

Series-5000 Pneumatic Instruments

Instructions for Use





























MICROAIRE®
For Surgery. For Life.™

TABLE OF CONTENTS

• Symbol Glossary	3-4
• Warnings and Cautions	5-6
• System Components	7
• Assembly / Disassembly Instructions	8-13
• Reprocessing Instructions	14-16
• Storage	16
• Periodic Inspection	16
• Repair Service	16
• Power Output, Noise and Vibration	17
• Disposal	17
• Warranty	17

SYMBOL GLOSSARY

Symbol	Name	Designation Number	Use Standard	Description
	Refer to Instruction Manual / Booklet	ISO-7010 M002	IEC 60601-1:2005 ¹	Indicates a MANDATORY action for the user to consult the Instructions For Use (IFU). Symbol must be blue.
	Consult Instructions For Use (IFU)	1641	ISO 15223-1:2012 ¹	Indicates the need for the user to consult the Instructions For Use (IFU). Not required in conjunction with the Caution symbol, if applicable.
	Caution	0434A / 0434B	ISO 15223-1:2012 ¹	Indicates the need for the user to consult the Instructions For Use (IFU) for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the device itself.
	Non-sterile	ISO 7000-2609	ISO 15223-1:2012 ¹	To indicate that the device that is normally provided sterile in the same or similar packaging has not been sterilized.
	Locked	5569	IEC 60878:2015 ¹	To identify on a control that a function is locked or to show the locked status.
	Unlocked	5570	IEC 60878:2015 ¹	To identify on a control that a function is not locked or to show the unlocked status.
	Lock	0018	N/A	To indicate the function of locking or clamping two machine parts together, or location of a machine element in a fixed position.
	Unlock	0019	N/A	To indicate the function of releasing two machine elements locked or clamped together, or the releasing of a machine element from a fixed position.
	Temperature Limitation	0632	ISO 15223-1:2012 ¹	Indicates the temperature limits to which the medical device can be safely exposed. The upper and lower limits to temperature shall be indicated adjacent to the upper and lower horizontal lines.
	Atmospheric Pressure Limitation	2621	ISO 15223-1:2012 ¹	Indicates the range of atmospheric pressure to which the medical device can be safely exposed. The atmospheric pressure limitations shall be indicated adjacent to the upper and lower horizontal lines.
	Humidity Limitation	2620	ISO 15223-1:2012 ¹	Indicates the range of humidity to which the medical device can be safely exposed. The humidity limitations shall be indicated adjacent to the upper and lower horizontal lines.
	Authorized Representative in the European Community	N/A	ISO 15223-1:2012 ¹	Indicates the authorized representative in the European Community. This symbol shall be accompanied by the name and address of the authorized representative, adjacent to the symbol.
	Serial #	2498	ISO 15223-1:2012 ¹	Indicates the manufacturer's serial number so that a specific medical device can be identified.


