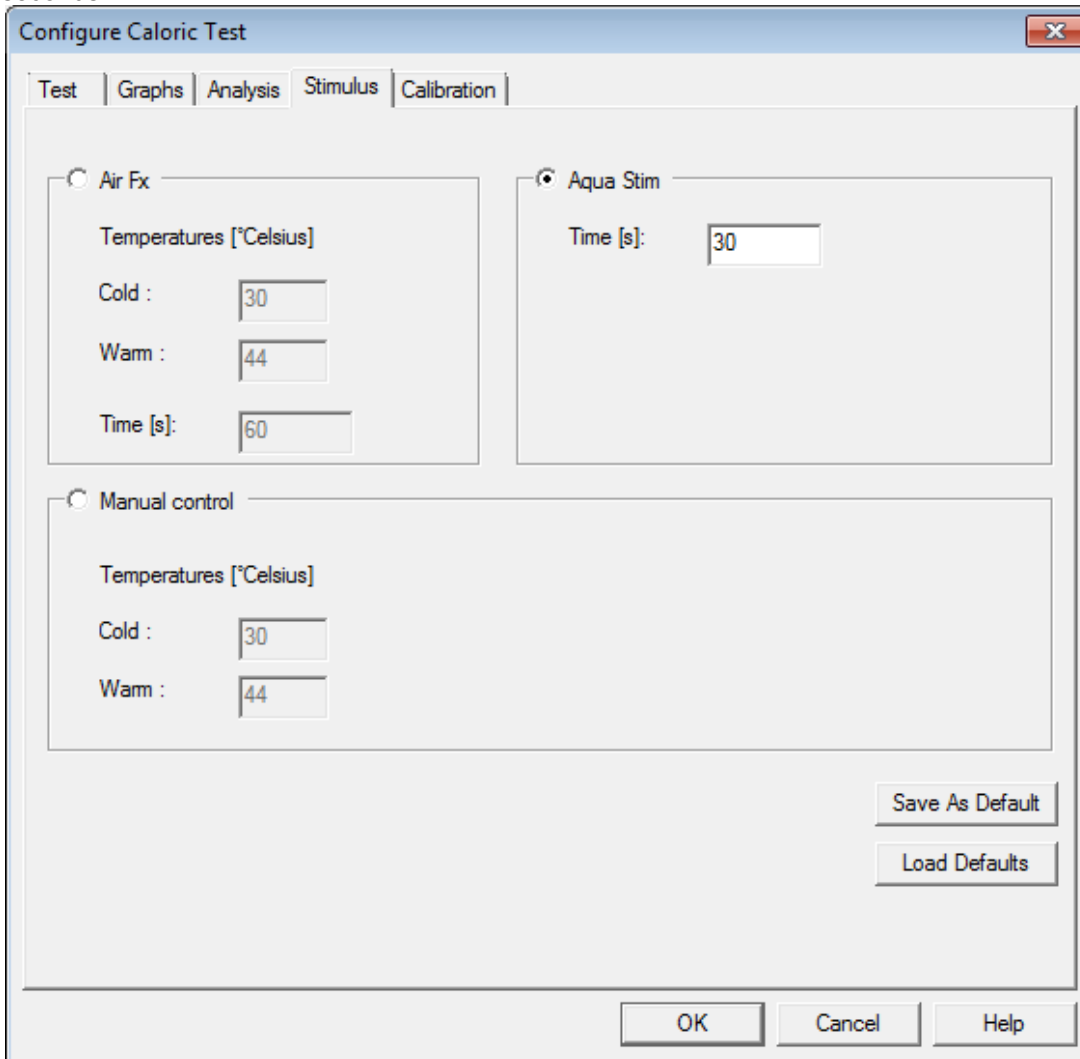
If you have not used or do not plan to use the irrigator for a couple of weeks, drain the irrigator using the drain procedure in the **Error! Reference source not found.** to remove any water. Then empty the external tank.



