



Instruction Manual

Solo™

MICROAIRE®

Instrument Manual Translation Information

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Instruction Manual**

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INTRODUCTION

This manual has been written to help describe the procedures required to keep the MicroAire REF 5995U Solo™ Driver (*Patent Pending*) handpiece 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.

NOTE: Used to point out the easiest means of carrying out techniques.

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.

GENERAL WARNINGS

WARNING: Explosion Hazard. Not suitable for use in the presence of flammable anesthetics or oxygen.

WARNING: Electric Shock. Do not remove cover. Refer servicing to qualified personnel only.

WARNING: Type BF rating may only be maintained if the instrument is not used to bridge between the patient and ground.

WARNING: Use care to ensure that there is no electromagnetic interference between this device and other devices in use.

WARNING: Short-Time operation only (20 seconds ON then 1 minute OFF for 3 consecutive cycles). Irrigation must be used when cutting bone to ensure that the temperature at the cutting accessory does not exceed 41°C.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

WARNING: Prior to use, all system components (handpiece and accessories) should be inspected to detect any damage or malfunction.

DO NOT use any component if damage is apparent.

WARNING: Prior to use, all system component manuals should be reviewed for important warnings and instructions for use.

WARNING: Eye protection must be worn when operating any power equipment. Dislodged wires, accessories or bone fragments can result in eye injury, blindness, or contamination of the eye from patient tissue or body fluids.

NOTE: All personnel should become familiar with the power equipment before it is set-up for use in any procedure. Personnel inserviced should include, but not be limited to, central processing personnel, members of the surgical team, and the bioengineering department.

SYMBOL DEFINITIONS

	Attention - See Instructions for Use
F	Clockwise Rotation Indicator (Forward)
R	Counterclockwise Rotation Indicator (Reverse)
O	Oscillate Rotation Indicator
	DO NOT Lubricate
	DO NOT Immerse
	Temperature Limitations
	European conformity mark with MicroAire's Notified Body Number
	Atmospheric Limitations
	Authorized European Representative

SYMBOL DEFINITIONS - Continued

	Product Catalog Number
	Product Serial Number
	“ON” Position
	“OFF” Position (Safety)
	Date of Manufacture YYYY-MM
	Manufacturer
	Must be collected separately from household waste. Dispose of as per WEEE Directive 2002/96-EED
	Complies with BF Isolation requirements in accordance with UL 60601-1
	DO NOT expose to stray magnetic fields

SOLO™ DRIVER DRILL ACCESSORIES

△ **WARNING:** Use only MicroAire® approved accessories. Standard Kirschner Wires and Pins (.7 through 2.0 mm) are acceptable. Use of unapproved accessories may void your warranty. **DO NOT** modify any accessory. Failure to comply may result in patient and/or operating-room staff injury and equipment damage.

Accessories Description

1.1 MM Solo™ Drill Accessory
 1.6 MM Solo™ Drill Accessory
 2.0 MM Solo™ Drill Accessory
 2.4 MM Solo™ Drill Accessory
 3.2 MM Solo™ Drill Accessory
 .7 to 2.0mm Kirschner Wires/Pins

MicroAire Part (Ref.) Number

REF. 5995U-011
 REF. 5995U-016
 REF. 5995U-020
 REF. 5995U-024
 REF. 5995U-032
 N/A

STANDARDS

The REF 5995U Solo™ System meets the following standards:

- UL 60601-1 AND CAN/CSA C22.2 No. 601.1-M90
- IEC 60601-1
- IEC 60601-1-2

ENVIRONMENTAL PARAMETERS

OPERATING CONDITIONS

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

		
Temperature	Humidity	Atmospheric

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SHIPPING & STORAGE CONDITIONS

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

		
Temperature	Humidity	Atmospheric

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.

TECHNICAL DATA - SPECIFICATIONS

Operating Speed:	0-1850 RPM (nominal)
Cannulation:	0.7mm - 2.0mm
5995U Handpiece Weight: (without cable)	14.8 oz. (6.3 g)
Duty Cycle:	Short-Time Operation only (20 seconds ON then 1 minute OFF for 3 consecutive cycles.) Irrigation must be used when cutting bone to ensure that the temperature at the cutting accessory does not exceed 41° C.

HANDPIECE OVERVIEW AND FEATURES

The Solo™ Driver REF 5995U *Patent Pending*, is a hybrid wire and drill driver handpiece designed for smaller more delicate hand and forefoot surgery. It is a variable speed handpiece used for precision k-wire driving and drilling. Please see the MicroAire Powered Instruments catalog for a complete listing of available accessories. The Solo™ Driver is an electric handpiece and requires a REF 5025 iSIS™ power console to run.