Symbol	Name	Designation Number	Use Standard	Description
	Lot / Batch Code	2492	ISO 15223-1:2012 ¹	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	REF (Catalog #)	2493	ISO 15223-1:2012 ¹	Indicates the manufacturer's catalog number so that the medical device can be identified.
	Do Not Lubricate	N/A	N/A	Indicates a medical device that is not to be lubricated.
	Do Not Immerse in any Liquid	5995	IEC 60335-2-15	Indicates a medical device that is not to be immersed in any liquid.
	UL symbol	N/A	UL	MEDICAL-GENERAL MEDICAL EQUIPMENT AS TO ELECTRIC SHOCK, FIRE, AND MECHANICAL HAZARDS ONLY. IN ACCORDANCE WITH ANSI/AAMI ES 60601-1 (2005) + A1 (2012) + CAN/CSA C22.2 No. 60601-1 (2014) Control Number: E494242
	Type BF Applied Part	5333	IEC 60601-1:2005	Indicates a medical device complying with the specified requirements of IEC 60601-1 to provide a higher degree of protection against electric shock than that provided by Type B Applied Parts.
	Do Not Expose to Stray Magnetic Fields	N/A	N/A	Indicates a medical device that is not to be exposed to stray magnetic fields.
	Date of Manufacture	2497	ISO 15223-1:2012 ¹	Indicates the date when the medical device was manufactured. The date is expressed as YYYY-MM (e.g. 2015-11) or YYYY-MM-DD (e.g. 2015-11-29).
	Manufacturer	3082	ISO 15223-1:2012 ¹	Indicates the medical device manufacturer.
	CE Mark for EU Class IIa and Higher Products	N/A	Council Directive 93/42/EEC	European Conformity Mark 2797 = Notified Body Number
	Prescription	N/A	FDA Title 21, Chapter 1, Subchapter H, Part 801.15(F)	Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).
	Dispose of per WEEE Directive 2012/19/EU	N/A	Council Directive 2012/19/EU (Symbol: European Standard EN 50419)	Indicates a medical device that is not to be disposed of as unsorted municipal waste. Medical device is to be disposed of per WEEE Directive 2012/19/EU.
	Use-By Date	2607	ISO 15223-1:2012 ¹	Indicates the date after which the medical device is not to be used. This symbol shall be accompanied by a date to indicate that the medical device should not be used after the end of the month shown. The date is expressed as YYYY-MM \ (e.g. 2015-11) or YYYY-MM-DD (e.g. 2015-11-29).



¹ISO 15223-1:2012 – “Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements”

²ISO 7000/IEC 60417 – “Graphical symbols for use on equipment – Registered symbols”

WARNINGS AND CAUTIONS

The following terms are used to identify precautions that will help avoid accidental injury to patients or personnel, or to prevent product damage:

- WARNING:** Indicates a risk to the safety of patients or hospital personnel.
- CAUTION:** Indicates a risk of damage to the system/instrument.
- CAUTION:** Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician or properly licensed practitioner.
- CAUTION:** All personnel should become familiar with this manual before using the instruments in any procedure or during reprocessing. Personnel who are trained should include, but are not be limited to, members of the surgical team, bioengineering department, and central processing personnel.
- WARNING:** Irrigation must be used when cutting bone in order to ensure that the temperature at the cutting accessory does not exceed 41°C / 105.8°F
- WARNING:** Use irrigation to prevent overheating.
- WARNING:** Verify that accessories are secure before use.
- WARNING:** Monitor the temperature of the nose section.
- WARNING:** Risk of pinching from moving parts.
- WARNING:** Risk of wrapped tissue from rotating parts.
- WARNING:** Risk of kick-back from high-torque devices.
- WARNING:** When inserting blades, burs, rasps or twist drills, the coupler should be attached to the handpiece, and the throttle lock should be set to LOCKED .
- WARNING:** Do not activate a powered instrument without first inserting the proper blade, bur, rasp or twist drill.
- WARNING:** Inspect all system components for damage, corrosion, or excessive wear. Do not use if any of these conditions are present. Contact MicroAire for service.
- WARNING:** If corrosion or debris are detected in or on the instrument, the instrument is contaminated. Replace the instrument, or remove it from the sterile field to be reprocessed.
- WARNING:** Do not use single-use accessories that are dull or damaged.
- CAUTION:** MicroAire pneumatic instruments are powered by compressed nitrogen. Compressed air can be used only if it is dried and filtered to 3 micrometers / 3 microns due to the potential presence of oil vapor, moisture, and bacteria.
- WARNING:** Sterile accessory packages should be examined closely prior to opening to ensure that there has been no loss of package integrity. Do not use sterile accessories if the package is open or damaged because of the risk of infection.