You should 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. **Deminerlized 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 in your mind about water purity. Unclip and remove the top from the external water tank. Wash the container weekly using mild dish soap. Rinse the tank after washing to remove soap residue. Replace cover and check tube connections. Fill with fresh, clean water.

3.3 Select Automatic Control of the Irrigator

If you have an Interacoustics VN415/VO425 video recording system, then you can set up the Interacoustics software to automatically control the Aqua Stim irrigator. In the “Configure Caloric Test” menu for caloric testing, select the stimulus tab and then select the test time in seconds. The flow standard defines the water flow during test. The Aqua Stim follows the BSA (British Society of Audiology) standard, which is 500ml/min (recommended time = 30 sec.). The water temperature is fixed to 30°C for cold irrigation and 44°C for warm irrigation. The irrigation time can be set between 15 and 40 seconds.

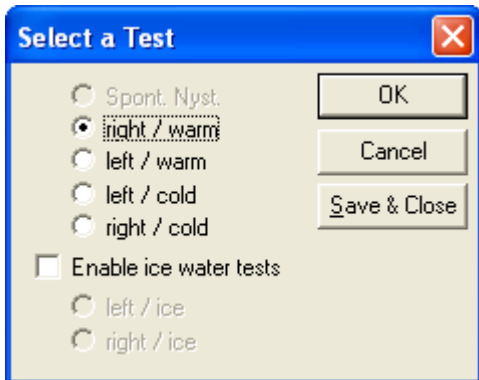


3.4 Select the Irrigation Temperature

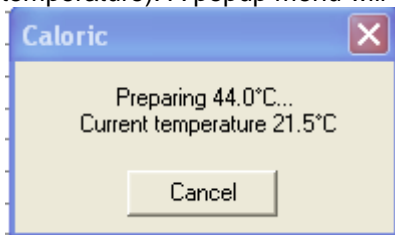
Select the irrigation you wish to perform from the Interacoustics software by first clicking on the caloric test



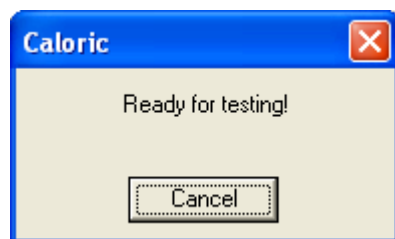
icon and then selecting the green arrow to start/stop a caloric test. From the pop-up menu click the button for the test you would like to start and then press OK to begin the test process.



The Irrigator will be automatically initiated to the correct temperature setting (cool or warm default temperature). A popup menu will show you the status of the irrigator preparation of the temperature.



When the irrigator reaches the correct temperature, you will hear a beep and a popup menu will appear letting you know you can now begin testing.



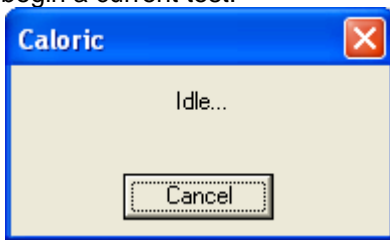
You may now lift the irrigator handle and position the irrigator tip in the ear canal. Once the tip is properly positioned and the patient has been instructed, press the start button on the irrigator handle and water will begin to flow, and the test recording time will start. After the designated time is reached, the water flow will stop and the recording will continue until the test completion time is reached.

Note: if you manually change the temperature on the Aqua Stim itself by depressing one of the temperature buttons, it will not change the temperature in the Interacoustics software. If you cancel the test at anytime the irrigator will go into rest mode until you click on the green arrow button to start another test.

If you attempt to manually change the temperature once you have collected data you will receive an error message warning you that the temperature change is not allowed.



If you attempt to manually change the temperature while it is trying to reach a selected temperature, you will get a message telling you the irrigator is idle and the irrigator will go into rest mode. The irrigator will also show an idle state if you attempt to manually change the temperature while the software is waiting for you to begin a current test.



If the Aqua Stim is used as a stand-alone device without Interacoustics software, 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 tell you when the irrigator is ready for you to irrigate.

