Science **made** smarter

Instructions for Use - EN

Air Fx

Caloric Irrigator

Interacoustics

8525530 / D-0128355 –B – 2024/05

Table of Contents

1 Introduction

1.1 About this manual

This manual is valid for the Air Fx Caloric 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. 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 Air Fx 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 Air Fx irrigator will start the caloric test with the correct irrigation temperature.

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.

Air Fx 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.

The otoscope handle uses disposable specula and has an integrated 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.

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 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.

Contraindications

Do not perform caloric stimulation with water on patients with tympanic membrane (TM) perforations. On patients with TM perforations, only perform a brief stimulation by air to determine whether a vestibular response is present. Calculation of unilateral weakness and directional preponderance measures are not possible on patients with TM perforations.

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 Manual
1	Drain & Fill Kit
1	Hose Management Tape

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 Air Fx is not suitable for use in the presence of flammable anaesthetic mixtures with air or oxygen or nitrous oxide as there may be an explosion risk.

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 main with protective earth.

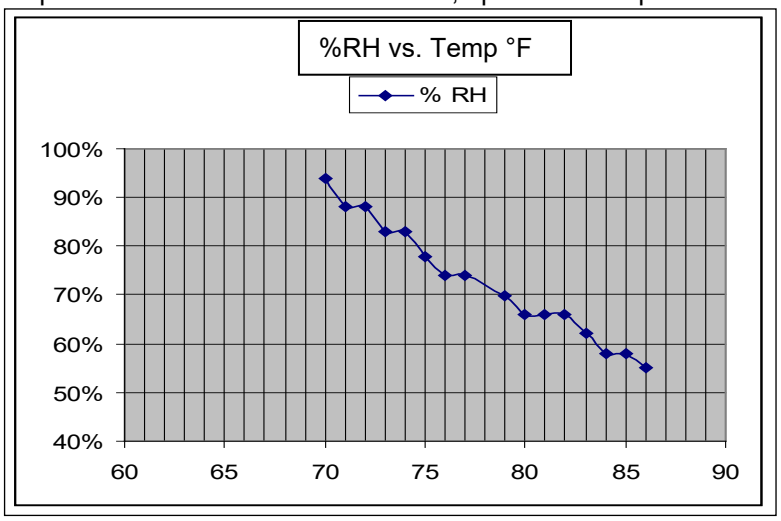
Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided.

- 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	Transport
Temperature	10°C ~ 40°C 60°F ~ 104°F	1°C ~ 50°C 34°F ~ 122°F	-15°C ~ 50°C 5°F ~ 122°F
Relative Humidity	See chart	10% ~ 90%	10% ~ 95%
	Non-condensing	Non-condensing	Non-condensing

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 Markings

The following markings can be found on the instrument:

[Esc]	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 device is a Type B part.
	Refer to the Instructions for Use
	Observe precautions for handling electrostatic sensitive devices
	WEEE (EU-directive) This symbol indicates that the product should not be discarded as unsorted waste but must be sent to separate collection for facilities for recovery and recycling.
	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
 0123	The CE-mark in combination with MD symbol indicates that Interacoustics A/S meets the requirements of the Medical Device Regulation (EU) 2017/745 Annex I Approval of the quality system is made by TÜV – identification no. 0123
	Medical Device