- CAUTION:** To prevent damage to couplers, do not activate the instrument without first inserting a single-use accessory.
- WARNING:** If the instrument runs slowly or irregularly, be alert for the possibility of overheating or other malfunctions.
- WARNING:** Instrument temperature should not exceed 105°F (40°C). Monitor the instrument temperature to prevent injury.
- WARNING:** Place handpiece throttle into the LOCKED  position when not in use.
- WARNING:** Disconnecting air hoses improperly can cause injury to patients or hospital personnel. Make sure the air supply to the regulator is fully closed OFF and the air hose has been bled of residual air prior to disconnecting air hoses.
- WARNING:** When inserting a blade into REF 5922, the hole in the blade must be seated over the indexing pin to avoid damage or injury. Do not force the locking lever closed.
- WARNING:** Do not activate REF 5930 without first inserting a bur. Activation without a bur will cause overheating.
- WARNING:** Do not use REF 5930 with wires or pins.
- WARNING:** Bur shaft-diameter for REF 5930 must be within the range of 2.3mm to 2.4mm. Smaller shaft-diameters may slip, resulting in a rapid overheating; or they may eject, causing injury.
- WARNING:** Select the bur-guard size for REF 5930 that properly matches the length of the bur:
- WARNING:** The chuck collar on REF 5930 must be fully in the LOCKED  position to prevent overheating.
- WARNING:** Make sure that the blade is centered between the two locking plates on REF 5955, and not between just one locking plate and the edge of the instrument.
- WARNING:** If the blade or rasp becomes loose while the handpiece is running, the accessory is seated improperly in REF 5945 and must be corrected.
- WARNING:** Protect the patient's soft tissue near the REF 5945 chuck to prevent pinching.
- WARNING:** Make sure that the blade is centered between the washer and the locking plate on REF 5972, and not between just the washer and the locking nut.
- WARNING:** Where there is a concern about TSE/vCJD contamination, the World Health Organization recommends processing through a pre-vacuum steam sterilization cycle for 18 minutes at 134°C (273°F). (WHO/CDS/CSR/2000.3, "WHO Infection Control Guidelines for TSE," March 1999).
- WARNING:** After sterilization, allow instruments to cool to room temperature. Do not use instruments that are still warm. Do not soak instruments or wrap in wet towels to cool.

SYSTEM COMPONENTS

REF	Description
5000-100	Pneumatic Motor with MicroAire Connector
5000-200	Pneumatic Motor with Hall Connector
7000-000 / 7000-020	MicroAire Whisper Air Hose (3m / 6m)
7013-000 / 7013-020	Hall-style Whisper Air Hose (3m / 6m)
9000-000 / 9000-020	MicroAire Air Hose (3m / 6m)
9013-000 / 9013-020	Hall-style Air Hose (3m / 6m)
9300-010	Air Hose Extension (3m) Schrader to Schrader
9300-015	Air Hose Extension (4.5m) Schrader to Schrader
9300-020	Air Hose Extension (6m) Schrader to Schrader
9300-030	Air Hose Extension (3m) Schrader to DISS-Ohio
9500-000	Single-Regulator
9500-001	Multiple Connection Manifold (Stryker to Schrader)
9500-002	Schrader Input Connector
9500-003	Multiple Connection Manifold (Stryker Adaptor)
9500-004	Multiple Connection Manifold (DISS-Ohio to Schrader)
9502-000	Dual Regulator
5000SC	Instruments Sterilization Case 5000-Series
5922	Micro Sagittal Saw Module
5930	30K Micro Drill Module
5945	Reciprocating Saw Module
5950	Hall Style Sagittal Saw Module, Keyless
5955	Hall Style Sagittal Saw Module, with Key
5972	Oscillating Saw Module, with Key
5980	Jacobs Drill Module
5990	AO Drill (Synthes Style (Quick-Connect) Module

Accessories
MicroAire 1200-Series Sagittal Saw Blades
MicroAire ZB-Series Burs
MicroAire 1400-Series and ZR-Series Reciprocating Saw Blades and Rasps
MicroAire Z5-3XX Sagittal Blades
MicroAire Z5-Series Sagittal Blades
MicroAire ZO-Series Small Oscillating Blades
MicroAire 8054-Series Standard Twist Drills
MicroAire 8053-Series Synthes-Style Twist Drills
Hex Driver (REF 2250-001)
Locking Tool (REF 1745-001)
Drill Chuck Key (REF 1645-004)

ASSEMBLY / DISASSEMBLY INSTRUCTIONS

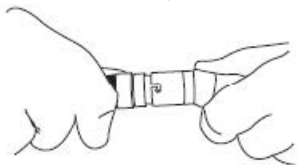
WARNING: Inspect all system components for damage, corrosion, or excessive wear. Do not use if any of these conditions are present. Contact MicroAire for service.

