
Instructions for Use – US

Air Fx

Caloric Irrigator



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1 Introduction

1.1 About this Manual

This manual is valid for the Air Fx Air Irrigator.

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1.2 Intended Use

The Air Fx air irrigator dispenses cool or warm air to perform caloric tests for vestibular diagnosis. The Air Fx requires the operator to aim the air stream at the tympanic membrane through the patient's ear canal, creating a differential in ear temperatures and resulting in the patient's eyes displaying nystagmus.

NOTICE

The Air Fx is used in conjunction with the Interacoustics VN415/VO425 VNG systems during caloric testing. The Air Fx will interface with the computer when using Interacoustics VNG software version 7.06 or later.

CAUTION

All personnel who operate the Air Fx should familiarize themselves with the contents of this manual prior to using the Air Fx with a patient. Additional training can be requested via Interacoustics or one of their sales representatives.

The Air Fx micro-controller technology is very simple to use and maintains an accurate temperature of dispensed air. Air Fx has an otoscope handle with an integrated light. The otoscope handle uses disposable specula and has an LED, which lights the eardrum without obstructing the air flow or view of the ear canal. The otoscope handle has a magnifying glass designed to improve visibility of the tympanic membrane.

Air Fx uses a USB cable to communicate with the host computer. Interacoustics software version 7.06 and later can coordinate testing with the Air Fx irrigator so the operator starts recording eye movements when starting the irrigation from the handle. The USB cable also is used to configure the Air Fx irrigator's default temperature settings whether used as a standalone device or used in conjunction with the Interacoustics VNG software.

The intended use of this product is for irrigation of the patient's external auditory canal with either warm or cool air 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.

Air Fx requires minimal maintenance. If service is required, please contact Interacoustics or one of their sales representatives.

1.3 Product Description




The Air Fx air irrigator dispenses cool or warm air to perform caloric tests for vestibular diagnosis.

The systems consist of the following included and optional parts:

Qty	Designation
Included parts:	
1	Air Fx
1	Power cord IEC 10 Amperes
1 pack	Speculum Ø 2.75 mm
1 pack	Speculum Ø 4.25 mm
1	60cc syringe and tube
1	USB Cable, 3m (9.8ft)
1	User's Manual
Accessories:	
	Specula (34 pieces) - 2.75mm size (Recommended for irrigation) - 4.25mm size (Recommended for viewing the tympanic membrane)
	Irrigator specula used with the Air Fx, recommended to be replaced for each patient Drain & Fill Kit Used to fill and drain water from internal plastic tubing
	Hose Management Tape used to coil the handle for storage purposes.

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 Air Fx Air Irrigator comes in its own shipping carton, which is specially designed for the Air Fx Air 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.

Please use "Return Report"

Please realise that if the service engineer does not know what problem to look for he may not find it, so using the Return Report will be of great help to us and is your best guarantee that the correction of the problem will be to your satisfaction.

2.2 Storage

Environmental Conditions



The Air Fx 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.

IEC 60601-1 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 can be damaged if any water is spilled on the electronic equipment)



To avoid the risk of electrical shock, the Air Fx must only be connected to a supply mains with protective earth.

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.

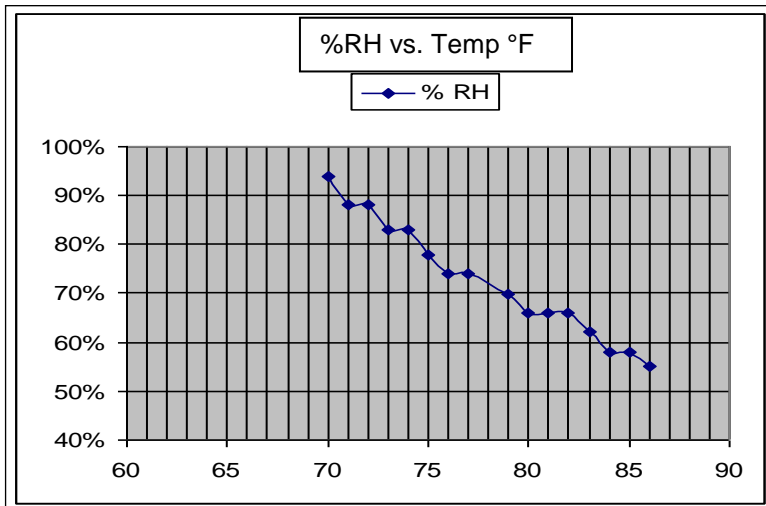
- Portable and mobile radio frequency (RF) communications equipment (e.g. cell phones, personal data assistants, etc.) can affect medical electrical equipment. This equipment should not be used at close distances to the equipment.
- Power frequency magnetic fields should be at levels characteristic of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