2.4 Panel connections

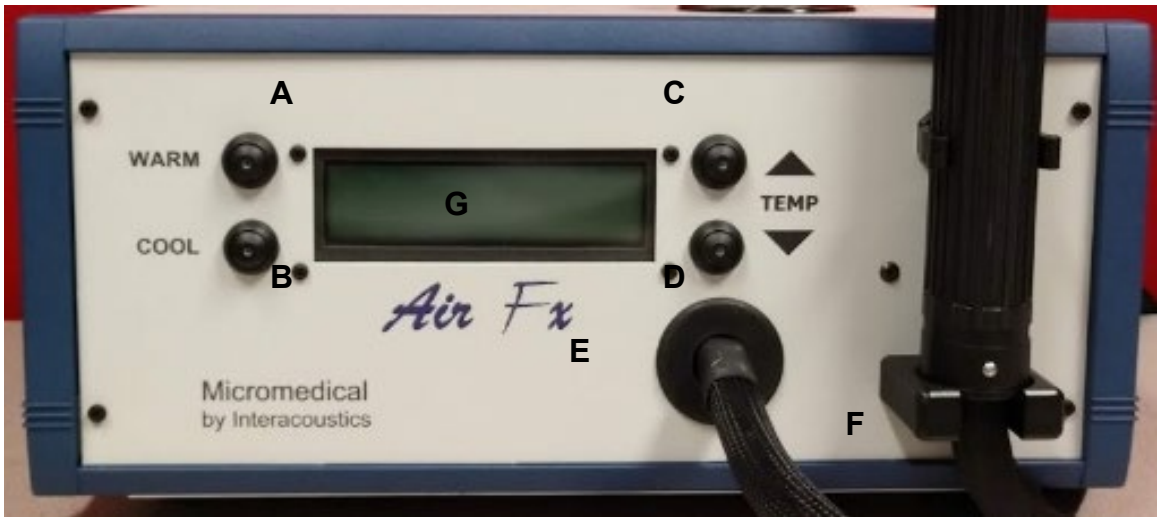


Figure 1 Front Panel Diagram

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

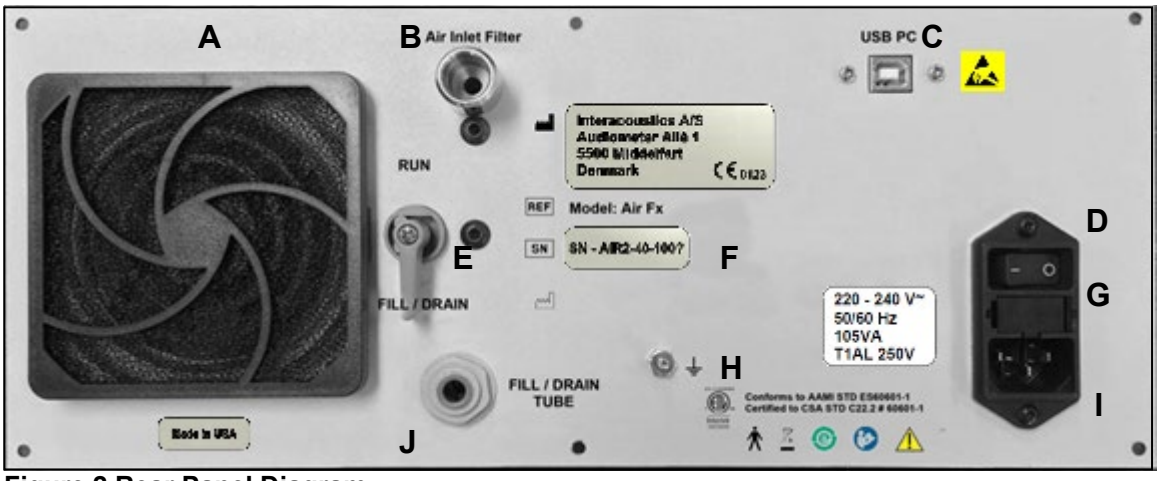


Figure 2 Rear Panel Diagram

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

2.5 Preparing the irrigator for first use

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. Check that the irrigator is powered OFF.
2. Remove the cap to the water reservoir on the top of the irrigator. Do not force the cap or use mechanical tools to remove the cap.
3. Fill the reservoir with distilled water up to 1cm from the bottom of the cap. Take care not to spill any water into the unit except into the water reservoir to prevent damage to the circuitry and prevent any electrical shock to the user. If any water is spilled, wipe it up immediately.
4. Purge air from the hoses, pump and handle by connecting the included 60cc syringe & tube to the Fill / Drain Water Outlet. Fully push the tube into the Fill / Drain Water push-in connector (about 1” (2cm) of tubing). Gently pull on the tubing to confirm the tube is secure.
5. Switch the Fill / Drain Valve to the Fill / Drain position.
6. Draw back the syringe to draw the air out of the internal tubing and draw distilled water into the syringe. If there is a train of air bubbles or there is no suction, then set the Fill / Drain Valve to the Run position and reconnect the tube. Once reconnected, set the Fill / Drain Valve to the Fill / Drain position.
7. Disconnect the syringe from the tube and keep the tube held above the irrigator to prevent the water from exiting the tube. Squirt any distilled water drawn back into the reservoir. Reconnect the syringe to the tube.
8. Repeat steps 6 to 7 two more times to draw the remaining air out of the lines.
9. Set the Fill / Drain Valve to the Run position.
10. Disconnect the syringe. The tube can be removed by pushing on the sides of the tubing connector’s grey collar around the tubing while simultaneously pulling on the tubing.
11. Place the cap back on the water reservoir.
12. Attach the AC power cord to the back of the irrigator and switch on the Air Fx using the power switch next to the power cord. Water will automatically be pumped through the hoses into the handle and returned to the reservoir.
13. Test system by running irrigator on the warm cycle then the cool cycle. If the irrigator is able to do this, then it is ready to use. If the irrigator is unable to reach the desired temperature, then repeat the fill instructions.