WARNING: If corrosion or debris are detected in or on the instrument, the instrument is contaminated. Replace the instrument, or remove it from the sterile field to be reprocessed.

WARNING: Do not use single-use accessories that are dull or damaged.

CAUTION: MicroAire pneumatic instruments are powered by compressed nitrogen. Compressed air can be used only if it is dried and filtered to 3 micrometers / 3 microns due to the potential presence of oil vapor, moisture, and bacteria.


1. Inspect single-use accessories (blades, burs, rasps, twist drills) for damage.
2. Connect a MicroAire air hose to a compressed air/nitrogen source using the REF 9500-000 regulator.
 - The main-tank pressure gauge should indicate a minimum of 500 p.s.i. (35kg/cm²).
 - Set the output pressure gauge to 100 p.s.i. (7kg/cm²).
 - If using a wall-mounted or ceiling-mounted air system, and the air hose is longer than 3m, the air pressure must be increased by 10 p.s.i. (0.7kg/cm²), for each additional 3m of hose length.
3. Connect the air hose to the pneumatic motor module.

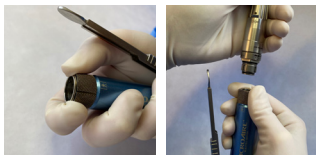


Make sure that air hose connections are fully seated and secure.



Throttle safety lock in the LOCKED  position and unlocked UNLOCKED  position.

4. Set the handpiece throttle to the **LOCKED**  position.
5. Connect a MicroAire Series-5000 coupler to the handpiece by retracting the collar on the handpiece and pushing the coupler into the receptacle.
6. Insert a single-use accessory (blade, bur, rasp, twist drill) into the coupler.





Retract the collar on the handpiece to connect a coupler.

WARNING: Sterile accessory packages should be examined closely prior to opening to ensure that there has been no loss of package integrity.


CAUTION: To prevent damage to couplers, do not activate the instrument without first inserting a single-use accessory.


7. Test the instrument:

- Set the throttle safety lock to the UNLOCKED  position.
- Press the throttle lever and test run the instrument for five seconds.
- Confirm that the throttle does not stick in the depressed position.
- Check for irregular noise, heat, or vibration.
- Set the throttle safety lock to the LOCKED  position.
- Contact MicroAire for service if irregularities are observed.

WARNING: If the instrument runs slowly or irregularly, be alert for the possibility of overheating or other malfunctions.

WARNING: Instrument temperature should not exceed 105°F (40°C). Monitor the instrument temperature to prevent injury.

WARNING: Place handpiece throttle into the LOCKED  position when not in use.

8. Following the surgical procedure, place the handpiece throttle into the LOCKED  position, and disassemble the system for reprocessing.

9. The air hose will stay connected to the handpiece during cleaning, so disconnect it only from the air supply, as follows:



- Close off the air supply to the regulator.
- Remove residual air in the hose by activating the hand piece with the throttle lever until it stops.
- Disconnect the air hose from the regulator by firmly holding the air hose connector while turning its slot to the open position. Be prepared for residual air to expel the hose and to produce a short burst of air.

WARNING: Disconnecting air hoses improperly can cause injury to patients or hospital personnel. Make sure the air supply to the regulator is fully closed OFF and the air hose has been bled of residual air prior to disconnecting air hoses.

REF 5922 - MICRO SAGITTAL SAW MODULE

- A sagittal-motion device intended for transverse or wedge osteotomies.
- Accepts MicroAire 1200-Series blades, which are ultra-thin (0.3mm) straight, angled, bent, or offset blades.

To insert a blade into the Micro Sagittal Saw Module (REF 5922):

1. Set the throttle safety lock to the LOCKED  position.
2. If using the REF 5000E with a Foot Pedal, avoid accidentally activating the Foot Pedal while inserting the blade.
3. Press the release lever to open the blade receptacle.
4. Insert the blade into the receptacle, making sure to fit the hole in the blade over the indexing pin.
5. Release the lever.
6. Confirm that the blade is secure.
7. To use the instrument, set the throttle safety lock to the UNLOCKED  position.




