Series 5000 Electric Modular Instruments

Instructions for Use





SYMBOL DEFINITIONS

6	This icon is blue. Refer to Instruction Manual / Booklet			
\bigotimes	DO NOT Lubricate	DT Lubricate		
1	Lock/Safe	1	Run	
\$•	Atmospheric Pressure Limitations	<u>%</u>	Humidity Limitation	
X	Temperature Limitations	Ŵ	DO NOT expose to stray magnetic fields	
X.	Waste Electrical and Electronic Equipment (WEEE) European Community Symbol. Regarding Electrical Equipment European Union end of life of product, indicating separate collection for electrical and electronic equipment. ALWAYS follow the current local recommendations and/or regulations governing environmental protection and the risks associated with recycling or disposing of the equipment at the end of its usual life.			
cus E494242	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			
C E 0086	European Conformity Mark with MicroAire's Notified Body Number			
EC REP	Authorized European Representative R_{only}		Prescription	
	Expiration Date YYYY-MM	LOT	Lot Number Example (1010175891)	
REF	Product Catalog Number	t Catalog Number SN		
уууу-мм	Date of manufacture. Y=year, M=month.		Manufacturer	
Ŕ	IEC60601-1 TYPE BF Applied Part		Caution; specific warnings or precautions associated with medical device, consult IFU.	

APPLICABLE INSTRUMENT PART NUMBERS

REF Number	Description / Type BF Applied Parts		
5000ET	MicroAire Electric Motor Module with Throttle		
5000E	MicroAire Electric Motor Module without Throttle		
Other Accessories			
5025	MicroAire Electric Instrument Control Console		
5006-5000	Series 5000 Instrument Cable		
5401	Series 5000 Electric Foot Pedal		
5025-5401	Series 5000 Foot Pedal Cable		
5000SC	Series 5000 Small-Bone Instruments Sterilization Case		
5601-IT	Series 5000 Irrigation Tubing		
5922	MicroAire Sagittal Saw Head Module		
5930	MicroAire 30K Drill Head Module		
5945	MicroAire Reciprocating Saw Module		
5950	MicroAire Hall Style Keyless Sagittal Saw Module		
5955	MicroAire Hall Style Keyed Sagittal Saw Module		
5972	MicroAire Keyed Oscillating Saw Module		
5980	MicroAire Jacobs-Style Drill Module		
5990	MicroAire AO Synthes Style Drill Module		

Type BF Applied Part Disposable Families		
MicroAire 1600 Series K-Wires		
MicroAire 1600 Series Steinmann Pins up to 3.2mm in diameter		
MicroAire 1200 Series Sagittal Saw Blades		
MicroAire ZB-XXX Burs		
MicroAire 1400 Series and ZR Series Reciprocating Saw Blades and Rasps		
MicroAire ZS-3XX Sagittal Blades		
MicroAire ZS-XXX Sagittal Blades		
MicroAire ZO Series Small Oscillating Blades		
MicroAire 8054 Series Standard Twist Drills		
MicroAire 8053 Series Synthes® Style Quick Connect Twist Drills		

INTRODUCTION

This manual has been written to help describe the procedures required to keep the MicroAire Series 5000 Modular Instruments operating properly.

Throughout the manual, the following terms are used to identify tips and precautions that will help avoid accidental injury to patients or personnel, or prevent damage to the system.

WARNING: Used to indicate that the safety of the patient and hospital personnel could be involved.

- **CAUTION:** Used to point out special procedures or precautions that must be followed to avoid damaging the system/instrument.
- **NOTE:** Used to point out the easiest means of carrying out techniques.

General Warnings:

WARNING: See IM-5025 for operation of the instrument Control Console.

- **WARNING:** Use care to ensure that there is no electromagnetic interference between these devices and other devices in use. See IM-5025 for EMC information.
- **WARNING:** When inserting burs, blades, or drills, the head of the module should be attached to the motor module, and the motor module should be connected to its corresponding power source. The electric power sources should be set to SAFEs. Please see System Setup for instructions on connecting the motor to the module and its corresponding power source to the electric console.
- **WARNING:** 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 the power equipment before it is set-up for use in any procedure. Personnel that are trained should include, but not be limited to, central processing personnel, members of the surgical team, and the bioengineering department.
- **NOTE:** When the instrument is first plugged into the Electric Instrument Console, the speed value will automatically default to 100%.