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 remove the cap to the water reservoir and add **distilled or demineralized water** up to 1cm from the threads as shown by the label. Replace the cap back 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 Using the Air Fx with VNG/ENG software

The Air Fx air irrigator can be configured with compatible[1] VNG/ENG software. The caloric test settings or system settings must be configured to communicate with the Air Fx 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.

3.3 Turn on the irrigator

Turn on the power switch on the back panel. The Air Fx will initialize, show the firmware version, and then go into the standby state.

Select Cool / Warm
Air Fx v1. 4

3.4 Attaching the speculum

NOTICE

Each speculum is single use only and must be replaced for each new patient.

A speculum on the tip of the otoscope head is required for use. Interacoustics recommends the use of 2. 75mm diameter specula for irrigation and the 4. 25mm diameter specula for inspecting the ear canal for cerumen impaction or perforations in the tympanic membrane.

If the ear canal is blocked with wax, remove the cerumen first before irrigating. Irrigating a patient with cerumen impaction will give a reduced response to the irrigation stimulus.

To assemble a speculum on the ear tip of the handle, insert the speculum 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.

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

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. Do not put too much torque on the speculum or the plastic nub on the inside of the speculum will break, 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.**

3.5 Select the irrigation temperature

If the Air Fx is used as a standalone device, press the Cool or Warm button on the front panel to select the irrigation temperature. If the Air Fx is connected to a VNG/ENG system with compatible software, then the software will select the irrigation temperature based on the test or system settings.

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 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		

3.6 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 proceed with irrigation using the Air Fx irrigator.

Prior to irrigation, the patient should be supine with the head elevated 30 degrees to place the lateral semi-circular canals in the vertical plane. The operator should sit next to the patient alongside the ear being irrigated. Hold the irrigator handle in one hand and instruct the patient what will occur and what the patient will feel. Insert the otoscope with the 2. 75mm diameter speculum into the patient's ear while peering through the otoscope magnifying lens. Adjust the direction of the speculum looking for the tympanic membrane (TM). Direct the air stream continuously at the TM during the whole irrigation. Press the white push button on the irrigator handle to start the countdown timer. If connected to the computer with compatible VNG/ENG software, the test will begin recording as well. During irrigation the LCD display will display "Irrigating" and the amount of time that has elapsed. To restart the test hold down on the white button for 3 seconds and the timer will reset and abort the VNG/ENG tracing.

Cool: 24°C 24. 1°C **Irrigating 0:08**	
NOTICE	The patient's perceived spinning sensation experienced during caloric irrigation is the desired result of stimulating a functional ear with a caloric irrigator. The clinician should remain at the patient's side to calm and reassure the patient that the spinning will pass in a minute or so. Nausea is an undesirable side effect which is temporary and not experienced by every patient. If the patient becomes nauseated, discontinue testing until the nausea has passed. Be prepared to provide the patient with an emesis basin. Stop all caloric testing for that visit if the patient vomits.

3.7 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 the 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.

3.8 Turn off the irrigator

The Air Fx will go into standby mode after ten minutes has elapsed or the irrigation temperature selection button is pressed twice. If the Air Fx is used in conjunction with the compatible VNG/ENG software, then the software will send the Air Fx into standby mode at the end of the test. When the Air Fx is in the standby mode, it is safe to turn off the power switch on the back panel.