WARNING: When inserting a blade into REF 5922, the hole in the blade must be seated over the indexing pin to avoid damage or injury. Do not force the locking lever closed.




REF 5930 - 30K MICRO DRILL MODULE

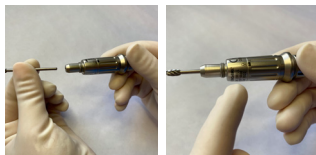
- A medium speed, medium torque rotary device intended for bone sculpting, drilling, wire passing, and reaming the intramedullary canals of small bones.
- Accepts MicroAire REF ZB-70, ZB-100, ZB-200, and ZB-300 burs.

To insert a bur into a 30K Micro Drill Module (REF 5930):

1. Set the throttle safety lock to the LOCKED  position.
2. Select the bur-guard size that properly matches the length of the bur:

Bur Length	Bur-Guard
47.8mm – 66.5mm	Medium (factory installed and cannot be removed)
69.1mm – 80mm	Long (REF 1100-005)
94.5mm – 95.3mm	Extra-Long (REF 1100-006)

4. Twist the chuck collar to the UNLOCKED  position.
5. Insert a bur into the chuck.
6. Twist the chuck collar to the LOCKED  position, confirming that it is fully locked.
7. Pull on the bur to make sure it cannot be removed.
8. To use the instrument, set the throttle safety lock to the UNLOCKED  position.




Make sure to fully lock the chuck after inserting a bur.

WARNING: Do not activate REF 5930 without first inserting a bur. Activation without a bur will cause overheating.

WARNING: Do not use REF 5930 with wires, or pins.

WARNING: Bur shaft-diameter for REF 5930 must be within the range of 2.3mm to 2.4mm. Smaller shaft-diameters may slip, resulting in a rapid overheating; or they may eject causing injury.




WARNING: Select the bur-guard size for REF 5930 that properly matches the length of the bur.

WARNING: The chuck collar on REF 5930 must be fully in the LOCKED  position to prevent overheating.

REF 5945 - RECIPROCATING SAW MODULE

- A reciprocating device intended for osteotomies using a blade; or for bone sculpting using a rasp.
- Accepts MicroAire small-bone ZR-series reciprocating blades and rasps.

To insert a blade or rasp into the Reciprocating Saw Module (REF 5945):

1. Set the throttle safety lock to the LOCKED  position.
2. Open the receptacle by turning the chuck counter-clockwise.
3. Insert the blade or rasp, making sure it is fully seated in the locking collar.
4. Close and tighten the chuck by turning clockwise.
5. To use the instrument, set the throttle safety lock to the UNLOCKED  position, or activate the Foot Pedal.
6. Test run the instrument for 3-5 seconds. After it stops, set the throttle safety lock to the LOCKED  position and attempt to pull out the blade or bur to confirm it is secure.





WARNING: If the blade or rasp becomes loose while the handpiece is running, the accessory is seated improperly in REF 5945 and must be corrected.

WARNING: Protect the patient's soft tissue near the REF 5945 chuck to prevent pinching.

REF 5950 - HALL® STYLE SAGITTAL SAW, KEYLESS MODULE

- A sagittal-motion device intended for transverse or wedge osteotomies.
- Accepts MicroAire ZS-series blades with five pin holes.

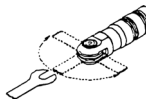
To insert a blade into the Hall® Style Sagittal Saw, Keyless Module (REF 5950):

1. Set the throttle safety lock to the LOCKED  position.
2. Press the small button to open the blade receptacle.
4. Insert the blade into the receptacle, making sure to fit the holes in the blade over the indexing pins.
5. Release the button.
6. Confirm that the blade is secure.
7. To use the instrument, set the throttle safety lock to the UNLOCKED  position.