DUTY CYCLE

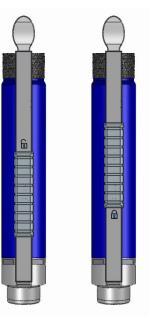
Continuous operation with intermittent loading. (20 seconds ON then 1 minute OFF for 3 consecutive cycles.)

ELECTRIC SYSTEM SETUP

- 1. Inspect the Handpiece, Console, Foot Pedal, and Cables for damage, corrosion, or excessive wear. If any of the components look damaged or show signs of excessive wear, do not use. Contact MicroAire Customer Service for repair.
- **WARNING:** If any corrosion or debris is detected in or on the instrument, it must be considered contaminated. Either replace the instrument immediately or remove it from the sterile field and reprocess, following the instructions provided in the Instructions for Use Document.
- 2. Check all surgical accessories. Make sure that blades and rasps are not dull or bent.
- 3. Place the Console (REF 5025/5020) on a sturdy, flat surface near a hospital-grade outlet. Install the power cord plug into the power receptacle on the console. Install the other end of the power cord into a hospital grade wall outlet. Wait for the console to initialize, then press and hold the blinking standby button to turn the console on. Refer to your REF 5025/5020 console manual for more information.
- 4. Insert handpiece cable into handpiece cable receptacle on front of Console. If using a Foot Pedal (REF 5401), plug the Foot Pedal cable into the Console port marked with a FOOT PEDAL symbol. Align the marks and gently push the connectors together. Only one foot control may be connected to the console at a time, but can be selected to operate either of the foot control compatible instruments.
- 5. Make sure handpiece throttle is set to the SAFE is position, and if using the Foot Pedal (REF 5401), take care to ensure the Foot Pedal is not activated accidentally.
- 6. Insert handpiece cable into receptacle on rear of handpiece, aligning the dots on both cable end and receptacle to ensure proper fit.

- 7. Attach a MicroAire Series 5000 Module (see page 2 for full listing) to the (REF 5000E or REF 5000ET) Electric Motor module.
- 8. Insert a surgical accessory into the handpiece. For detailed instructions for a specific handpiece, please refer to the corresponding section as shown in the table of contents in this manual.
- 9. Confirm the handpiece throttle is functional.
 - a. Ensure that when the throttle safety lock is set to SAFE it prevents activation of the motor by the hand throttle or foot control.
 - b. Ensure that when the throttle safety lock is set to RUN i it allows activation of the motor by the hand throttle or foot control.
 - c. Ensure that the throttle does not stick in the fully depressed position. If it has any tendency to stick, reclean and re-sterilize the handpiece. If the handpiece still does not meet the above requirements, return the handpiece to MicroAire or an Authorized MicroAire Repair Facility for service.
- 10. With the surgical accessory inserted, test run the instrument in the sterile field for five (5) seconds, checking for any indication of irregular noise, excessive heat, or vibration. Irregular grinding noises may indicate impending failure or overheating of the handpiece. If any irregular grinding noises are present, return the handpiece to MicroAire or an Authorized MicroAire Repair Facility for service.
- **WARNING:** Excessive heat is the most likely cause of patient injury. Periodically monitor the temperature of the nose section. The temperature should not rise above 115°F (46°C). If the instrument temperature exceeds 115°F (46°C) please return the handpiece, module and cable to MicroAire or an Authorized MicroAire Repair Facility for service.
- **NOTE:** When the instrument is first plugged into the Electric Instrument Console, the speed value will default to 100%.
- **NOTE:** The handpiece may be run in forward or reverse by pressing the direction arrow on the REF 5025 console touchscreen.
- 11. To set the throttle maximum speed at other than 100%:
 - a. Move handpiece throttle to the RUN $\stackrel{\frown}{=}$ position.
 - b. Fully depress the throttle of the instrument.
 - c. Use the Console touch screen to set the desired speed.
 - d. Desired maximum speed is now set for the desired instrument.
 - e. Move handpiece throttle back to the SAFE 🖻 position.
- 12. Move handpiece throttle to the RUN $\stackrel{\frown}{\blacksquare}$ position.
- Pre-use check: Run instrument for 3 seconds to ensure that the instrument functions properly prior to use.
 WARNING: If the handpiece runs slowly or irregularly, be alert for the possibility of instrument overheating or other malfunctions.
- 14. System is ready for use.
- **WARNING:** Place throttle into the SAFE $\widehat{\pm}$ position when not in use.