△ REF 5025/5020 Instruction Manual for additional information.

HANDPIECE FEATURE DESCRIPTIONS & SAFETY INFORMATION

- Ambidextrous Throttle Lever

Ambidextrous throttle lever is designed to allow the instrument to be operated left handed or right handed.

- Grip Lever / Automatic Safety Mechanism

The MicroAire Solo™ Driver incorporates an automatic safety which only allows the instrument to run if the grip lever is depressed *prior* to activating the throttle lever.

- Forward / Reverse / Oscillate Control

The Solo™ Driver will operate in forward “F” (clockwise), reverse “R” (counterclockwise), and oscillate “O” (back and forth from clockwise to counterclockwise). This oscillate feature will minimize soft tissue from wrapping around a twist drill, wire, or pin. The direction switch is located as shown below.

AMBIDEXTROUS THROTTLE LEVER

The Solo™ Driver REF 5995U operates with an ambidextrous throttle lever to control the speed at which the instrument operates. As the lever is depressed the speed increases from 0% to 100% when fully depressed. See Figures 1, 2, 3 and 4.

Note: Due to the automatic safety feature, the instrument will not operate unless both the gripping lever and the throttle lever are depressed, and the lever is positioned for either right or left-hand use. Please see the Auto Safety Mechanism, and Secondary Manual Safety Mechanism & Ambidextrous Settings section on page 6 of this instruction manual.

Note: Any attempt to use the throttle to run the instrument without having depressed the grip lever will result in the instrument not running.



Figure 1

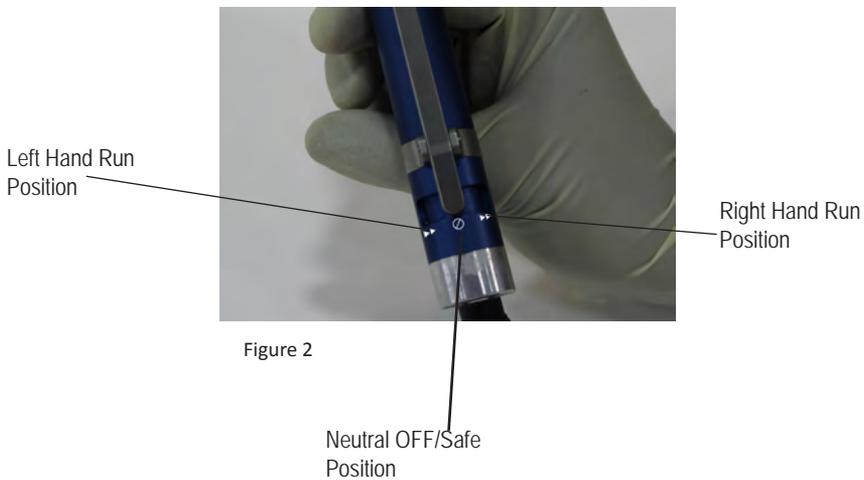


Figure 2

Right Hand Lever Position



Figure 3

Left Hand Lever Position



Figure 4

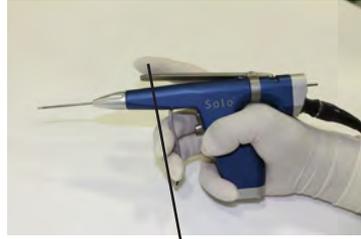
GRIP LEVER / AUTO SAFETY MECHANISM

The Solo™ handpiece is equipped with an automatic safety feature which only allows the instrument to run when the grip lever is depressed **prior** to activating the throttle lever.

Note: *The instrument will not operate unless both levers are depressed.*



Depress gripping lever prior to activating the throttle lever as shown.



Once grip lever is depressed, activate the throttle by depressing the throttle lever to achieve your desired speed.

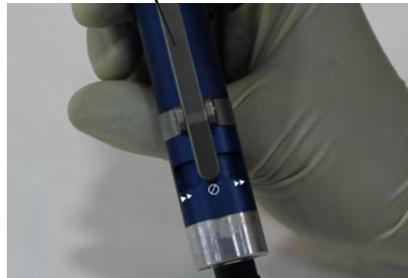
SECONDARY MANUAL SAFETY MECHANISM & AMBIDEXTROUS SETTINGS

The handpiece also incorporates a manual "OFF/Safety" feature which is activated by moving the throttle lever to the center/neutral position as shown below. In addition, the instrument can run in two positions to accommodate left and right handed personnel as shown below.