Select Cool / Warm

Cool:	30°C	30s
Temp:	25.5°	250ml

3.5 Set the IrrigationTime

The Aqua Stim default irrigation time is 30 seconds. Using the Aqua Stim default flow setting (500 ml/min) the irrigation volume is 250ml. This is indicated on the display while the temperature set point is being reached. For the next 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. If you wish to change the default irrigation time please refer to the **Error! Reference source not found..**

3.6 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.

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 will adversely affect the irrigation flow rate.

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 external ear canal, then click the button on the irrigator handle to begin water flow. 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.

NOTICE

You can irrigate using the handle button “press and hold” method. The irrigation will continue for the predefined duration even if the button is released from “press and hold”. Once the irrigator button has been pushed to begin testing, water will continue to flow until either the preselected test time is reached or until you hit Stop in the software icon tool bar



Caloric test eye movement recording will begin automatically after the irrigator handle’s button has been pressed.

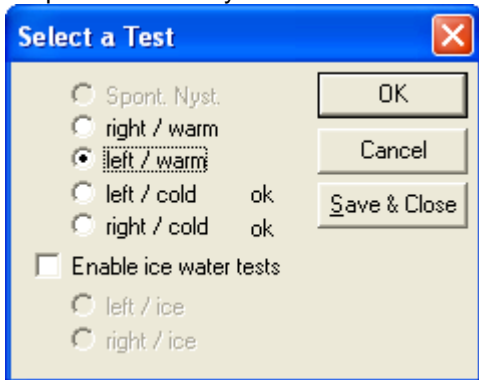
During irrigation, the display will show the elapsed test time.



If the irrigation needs to be suddenly aborted, remove the tip from the ear and direct flow into the catch 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. You will need to select the Cool or Warm temperature.

Continue eye movement recording and follow normal caloric testing protocol (e.g. alerting tasks, look for peak response, test for fixation suppression etc). The irrigator will be automatically set to the next irrigation’s temperature when you select the next irrigation subtest from the drop menu.



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

3.7 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.

Draining the internal water using handle

1. Aqua Stim allows you to drain the internal water using the irrigation handle. 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**

NOTICE

To remove the tubes you will need to push on the small ring next to the tube using two finger tips while pulling gently on the tube.

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. Set the handle assembly aside and drain manually.

If you need to perform the draining procedure manually, use the following steps:

Manual draining procedure

1. Disconnect the handle tubes (red and blue) and its electrical connector. Some water will come out of the handle tubes. Some water will come out of the Red outlet connector. Please have a towel handy to clean up drips. Set the handle assembly aside.
2. Disconnect the tube with white label from "Inlet" connector on the back panel **and** the inlet connector on the water tank.
3. Move the tube with grey label from the "Outlet" connector to the "Red" connector on the back panel. Do not disconnect this tube from the external tank.
4. Power on the irrigator and press the "Cool" button. The display will read "Filling" and water from within the irrigator will be purged out to the external tank.
5. When the irrigator gives the "No Water in Tank" message, turn off the irrigator.
6. Drain water from the handle assembly by allowing gravity to drain the water out.

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.

3.8 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) 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 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).

4 Maintenance

4.1 General Maintenance Procedures

The performance and safety of the instrument will be kept if the following recommendations for care and maintenance are observed:

- The instrument must go through at least one annual overhaul, which should be made by an authorised workshop in order to guaranty proper service and repair as Interacoustics provides the necessary circuit diagrams etc. to these repair shops.
- To ensure that the reliability of the instrument is kept, it is recommended that the operator at short intervals, for instance once a day, perform a test on a person with known data. This person could be the operator him/herself.
- After each examination of a patient, it should be ensured that there is no contamination on the parts in connection with the patient. General precautions must be observed in order to avoid that disease from one patient is conducted to others. If ear cushions or ear tips are contaminated, it is strongly recommended to remove them from the transducer before they are cleaned. By frequent cleaning water should be used, but by severe contamination it may be necessary to use a disinfectant. The use of organic solvents and aromatic oils must be avoided.