Performance Conditions		Storage Conditions	
Temperature of Room	10°C ~ 40°C 60°F ~ 104°F	Temperature of Room	4°C ~ 52°C 40°F ~ 125°F
Relative Humidity	See chart	Relative Humidity	10% ~ 90%



If the Air Fx is stored in near freezing conditions, allow time to thaw the unit prior to using with patients.

To prevent condensation in the device, operate at temperature and humidity below the graphed line.



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

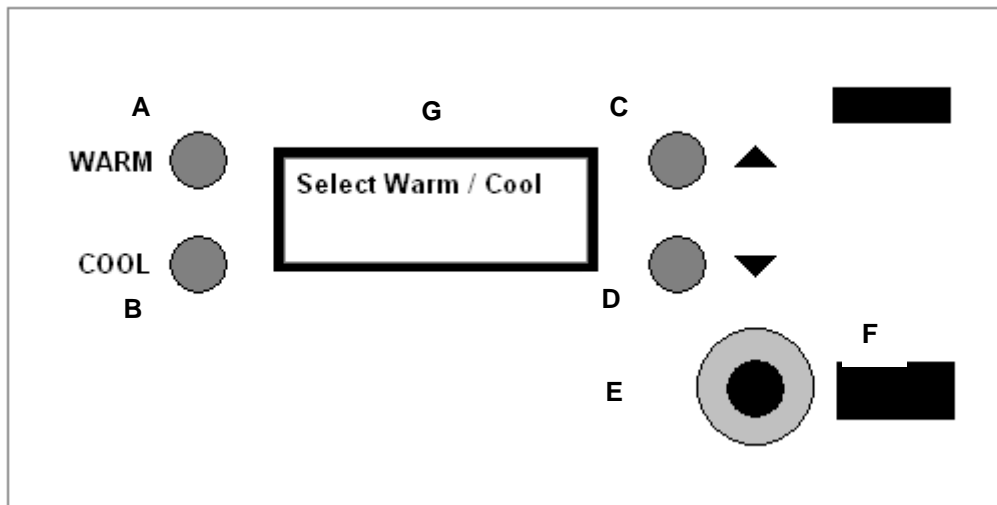


Figure 1 Front Panel Diagram

- A Specifies Warm Irrigation to be performed / returns to standby state
- B Specifies Cool Irrigation to be performed / returns to standby state
- C Adjust temperature set point up 1°C
- D Adjust temperature set point down 1°C
- E Hose connection
- F Handle support
- G LCD output screen