REF 5922 MICRO SAGITTAL SAW MODULE INSTRUCTIONS

The Sagittal Saw Module (REF 5922) offers control, power, and maneuverability for cutting transverse or wedge osteotomies.

This Sagittal Saw Module can be used with a variety of ultra-thin, 0.3mm (0.010"), straight, angled, bent, or offset blades, such as MicroAire's 1200 Series blades. Please see MicroAire catalog for a full listing of these blades.

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

- 1. If using the throttle-lever handpiece, move the throttle safety lock to 🔂. If using the handpiece with the Foot Pedal, take care to ensure that the Foot Pedal is not activated accidentally while inserting the blade.
- 2. Open the blade locking lever to release the floating jaw.

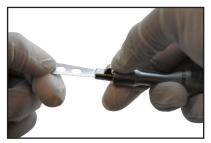


3. Insert the blade between the floating jaw and the indexing pin, making sure to fit the hole in the blade over the indexing pin.



CAUTION: When inserting a blade, the blade hole must be seated over the indexing pin. If it is not, the head will be damaged when the locking lever is closed. **DO NOT** force the locking lever if excessive resistance is felt.

- 4. Release the locking lever.
- 5. Attempt to pull the blade out of the handpiece to confirm it is secure. If the blade can be removed by hand, open the blade locking lever and attempt to insert the blade into the handpiece again.



REF 5930 30K MICRO DRILL MODULE INSTRUCTIONS

The Micro Drill Handpieces (REF 5930) 30K are the workhorses of small bone surgery. They are used for bone sculpting, drilling, wire passing, and reaming the intramedullary canals of small bones. These medium speed, high torque instruments come standard with a built-in, medium-length bur guard.

These drills will accept the MicroAire (REF ZB-100, -200, and -300) Series burs. Please see MicroAire catalog for a full listing of these accessories. If other burs are used, make certain that they are designed for use in orthopedic or oral surgery. The bur shaft diameter must be within the range of .0919" (2.3mm) to .0928" (2.4mm).

WARNING: If burs of insufficient diameter are used, they may slip under load, resulting in rapid overheating, or they may eject at great velocity, potentially causing harm to patients or personnel.
 WARNING: When using long or extra long burs, use the corresponding long (REF 1100-005) or extralong (REF 1100-006) bur guard to prevent whipping or shattering of burs.

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

1. If using the throttle-lever handpiece, move the safety lock to SAFE 🗈 . If using the handpiece with the Foot Pedal, take care to ensure that the Foot Pedal is not activated accidentally while inserting the bur.

- 2. Remove the silicone cap (if present).
- 3. If using long or extralong burs, use the long (REF 1100-005) or extra long (REF 1100-006) bur guard.
- 4. Twist the collet to the $\widehat{\Box}$ position.





- 5. Insert the bur.
- 6. Twist the nose collet to the [∩] position.
- 7. Pull on the bur to make sure it is secure.



WARNING: Collet must be in full position to prevent overheating of the instrument.WARNING: DO NOT run the instrument without a bur or drill, or the instrument will overheat.

REF 5955 HALL® STYLE KEYED SAGITTAL SAW MODULE INSTRUCTIONS

The Hall[®] Style Keyed Sagittal Saw Module (REF 5955) is a heavy duty design saw which permits use of the longer ZS series sagittal saw blades for performing transverse or wedge osteotomies. Please refer to MicroAire catalog for a full listing of these blades.

NOTE: The Hall[®] Style Keyed Sagittal Saw head module can be rotated to any position for the best blade angle, and the blade can be locked into the saw at any angle on a180° arc.

