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Technical Specifications

Air Fx

Caloric Irrigator



D-0128676-A – 2020/12



Interacoustics



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
1	Drain & Fill Kit
1	Hose Management Tape



General technical specifications

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

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

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

Compliance

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



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, 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 *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 <i>Air Fx</i> uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The <i>Air Fx</i> is suitable for use in all commercial, industrial, business, and residential environments.
Harmonic emissions IEC 61000-3-2	Complies Class A Category	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Recommended separation distances between portable and mobile RF communications equipment and the *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 2.7 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 **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	+8 kV contact +15 kV air	+8 kV contact +15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be greater than 30%.
Electrical fast transient/burst IEC61000-4-4	+2 kV for power supply lines +1 kV for input/output lines	+2 kV for power supply lines +1 kV for input/output lines	Mains power quality should be that of a typical commercial or residential environment.
Surge IEC 61000-4-5	+1 kV differential mode +2 kV common mode	+1 kV differential mode +2 kV common mode	Mains power quality should be that of a typical commercial or residential environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	< 5% <i>UT</i> (>95% dip in <i>UT</i>) for 0.5 cycle 40% <i>UT</i> (60% dip in <i>UT</i>) for 5 cycles 70% <i>UT</i> (30% dip in <i>UT</i>) for 25 cycles <5% <i>UT</i> (>95% dip in <i>UT</i>) for 5 sec	< 5% <i>UT</i> (>95% dip in <i>UT</i>) for 0.5 cycle 40% <i>UT</i> (60% dip in <i>UT</i>) for 5 cycles 70% <i>UT</i> (30% dip in <i>UT</i>) for 25 cycles <5% <i>UT</i> for 5 sec	Mains power quality should be that of a typical commercial or residential environment. If the user of the 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.



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

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

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