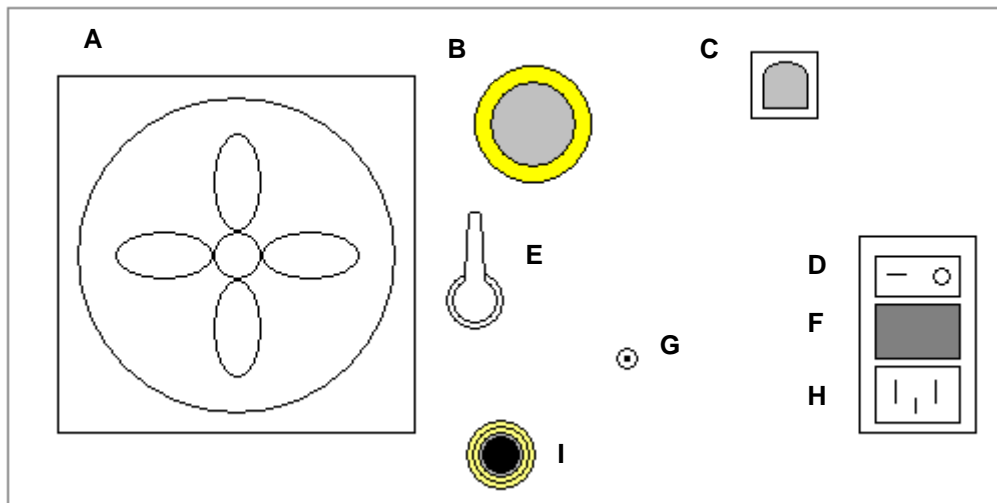


Figure 2 Rear Panel Diagram

- | | | | |
|---|--------------------|---|---------------------------|
| A | Exhaust fan | F | Fuse |
| B | Air Inlet Filter | G | Ground Screw |
| C | USB B Connector | H | AC Input |
| D | Power Switch | I | Fill / Drain Water Outlet |
| E | Fill / Drain Valve | | |

2.5 Preparing the Irrigator for First Use

The Air Fx requires a power source with ground and either 115VAC or 230VAC, based on the model of the device.

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

Filling the Water Reservoir

The Air Fx will be shipped from Interacoustics without any **distilled or demineralized water** in the reservoir. Please fill according to the following instructions.



The Air Fx cannot be used without adequate **distilled or demineralized water** present in the water reservoir. The **distilled or demineralized water** must be added before applying power. Failure to maintain the proper level of fresh **distilled or demineralized water** can result in permanent damage to the unit.

1. Unscrew the cap to the water reservoir on the top of the irrigator.
2. Fill the reservoir with **distilled or demineralized water** up to 1cm from the top as shown by the water level label.
3. Connect the syringe and tubing to the Fill / Drain Water Outlet (see **Figure 2**). Fully push the tubing into the Fill / Drain Water Outlet (about 1" of tubing), and then gently pull on the tubing to verify the connection is secure.
4. Switch the Fill / Drain Valve to the Fill / Drain position.
5. Draw back the syringe to draw the air out of the internal tubing and draw the **distilled or demineralized water** into syringe.
6. Set the Fill / Drain Valve to the Run position.
7. Disconnect the syringe from the tubing and squirt any **distilled or demineralized water** drawn back into the reservoir.
8. Reconnect the syringe.
9. Repeat steps 4 to 8 to draw the air out again. Repeat this drawing process until all of the air is removed from the internal lines, leaving only **distilled or demineralized water** drawn into the syringe. Draw at least 2 full syringes of **distilled or demineralized water**.
10. Set the Fill / Drain Valve to the Run position.
11. Disconnect the syringe and tubing. The tubing can be removed by pushing on the sides of the gray gasket around the tubing while pulling on the tubing.
12. Screw the cap back on the water reservoir.
13. Turn on the Air Fx. Run for one minute. Turn off the Air Fx. Repeat steps 3 through 11 to ensure the air bubbles have been removed from the system.

2.6 Installing the Air Fx USB Drivers

The device drivers will need to be installed whether the Air Fx is used as a standalone device or used in conjunction with the Interacoustics VNG software. Connect the USB cable to the back of the irrigator and to an available USB port on your computer. Use a dedicated USB port for the irrigator to prevent having to reinstall the drivers at a later time.

Once the irrigator is connected to the computer, turn on the Air Fx. Windows will launch the "Found New Hardware Wizard" and automatically install the drivers.