To engage the manual OFF/safety switch, turn the throttle lever by rotating the lever to the neutral position so that it sits directly on top of the instrument as shown below.



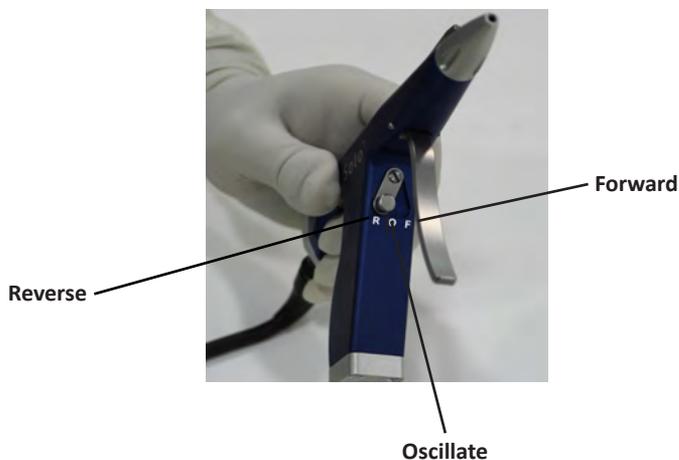
Manual Neutral
OFF/Safe position



FORWARD, REVERSE & OSCILLATE FEATURE

The Solo™ Driver will operate in forward “F” (clockwise), reverse “R” (counterclockwise), and oscillate “O” (back and forth from clockwise to counterclockwise). The oscillate feature is used to minimize soft tissue from wrapping around a drill, wire, or pin.

1. To change direction of the handpiece move the switch in the direction as marked on the instrument and shown below.



5995U SOLO™ DRIVER - SYSTEM SET UP

The Solo™ Driver is an electric variable speed, multi-purpose handpiece used for k-wire driving and drilling applications for small bone (hand & foot extremity) procedures. This instrument provides a smaller more ergonomic approach, allowing less fatigue and better precision when performing procedures with smaller bones. In addition, MicroAire offers a selection of k-wires and surgical drill accessories for use with this device. Please see the MicroAire Powered Instruments and the MicroAire Value Disposables catalogs for a complete listing of available accessories.

All personnel should become familiar with the power equipment before it is set-up for use in any procedure. Personnel to be in-serviced should include, but not be limited to, central processing personnel, members of the surgical team, and the bio-engineering department.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

WARNING: To prevent inadvertent running of handpiece while loading a k-wire or surgical accessory, make sure instrument safety switch is set to the “OFF” position as a secondary precaution to the automatic safety feature.

1. Inspect the handpiece and accessories for damage, or corrosion, or excessive wear.

WARNING: If any corrosion or debris is detected in/on the instrument, it must be considered contaminated. Either replace the instrument immediately or remove it from the sterile field and reprocess. If the instrument looks damaged or shows signs of excessive wear, it should not be used.

2. Check all surgical accessories. Make sure that wires, and/or drills are not dull or bent, and that they fit correctly into the handpiece.

3. Insert REF 5006-5000 cable into receptacle on rear of handpiece, aligning the dots on both the cable end and the handpiece end to ensure a proper fit as shown below.



4. Insert the other end of the cable into one of the instrument receptacles on the REF 5025/5020 Electric Power Console (See REF 5025-5020 Instruction Manual for additional information on the console settings).

5. Choose the designated drive direction with the Forward, Reverse, Oscillate switch located on the instrument. (See page 7 of the instruction manual for specific instructions on setting instrument run direction.)

Forward, Reverse,
Oscillate Switch



Note: The oscillate function is intended to make percutaneous drilling and fixation easier by minimizing soft tissue wrapping around the wire or drill accessory.

6. Insert the k-wire or drill accessory into the front of the instrument as shown below.

Note: The REF 5995U Solo™ Driver is designed with a unique gripping system that eliminates accessories falling out of the instrument inadvertently. As a result, when loading the instrument with an accessory a slight resistance will be felt shortly after insertion of the accessory. Once the resistance is felt slight additional force should be applied for the accessory to pass through the gripping mechanism. This should not require a tremendous amount of force. If the accessory is difficult to load, check to make sure that a compatible accessory is being used. In addition, check to make sure that accessory (i.e. k-wire, pin or drill) is not bent preventing proper insertion.



7. With the surgical accessory inserted, test run the instrument in the sterile field for three 10-second intervals, checking for any indication of irregular noise, or vibration. Irregular grinding noises may indicate impending failure or over heating of the hand-piece. If any irregular grinding noises are present, return the instrument for service.