To insert a blade into the (REF 5955) Hall[®] Style Keyed Sagittal Saw module:

- 1. If using the throttle-lever handpiece, move the throttle safety lock to 🗈. If using the handpiece with the Foot Pedal, take care to ensure that the Foot Pedal is not activated accidentally while inserting the blade.
- 2. Insert the Hex Driver (REF 2250-001) and turn it counter-clockwise until a slight resistance is felt.



 Insert the blade in the space between the two jaws making sure that the blade is fully seated.



 Turn the hex driver clockwise to lock the blade. DO NOT over-tighten.



REF 5945 RECIPROCATING SAW MODULE INSTRUCTIONS

The Reciprocating Saw Module (REF 5945) can be used with a variety of surgical accessories from the MicroAire 1400 and small ZR series of micro-reciprocating blades and rasps. Please see MicroAire catalog for a full listing of these accessories.

NOTE: MicroAire Large Reciprocating ZR Series of blades (REF ZR-032, -032M, -058, -059, -060, -061, -073, -079, -160,) cannot be used with the (REF 5945) module.

To insert a surgical accessory into the (REF 5945) Reciprocating Saw module:

- 1. If using the throttle-lever handpiece, move the throttle safety lock to 🗈. If using the handpiece with the Foot Pedal, take care to ensure that the Foot Pedal is not activated accidentally while inserting the surgical accessory.
- 2. Loosen the locking collar by turning it approximately four (4) times in a counter-clockwise direction.
- 3. Insert the surgical accessory, making sure it is fully seated in the locking collar.
- 4. Tighten the locking collar by turning it in a clockwise direction. Turn the locking collar until tight.
- 5. Run the instrument for 3-5 seconds, once stopped, attempt to pull the surgical accessory out of the handpiece to confirm it is secure. If accessory can be removed by hand, re-insert and properly tighten locking collar.
- **NOTE:** If a surgical accessory becomes loose when the handpiece is running, the accessory was not seated properly in the locking mechanism. Move the accessory from side to side several times, then retighten the locking collar.
- **WARNING:** When operating Reciprocation Saw, be careful to retract or protect the patient's tissue near the locking collar. Pinching the tissue between the collar and the body of the instrument may cause injury.

REF 5950 HALL® STYLE KEYLESS SAGITTAL SAW MODULE INSTRUCTIONS

The Hall[®] Style Sagittal Saw, Keyless (REF 5950) handpiece is a powerful, heavy-duty saw for transverse or wedge osteotomies. This saw accepts MicroAire ZS series of Keyless Sagittal Blades. Please see MicroAire catalog for a full listing of these blades. This saw will not accept MicroAire (REF ZS-0XX) series of Sagittal Blades.

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

1. If using the throttle-lever handpiece, move the throttle safety lock to 🗈. If using the handpiece with the Foot Pedal, take care to ensure that the Foot Pedal is not activated accidentally while inserting the blade.

2. Depress push button and insert the blade between the two jaws, making sure that the blade is fully seated over the indexing pins.



3. Release push button.

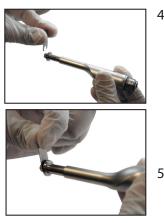


REF 5972 KEYED FOOT SURGERY OSCILLATING SAW MODULE INSTRUCTIONS

The Oscillating Saw Module (REF 5972) was specially designed for foot surgery. A wide selection of straight, bent, and crescentic saw blades (MicroAire's ZO Series small oscillating blades) are available for this special purpose module. Please refer to MicroAire catalog for a complete listing of these blades.

To insert a blade into the Oscillating Saw module:

- 1. If using the throttle-lever handpiece, move the throttle safety lock to $\widehat{\Box}$. If using a motor module with a Foot Pedal, take care to ensure that the Foot Pedal is not activated accidentally while inserting the blade.
- 2. Loosen the head nut with the Oscillating Saw locking tool (REF 1745-001).
- Insert the blade behind the washer (the washer goes next to the head nut) in any desired position.