4.2 Preventive Maintenance

Maintain the water level in the Aqua Stim external water tank. Use **distilled or demineralised water** if the tap water available in your clinic is of poor quality. This will prevent bacterial and algae growth and to prevent deposit of minerals on critical internal components.

When the Aqua Stim is not use, the hose should be coiled using the hose management tape.

Weekly

Clean the external water tank using soapy water and rinse with fresh water weekly. The external tank has a pickup filter in the line connected to the white (Inlet) connector.

Monthly

Check the pickup filter in the external water tank and the in-line filter once a month for debris. The pickup filter can be rinsed out and used again if the contamination is removed. Replacement pickup filters and in-line filters are available from Interacoustics.

Annually

Calibration of the irrigation temperatures should be performed on an annual basis by Interacoustics (or sooner if the operator suspects any change in performance). Please refer to the **Error! Reference source not found.** for instructions on draining the water prior to shipment.

4.3 Cleaning Procedure to Reduce Bio-film Build-up inside the AquaStim™ Caloric Irrigator

- With a pH strip measure and document the pH of water from the irrigator taken during cool irrigation before the cleaning solution is introduced.
- Add 1/4cup (60ml) of household bleach to a full Irrigator external tank
- Power on the irrigator and select a cool irrigation cycle.
- Perform three consecutive cool caloric irrigations into a irrigator catch basin or larger container. Carefully pour this bleach water into sink after each irrigation.
- This completes the sanitation process, now the irrigator must be returned to a clinically usable condition.
- Drain the water from the irrigator as described in the User's manual
- Empty of water and scrub the external tank in a sink with dish soap in warm water. Rinse external tank with warm water.

- Reconnect external tank tubing and fill external tank with fresh cool water.
- Reconnect the handle hoses and electrical cable to irrigator.
- Power on the irrigator and select a warm cycle.
- Irrigate the warm water into the catch basin cycle then repeat the warm irrigation to flush the bleach solution from the irrigator.
- Check the flow rate to confirm flow is within specifications and to determine that the water filters are not clogged and thus restricting flow.
- Check the pH of water in the catch basin after the second cycle to determine if the pH has returned to the normal pre-cleaning value. If the pH is still too low, repeat the warm cycle irrigations until the pH matches or exceeds the reading before the cleaning procedure was started. The unit is now ready for clinical use.
- Repeat this cleaning procedure monthly and follow the other preventative maintenance procedures outlined in the user's manual.

4.4 How to clean Interacoustics Products

If the surface of the instrument or parts of it are contaminated, it can be cleaned using a soft cloth moistened with a mild solution of water and dish washing cleaner or similar. The use of organic solvents and aromatic oils must be avoided. Always disconnect the USB cable during the cleaning process, and be careful that no fluid is entering the inside of the instrument or the accessories.



- Before cleaning always switch off and disconnect from the power supply
- Use a soft cloth lightly dampened with cleaning solution to clean all exposed surfaces
- Do not allow liquid to come in contact with the metal parts inside the earphones / headphones
- 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
- Rubber ear-tips or foam ear-tips are single use components
- Ensure that isopropyl alcohol does not come into contact with any screens on the instruments
- Ensure that isopropyl alcohol does not come into contact with any silicone tubes or rubber parts

Recommended cleaning and disinfection solutions:

- Warm water with mild, nonabrasive cleaning solution (soap)
- Normal hospital bactericides
- 70% isopropyl alcohol only on hard cover surfaces

Procedure

- Clean the instrument by wiping outer case with a lint free cloth lightly dampened in cleaning solution.
- Clean cushions and patient hand switch and other parts with a lint free cloth lightly dampened in cleaning solution.
- Make sure not to get moisture in the speaker portion of the earphones and similar parts

4.5 Concerning Repair

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

1. assembly operations, extensions, readjustments, modifications or repairs are carried out by authorised persons,
2. a 1 year service interval is maintained
3. the electrical installation of the relevant room complies with the appropriate requirements, and
4. the equipment is used by authorised personnel in accordance with the documentation supplied by Interacoustics.