2.7 Using Air Fx in Conjunction with Interacoustics VNG Software

Interacoustics VNG 7.06 software and later can be set to work in conjunction with the Air Fx air irrigator. By default the software will enable communication with the Air Fx irrigator. If the Air Fx irrigator is sent for service or has USB connection issues, then manual control can be enabled from the Interacoustics software. Launch the Interacoustics software, then go to Setup > System. Change the "Irrigator Control" option to Manual if the Air Fx is not to communicate with the Interacoustics software. The default setting is Interacoustics to coordinate recording between the Interacoustics software and Air Fx irrigator. Click on OK to exit Setup and save changes.

NOTICE

Air Fx should be powered on before selecting a caloric test. If the irrigator is not connected, close VNG and re-launch the VNG module with the irrigator USB cable connected.

If you have an Interacoustics Aqua Stim irrigator connected to the VNG, turn the Aqua Stim irrigator power switch to OFF so Interacoustics VNG can communicate only with the Air Fx irrigator.

3 Operating instructions

3.1 Maintain Distilled Water Level

Prior to testing, verify fresh **distilled or demineralized water** level is visible in the water reservoir above the top of the irrigator case. If the water level is too low, then unscrew the cap to the water reservoir and add **distilled or demineralized water** up to 1cm from the threads as shown by the label. Screw the cap back snugly on the water reservoir to prevent evaporation.

NOTICE

DO NOT USE tap water as minerals in water will be deposited on critical internal components and will cause damage that is not covered by warranty.

3.2 Attaching the Speculum

In order to use the Air Fx, you have to use a speculum on the tip of the otoscope head. The specula are single use only and must be replaced for each new patient. Interacoustics recommends the use of 2.75mm diameter specula to better deliver the air to the tympanic membrane. The 4.25mm speculum can be used to view the ear canal and tympanic membrane when looking for any ear wax build-up.

To assemble a speculum on the ear tip of the handle, you have to insert it on the tip of the otoscope and turn it clockwise about 45°. A small plastic tip will be locked in the metal part of the head and will fix the speculum on the handle. Pull gently on the speculum to verify it is secure.



Figure 3 Place Speculum on Otoscope Head



Figure 4 Turn Speculum Clockwise to Lock, Pull Gently on Speculum to Verify It's Secure

Specula are latex free and silicone free. Be aware not to put too much torque on the speculum or you will break the plastic nub on the inside of the speculum, preventing the speculum from securing to the handle. Once this tip is broken, the speculum cannot be secured again on the handle. The speculum can be removed from the handle by first turning the speculum counterclockwise to unlock. **The speculum must be tight to prevent air leaks that will reduce the caloric stimulation response.**

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 IA Air Fx irrigator. In the configure test menu for caloric testing, select the stimulus tab and then select Air Fx control and choose your temperatures. In this menu you can also choose a test time in seconds.

The air temperature default is set to 30°C for cold irrigation and 44°C for warm irrigation. The irrigation time is set for 60 seconds.

Configure Caloric Test

Test | Graphs | Analysis | **Stimulus** | Calibration

☒ **Air Fx**

Temperatures [°Celsius]

Cold : 30

Warm : 44

Time [s]: 60

☐ **Aqua Stim**

Time [s]: 30

☐ **Manual control**

Temperatures [°Celsius]

Cold : 30

Warm : 44

Save As Default


Load Defaults

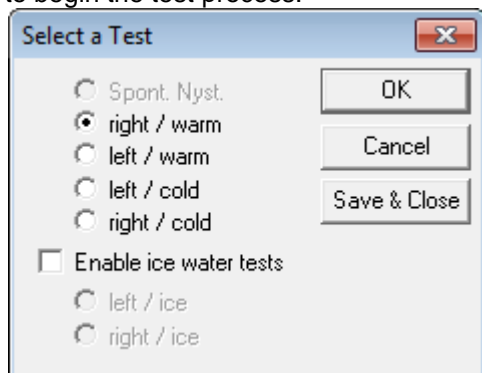
OK Cancel Help

3.4 Select the Irrigation Temperature

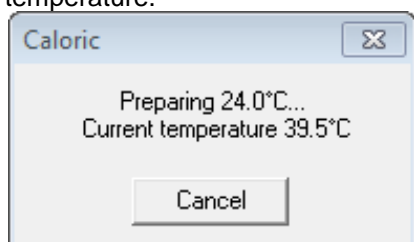
Select the irrigation you wish to perform from the Interacoustics software by first clicking on the