 Tighten the nut using the MicroAire (REF 1745-001) Oscillating Saw Locking Tool, and then pull on the blade to make sure it is secure.



- 5. Run the instrument for 3-5 seconds, then retighten nut.
- **CAUTION:** When inserting a blade into the Keyed Foot Surgery Oscillating Saw Module blade must be placed behind the washer or instrument will be damaged.

REF 5980 JACOBS® STYLE DRILL MODULE INSTRUCTIONS

The Jacobs[®] Style Drill Module (REF 5980) is a low-speed, high-torque drill. The Jacobs[®] Style Drill Head handpiece accepts MicroAire (REF 8051) and (REF 8054) Series Jacobs[®] Style twist drills with diameters between 1.0mm (.039") and 4.0mm (.15"), up to 127mm (5") in length. Please refer to MicroAire catalog for a full listing of these drill bits.

To insert a twist drill into the Jacobs® Style Drill module:

- 1. If using the throttle-lever handpiece, move the throttle safety lock to 🗈. If using a motor module with a Foot Pedal, take care to ensure that the Foot Pedal is not activated accidentally while inserting the drill bit.
- 2. Using a 5/32" Jacobs® Style chuck key (REF 1645-004), open the chuck to the desired size.
- Insert the twist drill, making sure that it seats properly.





- Tighten the Jacobs[®] style chuck using the same Jacobs chuck key (REF 1645-004).
- 5. Being careful of sharp drill flutes, pull on the drill bit to make sure it is secure.



REF 5990 SYNTHES® STYLE DRILL MODULE INSTRUCTIONS

The Synthes[®] Style Drill Module (REF 5990) is a low speed, high torque drill that allows the use of Synthes[®] Style quick-connect twist drills.

The Synthes[®] Style Drill handpiece accepts any MicroAire (REF 8053) Series quick-connect twist drills with diameters between 1.1mm (.05") and 3.5mm (.14"), up to 127mm (5") in length. Please refer to MicroAire catalog for a full listing of these drill bits.

To insert a twist drill into the Synthes® Style Drill module:

- 1. If using the throttle-lever handpiece, move the throttle safety lock to 🗈. If using a motor module with a Foot Pedal, take care to ensure that the Foot Pedal is not activated accidentally while inserting the drill bit.
- 2. Retract the collar at the front of the handpiece.
- 3. Insert a quick connect Synthes[®] type twist drill.
- 4. Make sure the drill is fully inserted and seated.
- 5. Release the collar to lock the drill in place.
- 6. Being careful of sharp drill flutes, pull on the drill bit to make sure it is secure.



INSTRUMENT CLEANING AND STERILIZATION INSTRUCTIONS

per ISO 17664:2003 & AAMI ST 81:2004

INSTRUCTIONS

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 (MAXIMUM 30 minutes).			
NOTE:	It is recommended that instruments and all non-disposable accessories be cleaned within 30 minutes of end of use to minimize the potential for organic material to dry on the instrument.			
Preparation for decontamination:	 Remove all inserted surgical cutting accessories (blades, burs, rasps, drill bits, etc.) from the handpiece. Disposable surgical accessories should be discarded after use, handling them as any contaminated sharp accessory is handled. Reuse of surgical cutting accessories is not recommended. Disassemble instruments and accessories. For Automated Cleaning install the electric cable for the instrument. For Manual Cleaning install the electric cable for the instrument. 			
Preparation of Cleaning Agent:	Prepare a neutral pH enzyme and cleaning agents at the use-dilution and temperature recommended by the manufacturer. Determination of cleaning agents shall be by local or country regulations.			
Cleaning - Automated:	 Load the medical devices into the Washer Disinfector a) Avoid contact between devices (movement during washing could cause damage and washing action could be ostructed). DO NOT overload the trays. b) Arrange medical devices so that cannulations are not horizontal and any openings are oriented downwards (to assist drainage). The minimum recommended Washer/Disinfectant cycle is on the following page: 			