REF 5955 - HALL® STYLE SAGITTAL SAW MODULE, WITH KEY

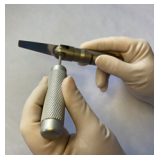
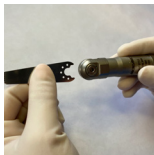
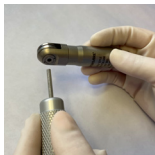
- A sagittal-motion device intended for transverse or wedge osteotomies.
- Accepts MicroAire ZS-series sagittal saw blades.



The blade can be locked into the saw at any angle along a 180° arc.

To insert a blade into the Hall® Style Sagittal Saw Module, with Key (REF 5955):

1. Set the throttle safety lock to the LOCKED  position.
2. Use Hex Driver (REF 2250-001) to open the blade receptacle by turning the locking nut counter-clockwise until a slight resistance is felt.
3. Insert the blade in the space between the two jaws making sure that the blade is fully seated.
4. Turn the hex driver clockwise to lock the blade. Do not over-tighten, but confirm that the blade is secure.
5. To use the instrument, set the throttle safety lock to the UNLOCKED  position.






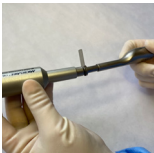
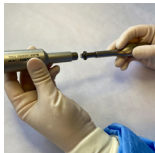
WARNING: Make sure that the blade is centered between the two locking plates on REF 5955, and not between just one locking plate and the edge of the instrument.

REF 5972 - OSCILLATING SAW MODULE, WITH KEY

- An oscillating device intended for osteotomies, especially foot procedures.
- Accepts MicroAire ZO-series small, straight, bent, and crescentic oscillating blades.

To insert a blade into the Oscillating Saw Module, with Key (REF 5972):

1. Set the throttle safety lock to the LOCKED  position.
2. Loosen the locking nut using Locking Tool (REF 1745-001).
3. Insert the blade in any position along an arc, between the washer and the locking plate.
4. Tighten the locking nut.
5. Confirm that the blade is secure.
6. To use the instrument, set the throttle safety lock to the UNLOCKED  position.
7. Test run the instrument for 3-5 seconds. After it stops, set the throttle safety lock to the LOCKED  position and retighten the locking nut.





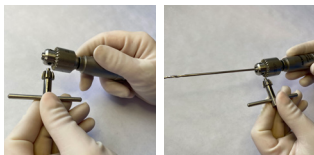
WARNING: Make sure that the blade is centered between the washer and the locking plate on REF 5972, and not between just the washer and the locking nut.

REF 5980 – JACOBS DRILL MODULE

- A low-speed, high-torque rotary device intended for drilling.
- Accepts MicroAire 8051-series and 8054-series twist drills with diameters between 1.0mm and 4.0mm, up to 127mm in length.

To insert a twist drill into the Jacobs Drill Module (5980):



1. Set the throttle safety lock to the LOCKED  position.
2. Open the chuck using Drill Chuck Key (REF 1645-004).
3. Insert the twist drill, making sure that it seats properly.
4. Close and tighten the chuck.
5. Confirm that the twist drill is secure.
6. To use the instrument, set the throttle safety lock to the UNLOCKED  position.

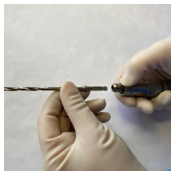


REF 5990 – AO DRILL (SYNTHESES® STYLE QUICK CONNECT) MODULE

- A low speed, high torque rotary device intended for drilling.
- Accepts MicroAire 8053-series quick-connect twist drills with diameters between 1.1 mm and 3.5mm, up to 127mm in length.

To insert a twist drill into the AO Drill (Synthes® Style) Module (REF 5990):

1. Set the throttle safety lock to the LOCKED  position.
2. Retract the chuck collar.
3. Insert the twist drill, making sure that it seats properly.
4. Release the chuck collar.
5. Confirm that the twist drill is secure.
6. To use the instrument, set the throttle safety lock to the UNLOCKED  position.



REPROCESSING INSTRUCTIONS

(PER ISO 17664:2003 & AAMI ST 81:2004)

Point of Use

Remove excess body fluids and tissue with a disposable, non-shedding wipe and cover with a cloth dampened with purified water. Body fluids and tissue should not be allowed to dry on instruments prior to cleaning.