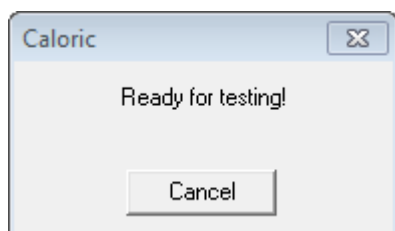
caloric test icon and then selecting the green arrow  to start/stop a test a caloric test. From the pop-up menu click the button for the irrigation you would like to start and then press ok to begin the test process.



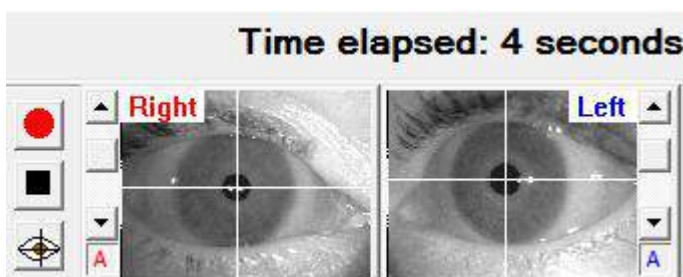
The Irrigator will be automatically initiated to the correct temperature setting (cool or warm default temperature). A pop-up menu will show you the status of the irrigator preparing the desired temperature.



When the irrigator reaches the desired temperature, an indicator tone will sound and a dialog box will appear letting you know you can now begin testing.

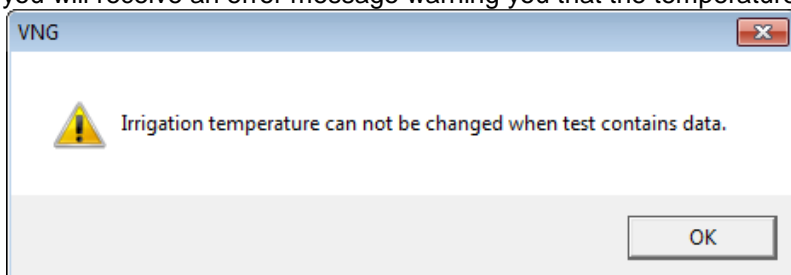


You may now lift the irrigator handle and position the irrigator tip in the ear canal. Once the tip is properly positioned and the patient has been instructed, press the start button on the irrigator handle and the caloric test recording time will start. After the designated time is reached another indicator tone will sound and the air flow will stop. The recording will continue until the selected caloric test completion time is reached. The elapsed test time will appear in the software.



Note: if you manually change the temperature on the Air Fx itself by depressing one on the temperature buttons during the preparing stage, it will also change the temperature in the Interacoustics software. If you cancel the test at any time the irrigator will go into rest mode until you click on the green arrow button to start another caloric test.

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



If the irrigator is not properly plugged into the computer's USB port, when the green arrow button is pushed to start the caloric test, the following message will appear:



If the Air Fx is used as a stand-alone device without Interacoustics' VNG software, then press the Cool button to select the Cool Irrigation or press the Warm button to select the Warm Irrigation. The desired temperature can be adjusted up or down by using the front panel temperature adjustment push buttons. This temperature adjustment will only be effective for this irrigation. If you want to adjust the default cool or warm temperature, see the section **Error! Reference source not found..**

NOTICE

Recommended caloric irrigation sequence is warms first, then cools. After the last warm irrigation, push the cool irrigation button and allow the irrigator to run for 5 to 7 minutes before performing the cool irrigation. This 5-7 minute period is the standard recommended duration between irrigations when changing temperature to allow the patient's ears to equilibrate. The time will also produce a more accurate air irrigation temperature, even if the irrigator display reads 'Ready' before the 5-7 minutes have elapsed.