	#	Title	Detergent	Minutes	Temp	
	1	Pre-Wash	Neutral pH Enzymatic*	4	$< = 50^{\circ}C (122^{\circ} F)$	
	2	Rinse	None	1**	$< = 50^{\circ}C(122^{\circ}F)$	
		Wash		4	$> = 60^{\circ}C (140^{\circ}F)$	
	3 Wash Neutral pH 4 4 Drain for 1 Minute Minimum				/ = 00 C (140 T)	
	5	Rinse	None	2**	> = 60°C (140°F)	
	6 Drain for 1 Minute Minimum					
	7	Thermal Disinfect	None	10	> = 93°C (200°F)	
	8	Drain for 1 Minute Minimu	m	1		
	* Detergent can be omitted at the pre-wash stage if the equipment do ** If not using mild pH detergent, extend rinse time if possible to redu					
NOTE:	Washer/Disinfectors should comply with the requirements of ISO 15883 (in preparation). They should be properly installed and be regularly tested in accordance with ISO 15883.					
Cleaning - Manual:	1) Clean the handpiece and couplers thoroughly with warm $(< = 50^{\circ}C / 122^{\circ}F)$ water, enzymatic detergent, and soft brush. Scrub the handpiece with the brush, paying clos attention to instrument crevices.				-	
		Rinse handpieces, couplei = 50°C / 122° F) water for a	rs and electric cables thorou minimum of 2 minutes.	ighly under runr	ning	
	3) Clean the handpieces and couplers thoroughly with warm (> = 60° C / 140° F) water, mile pH enzymatic detergent, and soft brush. Scrub the handpiece with the brush, paying clos attention to instrument crevices.					
4) Flush the lumens of instruments and the nose of drills and wire drivers v similar device. Flushing removes blood, debris and saline deposits.				s with a Water-Pik or		
	5) Rinse handpieces, couplers and electric cables thoroughly under running (> water for a minimum of 2 minutes. If possible, use distilled water for the final ri				-	
	6) After rinsing all electric cables, it is required that the cables be drained of all residual cleaning fluids.					
Disinfection:	Disinfection is only acceptable as an adjunct to full terminal sterilization for reusable surgical instruments. See sterilization section below.					
Drying:	Wipe off any water from the handpiece with a soft lint free towel. An airgun can also be used to dry the handpiece.					
Maintenance, Inspection and Function Testing:	 Remove the electric cable from the hand piece. Carefully inspect each device to ensure all visible blood and soil has been removed. Visually inspect for damage and/or wear. Check the action of moving parts to ensure smooth operation throughout the intended range of motion. Where instruments form part of a larger assembly, check that the devices assemble with their mating components. 					
NOTE:	If concerns are noted that may compromise the function of any MicroAire device, do not use and contact MicroAire Customer Service or your Service Representative.					

Sterilization:

Steam sterilize using one of the following cycles.

Sterilization Cycle		Instrument Minimum Time & Temp		Min Heated Dry time	
Dynamic Air Removal (Pre-vacuum)		Circula la strucciant	3 minute full cycle @ 134 – 137°C (273 – 279°F)	8 minutes	
		Single Instrument	4 minute full cycle @ 132 – 135°C (270 – 275°F)	8 minutes	
		Ctorilization Trav	3 minute full cycle @ 134 – 137°C (273 – 279°F)	45 minutes	
		Sterilization Tray	4 minute full cycle @ 132 – 135°C (270 – 275°F)	45 minutes	
Gravity Displacement		Single Instrument	30 minute full cycle @ 132 – 135°C (270 – 275°F)	8 minutes	
		Sterilization Tray	35 minute full cycle @ 132 – 135°C (270 – 275°F)	60 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).					
Storage:		ted and provides prote	s should be stored in a designated, limi ection from dust, moisture, insects, verr		

Additional1) Sterile instrument packages should be examined closely prior to opening to ensure that there hasInformation:been no loss of package integrity.

2) Do not use instruments when they are still warm. Allow to cool to room temperature.