3.9 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. 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. Disconnect the syringe from the tubing and keep the tube held above the irrigator to prevent the water from exiting the tube. Squirt any **distilled or demineralized water** into a waste container. Reconnect the syringe to the tube. Repeat this process until all of the **distilled or demineralized water** is removed from the internal lines, until only air is drawn into the syringe.
6. Set the Fill / Drain Valve to the Run position.
7. Disconnect the syringe and tubing. The tubing can be removed by pushing in the gray gasket around the tubing with one's fingernails while pulling on the tubing to remove.
8. Replace the cap back on the water reservoir.

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 Air Fx Caloric Irrigator and the accessories. The gloves are to be changed after each patient, to minimize the contact points and cross contamination.
- 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 Air Fx caloric irrigator and the temperature-controlled air is intended for contact with intact skin only. According to the Spaulding classification used by WHO[1], 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 the system can be performed.

1. WHO "Decontamination and Reprocessing of Medical Devices for Health-care Facilities"

Cleaning Agent

The Air Fx 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 Air Fx 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 Air Fx Caloric Irrigator which is also approved by WHO as standard disinfectant agent. Isopropyl alcohol 70-85% v/v will also have a mild effect on the materials.

Frequency

The minimum requirement for cleaning and disinfection frequencies are discussed below in detail. However, 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.

4.1.3 After each patient

After each examination of a patient, it should be ensured that there is no contamination on the parts in connection with the patient. Wipe the outside of the otoscope head and replace the single use speculum after each patient.

4.1.4 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 doen't enter the critical areas of device. Cleaning solution should be changed at each cleaning session and when visibly soiled.

4.1.5 Quarterly maintenance

Drain the water completely from the irrigator. Remove the lid from the water tank and use a paper towel to reach inside and wipe down the inside wall of the water reservoir which is used for heat management. If the paper towel does not show a biofilm, then refill the reservoir with **distilled or demineralized water** for routine usage of irrigators.

If the biofilm is observed, fill the water reservoir of irrigator with the disinfectant **(70-85% v/v Isopropyl alcohol)**. Power on the irrigator for 30 minutes with cool Irrigation. The water pump will circulate the disinfectant through the lines as long as power is on. After 30 minutes, drain the solution from the irrigator. Then, fill the irrigator with **distilled or demineralized water** and run couple of cool irrigation cycles. Drain the irrigator to ensure that the disinfectant is washed out. Then refill the reservoir with **distilled or demineralized water** for routine usage of irrigator.

4.1.6 Annual maintenance

The Annual Cleaning Procedure should be performed by a qualified service technician.

4.1.6.1 Air filter cleaning

Check the exhaust fan filter for debris or dust. The filter can be removed and cleaned after turning off power to the irrigator and detaching the plastic retaining bracket on the exhaust fan.

Check the air inlet filter for debris or dust. Remove the grommet and tubing using a pair of needle-nosed pliers. Blow out debris with a can of compressed air.

4.1.6.2 Water filter cleaning

The Air Fx caloric irrigator uses an inline water filter to collect debris. The water filter cone should be replaced once a year by a qualified service technician. Refer to the section 4. 6 Replacing the Water Filter.

4.1.6.3 Irrigator cleaning

Annually the Air Fx should be cleaned to remove any biofilm and mineral deposits. The Annual Cleaning Procedure should be performed by a qualified service technician.

4.1.6.4 Annual irrigator verification

The Air Fx flow rate and air temperature should be verified by a qualified service technician. If the irrigator is outside of specifications for flow rate or temperature, then the irrigator must be sent back to Interacoustics for calibration.

4.2 Warranty and service

4.2.1 Product warranty

Interacoustics warrants that:

- The Air Fx system is free from defects in material and workmanship under normal use and service for a period of 24 **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.

4.2.2 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.

4.3 Disposal of the product

Interacoustics is committed to ensuring that our products are safely disposed of when they are no longer usable. The cooperation of the user is important to ensure this. Interacoustics therefore expects that local sorting and waste regulations for disposal of electric and electronic equipment are followed, and that the device is not discarded together with unsorted waste. In case the distributor of the product offers a take-back scheme, this should be used to ensure correct disposal of the product.