The irrigator front panel LCD display will show the irrigation method (Cool or Warm) followed by the desired irrigation temperature (24°C) and the current temperature (e.g. 23.4°C).

Cool:	24°C	23.4°C
--------------	-------------	---------------

Irrigation will be available after the desired temperature has been reached and stabilized. Once this occurs, the Air Fx will emit an indicator tone and will display **"Ready"** below the irrigation information.

Cool:	24°C	24.2°C
Ready		

3.5 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 proceed with irrigation using the AirFX irrigator.

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 (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". Place the speculum gently into the external ear canal, then click the button on the irrigator handle to begin air flow. Direct the speculum at the ear drum.



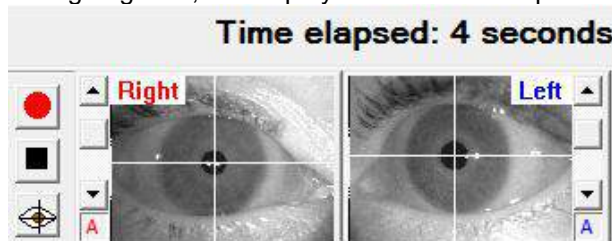
Once the irrigator button has been pushed to begin testing the air will continue to flow until either the preselected test time is reached or until you press Stop in the software

icon tool bar



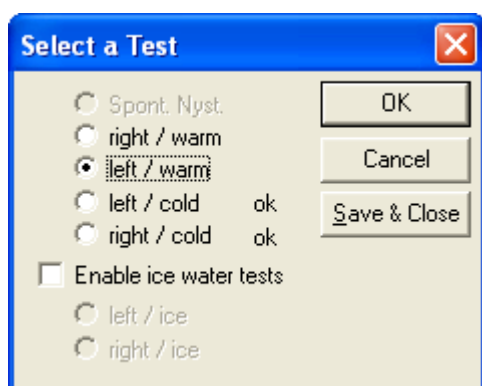
Caloric test eye movement recording will begin automatically after the irrigator's handle button has been pressed.

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



If the irrigation needs to be suddenly aborted, remove the speculum from the ear and direct air flow elsewhere. The irrigator air flow will continue until the pre-selected irrigation time has elapsed, at which time an indicator tone will sound and air flow will stop.

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 menu dialog box.



Once the final irrigations have been completed, remove the speculum from the ear tip of the handle and clean the handle tip with Sani-Cloth wipes.

3.6 Safety

The Air Fx air irrigator uses **distilled or demineralized water** to maintain the temperature in the cooler / heater element. While the temperature of the coolant is not displayed, it is monitored. If the coolant temperature goes over a certain limit, the unit will stop operation and an “Over Temp Error” message is displayed. This error could be a result of insufficient water in the water reservoir or bubbles in the water line. Operating the irrigator in very cold (<10°C conditions can also cause this error). Make sure the irrigator has warmed up slowly to room temperature before operating.

Over Temp Error
Call TechSupport

The air delivery temperature is also monitored for safety. If this temperature exceeds 50°C, the irrigator will stop operation and an “Air Temp Error” message will be displayed.

Air Temp Error
Call TechSupport

If either of these conditions occurs, then shut down the irrigator and isolate the problem (ambient temperature too low, bubbles in the water line, **distilled or demineralized water** level too low etc.). Contact Interacoustics’ Service Department or your local service representative if the problem cannot be resolved.

Set the Air Fx irrigator near the edge of the table or cart in order for the hose to hang down, allowing the handle to rest properly in its cradle. When the irrigator is not in use, coil the Air Fx handle tubing using the hose management tape while still allowing the handle to be secured in the cradle.

3.7 Draining the Water Reservoir

The Air Fx should have the water reservoir on the top of the irrigator filled with **distilled or demineralized water**. If the **distilled or demineralized water** needs to be drained prior to shipment or flushed before adding new **distilled or demineralized water**, then the Air Fx should be drained according to the following instructions. Do not store irrigator in a location below 0°C (32°F).