- 3) Do not soak instruments or wrap in cold towels to cool.
- Manufacturer MicroAire Surgical Instruments
- Contact: 3590 Grand Forks Boulevard

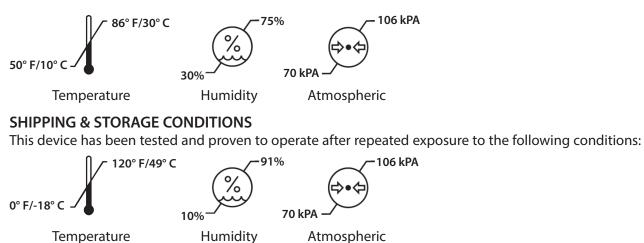
Charlottesville, VA 22911 U.S.A.

Inside the USA Dial: 1-800-722-0822 Outside the USA, dial the local international access code followed by +1-434-975-8000

ENVIRONMENTAL PARAMETERS

OPERATING CONDITIONS

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



Shipping: The materials and components used in the construction of this device were selected to ensure that the device could be shipped by any standard commercial method without special handling conditions.

WARRANTY, SERVICE AND REPAIR

MicroAire Surgical Instruments warrants the 5000 Series modular instruments to be free from defects in material and workmanship in their manufacture for a period of 1 (one) year from the original purchase date by the end customer. This warranty is limited to the repair or replacement of the product without charge.

This warranty is null and void in the event of abuse, misuse, or use in other than a normal surgical environment, or in the event of disassembly, alteration, or repair of the product not authorized by MicroAire, or in the event that the product has not been used in a reasonable manner and in compliance with the written instructions furnished by MicroAire. Using any accessory that is not a MicroAire product will void your warranty.

All other expressed or implied warranties and all other warranties of fitness or merchantability are excluded here from, and MicroAire shall have no liability of any kind for any incidental or consequential damages.

WARNING: Modification of this equipment is not allowed!

NOTE: Repairs or alterations to MicroAire products made by anyone other than MicroAire or an authorized MicroAire repair facility will void that product's warranty, and the customer will be responsible for any costs related to returning the product to working condition.

EXTENDED WARRANTY

Extended warranties may be purchased while the equipment is covered by the original warranty. If the equipment is out of warranty, it must first be restored, if necessary, to the full serviceable condition before being eligible for a service agreement.

Periodic inspection and service is essential to keep precision MicroAire products running properly. If repairs are required, they can be accomplished quickly with a minimal disruption to the hospital's schedule.

SERVICE AND REPAIR

Responsive service comes with every MicroAire product. If a problem with your equipment should arise, contact our Customer Service Department at:

	Telephone:	Fax: E-Mai	il:
USA	800-722-0822	800-648-4309	inquiry@microaire.com
Outside USA	434-975-8000	434-975-4134	intlsvc@microaire.com

MicroAire: mailing address information is located on the back cover.

MicroAire may be able to solve the problem quickly without requiring return of the item for service. DO NOT disassemble or attempt to service the equipment. It can only be serviced by MicroAire or an Authorized MicroAire Repair Facility. Unauthorized service will void the warranty.

To return an item for service, follow these guidelines listed below.

1. Contact Customer Service for a Return Material Authorization (RMA) number.

NOTE: DO NOT return equipment without an RMA number. This could cause delays in service, and/or problems tracking returns.

2. Clean and disinfect equipment before sending for repair.

3. Along with the items sent for repair, enclose a detailed description of the problem encountered, the type of use, the place of use, a contact name, and a telephone number. This information is helpful to our repair technicians.

4. If the instrument is out of warranty, enclose a purchase order number with the instrument. If the instrument is under warranty, include the purchase date.

5. In the United States, ship the merchandise by Express Mail, Federal Express, or UPS Blue Label to prevent shipping delays. From outside the United States, return goods by Federal Express, UPS, or Air Freight.

6. Return the merchandise prepaid.

7. If an estimate of repair costs is needed before the repair technicians begin work, include the name and telephone number of the person to contact.

8. MicroAire will repair and re-ship the item by 2nd Day Air within the United States and by Federal Express or Air Freight outside the U.S. unless specified otherwise.