4.4 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

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 (2 each):	110VAC units: T2AL 250V 220VAC units: T1AL 250V
Power consumed:	105VA

The CE-mark in combination with MD symbol indicates that Interacoustics A/S meets the requirements of the Medical Device Regulation (EU) 2017/745 Annex I.

Approval of the quality system is made by TÜV – identification no. 0123.

Compliance Standards:	IEC 60601-1:2005 + AMD1:2012- Basic safety & Essential Performance IEC 60601-1-2:2012+AMD1:2020 – EMC

5.2 EMC compliance

This section is valid for the Air Fx 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+AMD1:2020, 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 *Instrument* (Air Fx) is intended for use in the electromagnetic environment specified below. The customer or the user of the *Instrument* should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The ***Instrument*** 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 ***Instrument*** 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 *Instrument*.			
The ***Instrument*** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ***Instrument*** can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ***Instrument*** 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 *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 ***Instrument*** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***Instrument*** 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%.
Immunity to proximity fields from RF wireless communications equipment IEC 61000-4-3	Spot freq. 385-5.785 MHz Levels and modulation defined in table 9	As defined in table 9	RF wireless communications equipment should not be used close to any parts of the ***Instrument***.
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 Line to line +2 kV Line to earth	+1 kV Line to line +2 kV Line to earth	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	0% *U*T (100% dip in *U*T) for 0.5 cycle, @ 0, 45, 90, 135, 180, 225, 270 and 315° 0% *U*T (100% dip in *U*T) for 1 cycle 40% *U*T (60% dip in *U*T) for 5 cycles 70% *U*T (30% dip in *U*T) for 25 cycles 0% *U*T (100% dip in *U*T) for 250 cycles	0% *U*T (100% dip in *U*T) for 0.5 cycle, @ 0, 45, 90, 135, 180, 225, 270 and 315° 0% *U*T (100% dip in *U*T) for 1 cycle 40% *U*T (60% dip in *U*T) for 5 cycles 70% *U*T (30% dip in *U*T) for 25 cycles 0% *U*T (100% dip in *U*T) for 250 cycles	Mains power quality should be that of a typical commercial or residential environment. If the user of the ***Instrument*** requires continued operation during power mains interruptions, it is recommended that the ***Instrument*** be powered from an uninterruptable power supply or its battery.
Power frequency (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or residential environment.
Radiated fields in close proximity — Immunity test IEC 61000-4-39	9 kHz to 13.56 MHz. Frequency, level and modulation defined in AMD 1: 2020, table 11	As defined in table 11 of AMD 1: 2020	If the I***nstrument*** contains magnetically sensitive components or circuits, the proximity magnetic fields should be no higher than the test levels specified in Table 11
Note: *U*T is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration — electromagnetic immunity			
The ***Instrument*** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***Instrument*** should assure that it is used in such an environment,			
Immunity test	**IEC / EN 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any parts of the ***Instrument,*** including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC / EN 61000-4-6	3 Vrms 150kHz to 80 MHz 6 Vrms In ISM bands (and amateur radio bands for Home Healthcare environment.)	3 Vrms 6 Vrms	$d = \frac{3,5}{Vrms}\sqrt{P}$
Radiated RF IEC / EN 61000-4-3	3 V/m 80 MHz to 2,7 GHz 10 V/m 80 MHz to 2,7 GHz Only for Home Healthcare environment	3 V/m 10 V/m (If Home Healthcare)	$d = \frac{3,5}{V/m}\sqrt{P}$ 80 MHz to 800 MHz $d = \frac{7}{V/m}\sqrt{P}$ 800 MHz to 2,7 GHz 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). 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] Interference may occur in the vicinity of equipment marked with the following symbol: 
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 ***Instrument*** is used exceeds the applicable RF compliance level above, the ***Instrument*** should be observed to verify normal operation, If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ***Instrument.*** **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:	af:	Rev. dato: 30.01.2023	af:	Rev. nr.:	
2014-03-07	EC		MHNG	5	

Company: _____

Address: _____

_____

Phone: _____

e-mail: _____

Address
DGS Diagnostics Sp. z o.o.
Rosówek 43
72-001 Kołbaskowo
Poland

Mail:
rma-diagnostics@dgs-diagnostics.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 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.