It is important that the customer (agent) fills out the RETURN REPORT every time a problem arises and sends it to Interacoustics, 7625 Golden Triangle Drive, Eden Prairie, MN 55344, USA. This should also be done every time an instrument is returned to Interacoustics. (This of course also applies in the unthinkable worst case of death or serious deterioration to patient or user).

4.6 Warranty

INTERACOUSTICS warrants that:

- The Aqua Stim Air Irrigator 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 product requires service during the applicable warranty period, the purchaser should communicate directly with the local Interacoustics service centre 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, properly packed, 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, and Interacoustics does not give or grant, directly or indirectly, the authority to any representative or other person to assume on behalf of Interacoustics 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.

4.7 Component Disposal



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

Hazardous Material

Other than the lead in the electronics components, there are no hazardous materials in the system. This is verified by Material Safety Data Sheets on file at the company headquarters of Micromedical Technologies, Inc. 10 Kemp Dr. Chatham, IL 62629 U.S.A. (217) 483-2122, Fax (217) 483-4533.

Packing Material

If storage space allows, packing material for computers, printers and digital light bars 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

Within the United States

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



Electronic devices that comprise the Micromedical system must be recycled or disposed in accordance to local environmental regulations. The crossed-out wheeie bin symbol appears on the main electronic devices of the Micromedical system when sold outside the U.S. showing that the components cannot simply be tossed into the trash.



Outside the United States it is against the law to dispose of electronic devices in the trash. The crossed-out wheeie bin symbol appears on the main electronic devices of the Micromedical system when sold outside the U.S. showing that the components cannot simply be tossed into the trash. Those electronic devices that comprise the Micromedical system must be recycled or disposed in accordance to local environmental regulations.

The following table shows the Micromedical system components and their relative presence based on percentage of component weight as directed by the Chinese RoHS compliance. Substances marked with an "X" exceed 0.1% of component weight except for Cadmium (Cd) which is 0.01%.



Based on normal use, the products could pose an environmental risk after ten years.

Component 组成	Substance 物质					
	Pb	Hg	Cd	Cr6+	PBB	PBDE
Computer 电脑	X	0	0	0	0	0
Monitor 监察	X	0	0	0	0	0
Balance Quest 寻求平衡	X	0	0	0	0	0
DataLink 3 数据3	X	0	0	0	0	0
Goggles 护目镜	X	0	0	0	0	0
Compressor 压缩机	X	0	0	0	0	0
Packaging Oak 包装橡树	0	0	0	0	0	0
Packaging Plastic 塑料包装	0	0	0	0	0	0

5 General Technical Specifications

5.1 Device Specifications

Water Flow Rate:	250ml / 30 seconds (fixed)
Flow accuracy:	+/- 15ml / 30 seconds
Duration of irrigation:	Adjustable from 15 to 40 seconds
Irrigation Temperature:	30°C Cool irrigation 44°C Warm irrigation
Accuracy at tip:	+/- 1°C
Stability of temperature:	+/- 1°C
Time to temperature:	< 3 minutes
External water container:	~ 3.5 liters (approx. 14 irrigations)
VNG computer interface:	USB 1,1 or faster
Dimensions w/ handle mounted:	35(w) x 30(d) x 21(h) cm / 13.8(w) x 12(d) x 8.3(h) in.
Water hose length (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
Chassis leakage current:	< 300 µA (single fault)
Fuse size:	110 -130VAC: 2x 8A SB Fuses 220 - 240VAC: 2x 4A AT Fuses
CE Number:	500651
Product model:	Aqua Stim
Classification:	Ila according to MDD 93/42/EEC Annex IX, rule 10
Complies with:	Annex V of the Medical Device Directive 93/42/EEC as amended by Directive 2007/47/EC
Notified Body:	BSI Management Systems CE 0086
Compliance Standards:	EN 60601-1:2006 Basic safety and Essential Performance
	EN 60601-1-1:2001 Safety of Medical Electrical Systems
	EN 60601-1-2:2007 EMC Directive
	EN 62304:2006 Medical Device Software

Appendix A

Portable and mobile RF communications equipment can affect the Aqua Stim. Install and operate the Aqua Stim according to the EMC information presented in this chapter.