TECHNICAL DESCRIPTION

The Series 5000 electric modular system is a powered surgical instrument system comprised of a small electric brushless motor module and a variety of head modules designed for small bone surgery. The head modules are variable speed drills, sagittal, oscillating, and reciprocating saws. The system is powered by a MicroAire 5025 Instrument Control Console which provides IEC60601-1 Type BF isolated control signals to the 5000ET via the 5006-5000 Instrument Cable. The user can command the 5000ET to run or stop via a hand throttle located on the instrument. The 5000ET, 5006-5000, and associated head modules are reusable instruments. Single use burs, blades, and twist drills are used on the head modules while running from the 5000ET Motor Module.

ELECTRIC SYSTEM TROUBLESHOOTING

1. Handpiece cable is difficult to insert into the handpiece or the console.

- a. Align connectors and receptacles carefully. Make sure the pins on the cable are aligned with the matching holes in the console or handpiece receptacle. This connection is a tight fit to keep particles from getting inside the handpiece.
- b. Ensure the plug is pressed fully into the handpiece and that the "snap lock" is fully engaged.

2. Handpiece will not start.

- a. Check to make sure that the Console is "ON"
- c. Replace the handpiece cable.
- b. Make sure the 5000ET motor throttle is in the $\widehat{\pm}$ position.
- d. Make sure the maximum speed display indicates a maximum speed, and the light around the cable receptacle is illuminated.
- e. Remove the handpiece and plug a different handpiece into the Console and cable. If this handpiece runs properly, then return the faulty handpiece and cable to MicroAire or an authorized MicroAire Repair Facility for service.
- f. If the handpiece does not run properly, return the system (Console, handpieces and cables) to MicroAire or an Authorized MicroAire Repair Facility for service.
- 3. Handpiece runs slowly.
 - a. Check that the throttle safety lock is all the way in the $\widehat{\Box}$ position.
 - b. Replace the handpiece cable.
 - c. Remove the handpiece and plug a different handpiece into the Console. If this handpiece runs at the proper speed, return the faulty handpiece and cable to MicroAire or an Authorized MicroAire Repair Facility for service.
 - d. If the second handpiece does not run properly, return the system (Console, handpieces and cables) to MicroAire or an Authorized MicroAire Repair Facility for service.
- 4. Maximum speed set does not function properly.
 - a. Ensure that the lever was depressed in the proper sequence.
 - b. Try another handpiece in place of the one not adjusting properly.
 - c. If the second handpiece runs properly, then return the faulty handpiece to MicroAire or an Authorized MicroAire Repair Facility for service.
 - d. If the second handpiece does not run properly, return the system (Console, handpieces and cables) to MicroAire or an Authorized MicroAire Repair Facility for service.

PERIODIC INSPECTION

Because of the stressful nature of surgical use, decontamination, and sterilization, we recommend that all instruments be returned for routine inspection and service at least once a year. There is no charge for service during the warranty period.

MICROAIRE WILL NOT BE LIABLE FOR ANY INDIRECT, SPECIAL, PUNITIVE OR CONSEQUENTIAL DAMAGES ARISING OUT OF ANY USE OF THIS PRODUCT.

By using this handpiece and it's accessories, you acknowledge and agree that you have read, understood and agree to be bound by these terms and conditions.

Disposal - (2002/96/EC Directive on Waste Electrical and Electronic Equipment

In accordance with the 2002/96/EC Directive on Waste Electrical and Electronic

Equipment (the WEEE Directive) and the current national provisions, the organization of the transfer of these wastes for devices sold by MANUFACTURER shall be undertaken by DISTRIBUTOR. For this reason, DISTRIBUTOR shall organize a system for the collection, storage and arrange 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 and national provisions regarding the WEEE Directive. Please refer to **www.microaire.com/weee-directive** for WEEE Compliance Instructions.

Part Number	Unit of Measure	5000E Electric Motor Module	5000ET Electric Motor Module
Power Output	kW - KiloWatts	0.05	0.05
Vibration Exposure	ahv(m/s2) Uncertainty k (m/s2)	1.68 1.5	1.68 1.5
Noise Emission Value	LPA (db(A)) LC, Peak (db(C)) LWA (dbA))	74 - -	74 - -
Mass	Weight (kg)	0.22	0.25

POWER OUTPUT, NOISE AND VIBRATION INFORMATION:

The following company is not affiliated with MicroAire Surgical Instruments LLC.

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