NOTE: Instruments and multi-use accessories should be cleaned within 30 minutes of use to prevent organic material from drying on the instrument.

Preparation for Decontamination

1. Remove all surgical cutting accessories (blades, burs, rasps, twist drills) from the couplers.
2. Discard single-use accessories as contaminated sharps.
3. Disassemble instruments and accessories.
4. The air hose should stay connected to the handpiece to prevent the ingress of liquids during cleaning. (The air hose will be disconnected from the handpiece after cleaning, to be sterilized.)

Cleaning – Automated

1. Load instruments into the washer disinfecter.
 - Avoid contact between devices which can cause damage and can obstruct washing action.
 - Avoid overloading trays.
2. Arrange instruments so that cannulations are not horizontal, and openings are oriented downward to assist drainage.

Cycle	Detergent	Minutes	Temp
Pre-Wash	Mild pH Enzymatic*	4	< = 50°C (122° F)
Rinse	None	1**	< = 50°C (122° F)
Wash	Neutral pH	4	> = 60°C (140°F)
Drain for 1 Minute Minimum			
Rinse	None	2**	> = 60°C (140°F)
Drain for 1 Minute Minimum			
Thermal Disinfect	None	10	> = 93°C (200°F)
Drain for 1 Minute Minimum			

* Detergent can be omitted at the pre-wash stage if the equipment does not have this function.

** If not using mild pH detergent, extend rinse time to reduce material degradation.

Cleaning - Manual

1. Do not submerge instruments in water.
2. Rinse handpieces, couplers, bur guards, and air hoses thoroughly with warm water ($\leq 50^{\circ}\text{C} / 122^{\circ}\text{F}$) for a minimum of 60 seconds.
3. Clean handpieces, couplers, bur guards, and air hoses using a Cavi-Wipe (or similar).
4. Clean handpieces, couplers, bur guards, and air hoses thoroughly with warm water ($\leq 60^{\circ}\text{C} / 140^{\circ}\text{F}$), mild pH enzymatic detergent, and a soft brush to scrub all surfaces for 60 seconds, paying close attention to crevices.
5. Clean central lumens of bur guards using brush REF 5130-BR (or similar), wet with detergent but not dripping, until visibly clean.
6. Rinse handpieces, couplers, bur guards, and air hoses thoroughly under running water ($\leq 50^{\circ}\text{C} / 122^{\circ}\text{F}$) for a minimum of 2 minutes. While rinsing, use brush REF 5130-BR (or similar) in lumens and openings.
7. Repeat cleaning handpieces, couplers, bur guards, and air hoses thoroughly with warm water ($\leq 60^{\circ}\text{C} / 140^{\circ}\text{F}$), mild pH enzymatic detergent, and a soft brush to scrub all surfaces for 30 seconds, paying close attention to crevices.
8. Use a powered irrigator to flush lumens and openings. Focus the pressurized water stream into gaps, ridges and edges.
9. Rinse handpieces, couplers, bur guards, and air hoses thoroughly under running water ($\geq 50^{\circ}\text{C} / 122^{\circ}\text{F}$) for a minimum of 2 minutes. If possible, use distilled water for the final rinse.
10. Remove water from instruments with a soft lint-free towel or air gun.
11. Drain all water from air hoses with a hand-over-hand method, keeping one end lower so it can drain.

Inspection and Function Testing

1. Disconnect the air hose from the handpiece to allow sterilization of connections and proper drying.
2. Carefully inspect each device to ensure that all blood and soil has been removed.
3. Visually inspect for damage and/or wear.
4. Check the action of moving parts to ensure smooth operation throughout the intended range of motion.
5. Confirm that couplers can be connected to the handpiece.

NOTE: If concerns are noted that may compromise the function of any MicroAire device, do not use the device and contact MicroAire for service.