1. Unscrew and remove the water reservoir cap on the top of the irrigator.
2. Connect the supplied plastic syringe and tubing to the Fill / Drain Water Outlet on the back of the irrigator. Push the syringe plastic tubing fully into the Fill / Drain Water Outlet connector, and then gently pull on the tubing to verify the connection is secure and will not leak.
3. Switch the Fill / Drain Valve to the Fill / Drain position.
4. Draw back the syringe to draw the **distilled or demineralized water** out of the internal tubing and water reservoir.
5. Set the Fill / Drain Valve to the Run position.

6. Disconnect the syringe from the tubing and squirt any **distilled or demineralized water** into a waste container.
7. Reconnect the syringe tubing and repeat steps 3 to 7 to draw the **distilled or demineralized water** out again. Repeat this drawing process until all of the **distilled or demineralized water** is removed from the internal lines, until only air is drawn into the syringe.
8. Set the Fill / Drain Valve to the Run position.
9. Disconnect the syringe and tubing. The tubing can be removed by pushing in the gray gasket around the tubing with your finger nails while pulling on the tubing to remove.
10. Screw the cap back on the water reservoir.



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 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

4.3 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).

4.4 Warranty

INTERACOUSTICS warrants that:

- The Air Fx 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.

4.5 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 your area authorities for compliance.

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



Within the European Union it is illegal to dispose electric and electronic waste as unsorted municipal waste. Electric and electronic waste may contain hazardous substances and therefore has to be collected separately. Such products will be marked with the crossed-out wheeled bin shown below. The cooperation of the user is important in order to ensure a high level of reuse and recycling of electric and electronic waste. Failing to recycle such waste products in an appropriate way may endanger the environment and consequently the health of human beings.

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

Output Air Flow Rate:	8 to 12 liters/minute (fixed flow rate)
Output Air Temperature:	Cool 20°C to 30°C (1°C increments) Warm 40°C to 50°C (1°C increments)
Accuracy:	+/- 0.5°C
Stability:	+/- 0.5°C, +/- 0.5 liters/min
Time to temperature:	< 3 minutes
Distilled water:	220cc (7.4 oz)
Otoscope speculums:	2.75 mm and 4.25mm (single use)
Computer connection:	USB 1.1 or faster, 3 m (9.8 ft) cable
Case dimensions:	35W x 32D x 22H cm (13.8 x 12.6 x 8.7 in)
Air hose length:	3 m (9.8 ft)
Weight:	8 kg (18 lb)
Voltage:	110-130 VAC @ 50-60 Hz 220-240 VAC @ 50-60 Hz
Fuses:	1 x 2A (110VAC units) 2 x 1A (220VAC units)
Power consumed:	105VA
Chassis leakage current:	< 300 µA (single fault condition)
CE Number:	500651
Product model:	Air Fx
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 Air Fx. Install and operate the Air Fx according to the EMC information presented in this chapter.

The Air Fx has been tested for EMC emissions and immunity as a standalone instrument. Do not use the Air Fx 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 Air Fx is intended for use in the electromagnetic environment specified below. The customer or the user of the Air Fx should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Air Fx 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. The Air Fx is suitable for use in all commercial, industrial, business, and residential environments.
RF emissions CISPR 11	Class B Limits	
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 Air Fx.			
The Air Fx is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Air Fx can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Air Fx 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 Air Fx is intended for use in the electromagnetic environment specified below. The customer or the user of the Air Fx 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 +8 kV air	+6 kV contact +8 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	< 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

variations on power supply lines IEC 61000-4-11	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	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>	should be that of a typical commercial or residential environment. If the user of the Air Fx requires continued operation during power mains interruptions, it is recommended that the Air Fx 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.

Appendix B

Declaration of Conformity

Manufacturer: Technologies, Inc. **Manufactured for Interacoustics A/S by** Micromedical

10 Kemp Drive
Chatham, IL 62629 USA
Tel: 217-483-2122
Fax: 217-483-2122
www.micromedical.com

CE Number: 500651

Product model: Air Fx

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

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