The Aqua Stim has been tested for EMC emissions and immunity as a standalone instrument. Do not use the Aqua Stim adjacent to or stacked with other electronic equipment. If adjacent or stacked use is necessary, the user should verify normal operation in the configuration.

The use of accessories, transducers and cables other than those specified, with the exception of servicing parts sold by Interacoustics as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the device.

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

Guidance and manufacturer's declaration - electromagnetic emissions		
The Aqua Stim is intended for use in the electromagnetic environment specified below. The customer or the user of the Aqua Stim should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Aqua Stim 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 Limits	The Aqua Stim 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 Aqua Stim.			
The Aqua Stim is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Aqua Stim can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Aqua Stim 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 2.5 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 d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P 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 Aqua Stim is intended for use in the electromagnetic environment specified below. The customer or the user of the Aqua Stim 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	+6 kV contact	+6 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be greater than 30%.
	+8 kV air	+8 kV air	
Electrical fast transient/burst IEC61000-4-4	+2 kV for power supply lines	+2 kV for power supply lines	Mains power quality should be that of a typical commercial or residential environment.
	+1 kV for input/output lines	+1 kV for input/output lines	
Surge IEC 61000-4-5	+1 kV differential mode	+1 kV differential mode	Mains power quality should be that of a typical commercial or residential environment.
	+2 kV common mode	+2 kV common mode	
Voltage dips, short interruptions and voltage	< 5% UT (>95% dip in UT) for 0.5 cycle	< 5% UT (>95% dip in UT) for 0.5 cycle	(>95% dip in UT) for 5 sec Mains power quality

<p>variations on power supply lines</p> <p>IEC 61000-4-11</p>	<p>40% <i>UT</i> (60% dip in <i>UT</i>) for 5 cycles</p> <p>70% <i>UT</i> (30% dip in <i>UT</i>) for 25 cycles</p> <p><5% <i>UT</i> (>95% dip in <i>UT</i>) for 5 sec</p>	<p>40% <i>UT</i> (60% dip in <i>UT</i>) for 5 cycles</p> <p>70% <i>UT</i> (30% dip in <i>UT</i>) for 25 cycles</p> <p><5% <i>UT</i></p>	<p>should be that of a typical commercial or residential environment. If the user of the Aqua Stim requires continued operation during power mains interruptions, it is recommended that the Aqua Stim be powered from an uninterruptable power supply or its battery.</p>
<p>Power frequency (50/60 Hz)</p> <p>IEC 61000-4-8</p>	<p>3 A/m</p>	<p>3 A/m</p>	<p>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or residential environment.</p>
<p>Note: <i>UT</i> is the A.C. mains voltage prior to application of the test level.</p>			

Appendix B

Declaration of Conformity

Manufacturer:	Manufactured for Interacoustics A/S by Micromedical Technologies, Inc. www.Interacoustics.com	
CE Number:	500651	
Product model:	Aqua Stim	
Classification:	IIa according to MDD 93/42/EEC Annex IX, rule 10	
Complies with:	Annex V of the Medical Device Directive 93/42/EEC as amended by Directive 2007/47/EC	
Notified Body:	BSI Management Systems CE 0086	
Compliance Standards:	EN 60601-1:2006	Basic safety and Essential Performance
	EN 60601-1-1:2001	Safety of Medical Electrical Systems
	EN 60601-1-2:2007	EMC Directive
	EN 62304:2006	Medical Device Software

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: _____

Contact person: _____ Date : _____

Address

7625 Golden Triangle Drive Eden
Prairie
MN 55344
USA

Phone

(+1) 800 947 6334

Fax

(+1) 952 903 4200

E-mail

rmd@interacoustics-us.com

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 user¹

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.