Sterilization

Sterilization Method	Instrument Types	Minimum Time & Temperature	Minimum Heated Dry Time
Dynamic Air Removal (Pre-vacuum) Steam	Double-wrapped instrument or accessory only; or multiple instruments and accessories in a double-wrapped sterilization case	3-minute full cycle @ 135°C (275°F)	30 minutes
		4-minute full cycle @ 132°C (270°F)	30 minutes
Gravity-Displacement Steam	Double-wrapped instrument or accessory only; or multiple instruments and accessories in a double-wrapped sterilization case	15-minute full cycle @ 132°C (270°F)	45 minutes
		10-minute full cycle @ 135°C (275°F)	45 minutes

WARNING: Where there is a concern about TSE/vCJD contamination, the World Health Organization recommends processing through a pre-vacuum steam sterilization cycle for 18 minutes at 134°C (273°F). (WHO/CDS/CSR/2000.3, "WHO Infection Control Guidelines for TSE," March 1999).

WARNING: After sterilization, allow instruments to cool to room temperature. Do not use instruments that are still warm. Do not soak instruments or wrap in wet towels to cool.

DUTY CYCLE

Continuous operation with intermittent loading. (1-minute ON then 1-minute OFF for 6 consecutive cycles)

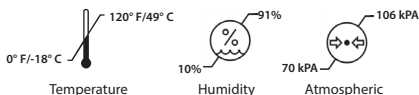
ENVIRONMENTAL PARAMETERS

OPERATING CONDITIONS – This device has been tested and proven to operate within the following conditions:



SHIPPING & STORAGE CONDITIONS

This device has been tested and proven to operate after repeated exposure to the following conditions:



STORAGE

Sterile, packaged instruments should be stored in a designated, limited-access area that is well ventilated and provides protection from dust, moisture, insects, vermin, temperature and humidity extremes.

PERIODIC INSPECTION

MicroAire recommends that all instruments be returned for routine inspection and service after 100 procedures. There is no charge for service during the warranty period.

REPAIR SERVICE

- Contact Customer Service for a Return Material Authorization (RMA) number.
- MicroAire may be able to solve the problem without requiring return of the item for service.
- Do not disassemble or attempt to service the equipment.
- Unauthorized repair service will void the warranty.

POWER OUTPUT, NOISE AND VIBRATION

	Unit of Measure	5000-XXX Handpiece
Power Output	kW - KiloWatts	–
Vibration Exposure	ahv(m/s ²) Uncertainty k (m/s ²)	1.68 1.5
Noise Emission Value	LPA (db(A)) LC, Peak (db(C)) LWA (dbA))	84 – –
Mass	Weight (kg)	0.18

DISPOSAL

To reduce the risk of contamination by biological waste, it is recommended that all devices shall first be cleaned and sterilized. Disposal shall comply with all local, state and federal laws and regulations.

Europe only: In accordance with the 2002/96/EC Directive on Waste Electrical and Electronic Equipment Directive (WEEE) the product distributor is responsible for organizing a system for the collection, storage and transfer of any and all WEEE components to Manufacturer's approved WEEE collection facility in Europe. Distributor shall provide on request to the manufacturer, the proof of compliance with the European provisions regarding the WEEE Directive.

WARRANTY

MicroAire Surgical Instruments warrants Series-5000 Electric Instruments to be free from defects in material and workmanship for a period of one year from the date of purchase. During the warranty period, products found to have a defect in material or workmanship will be repaired or replaced at the discretion of the manufacturer. All other expressed or implied warranties are excluded and MicroAire shall have no liability for incidental or consequential damages. Repairs or alterations to MicroAire products by anyone other than MicroAire, or an authorized MicroAire repair facility, will void the product's warranty.

NOTES

NOTES



MicroAire Surgical Instruments, LLC
3590 Grand Forks Boulevard
Charlottesville, Virginia 22911 USA

In the United States:
Phone: (800) 722-0822
Fax: (800) 648-4309

Outside the United States:
Phone: (434) 975-8000
Fax: (434) 975-4131

www.microaire.com



MediMark Europe
11, rue Emile Zola - BP 2332
F-38033 Grenoble Cedex 2
France



The following company is not affiliated with MicroAire Surgical Instruments LLC.
Synthes® is a registered trademark of Depuy Synthes (USA).