8. Check for excessive heat. To check for overheating, test run the handpiece for approximately 30 seconds. Periodically monitor the temperature of the instrument. The temperature should not become uncomfortable to touch with gloved fingers/hand.

WARNING: Excessive heat is the most likely cause of patient injury. Any power instrument is subject to overheating.

The following conditions may cause overheating or total failure of the instrument:

Surgical usage, cleaning and sterilization can be destructive to instrument for several reasons:

- Blood deposits, saline and bone fragments often enter the forward section of the handpiece during operation. Saline causes corrosion, and blood produces restrictive deposits.
- Repeated sterilization removes grease from the bearings, and leaves mineral deposits on moving parts. Regular maintenance is recommended to replace bearings, seals and o-rings.

9. System is ready for use.

INSTRUMENT CLEANING & STERILIZATION

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).

- Preparation for decontamination**
- 1) Remove all inserted surgical cutting accessories (k-wires, pins, drill bits, etc.) from the handpiece. Disposable surgical accessories should be discarded after use, handle them as any contaminated sharp accessory is handled. Reuse of surgical cutting accessories is not recommended.
 - 2) Disassemble instruments and accessories
 - 3) For Automated Cleaning install the electric cable for the instrument.
 - 4) For Manual Cleaning install the electric cable for the instrument.

Preparation of Cleaning Agent Prepare mild 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**
- 1) Load the medical devices into the Washer Disinfector
 - a) Avoid contact between devices (movement during washing could cause damage and washing action could be obstructed). **DO NOT** overload the trays.
 - b) Arrange medical devices so that cannulations are not horizontal and any openings are oriented downwards (to assist drainage).
 - 2) The minimum recommended Washer/Disinfector cycle is below:

#	Title	Detergent	Minutes	Temp
1	Pre-Wash	Mild pH Enzymatic*	4	< = 50°C (122° F)
2	Rinse	None	1**	< = 50°C (122° F)
3	Wash	Mild pH	4	> = 60°C (140°F)
4	Drain for 1 Minute Minimum			
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 Minimum			

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

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

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 hand piece and cables thoroughly with warm (> = 60°C / 140°F) water, mild pH enzymatic detergent, and soft brush. Scrub the hand piece with the brush, paying close attention to instrument crevices.
- 2) Rinse hand piece, couplers and electric cables thoroughly under running (< = 50°C / 122° F) water for a minimum of 2 minutes.
- 3) Clean the hand pieces and couplers thoroughly with warm (> = 60°C / 140°F) water, mild pH enzymatic detergent, and soft brush. Scrub the hand piece with the brush, paying close attention to instrument crevices.
- 4) Flush the lumens of instruments and the nose of the instrument drivers with a Water-Pik or similar device. Flushing removes blood, debris and saline deposits.
- 5) Rinse hand pieces, couplers and electric cables thoroughly under running (< = 50°C / 122° F) water for a minimum of 2 minutes. If possible, use distilled water for the final rinse.
- 6) After rinsing 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 hand piece with a soft lint free towel. An airgun can also be used to dry the hand piece.

**Maintenance,
Inspection and
Function Testing:**

- 1) Remove the electric cable from the hand piece.
- 2) Carefully inspect each device to ensure all visible 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) 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 the device, please contact your MicroAire representative.

- Packaging:**
- 1) **Single Instruments** - A standard medical grade steam sterilization wrap may be used. Ensure that the wrap is large enough to contain the instrument without stressing the packaging. (ANSI/AAMI ST46-1993)
 - 2) **Sets of Instruments** - Sets of instruments may be loaded into dedicated instrument trays or general purpose sterilization trays for sterilization. If applicable, use standard medical grade steam sterilization wrap following the AAMI double wrap method. (ANSI/AAMI ST46-1993)

Sterilization: Steam sterilize using one of the following cycles

Sterilization Cycle	Instrument	Minimum Time & Temp	Minimum Heated Dry Time
Pre-Vacuum Steam	Single Instrument	3 minute Full Cycle @ 134-137°C (273 - 279°F)	8 Minutes
	In Sterilization Tray	4 minute Full Cycle @ 134-137°C (273 - 279°F)	8 Minutes
Gravity Displacement	Single Instrument	30 minute Full Cycle @ 132-135°C (270 - 275°F)	8 Minutes
	In Sterilization Tray	30 minute Full Cycle @ 132-135°C (270 - 275°F)	8 Minutes

NOTE: 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: 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.

- Additional Information:**
- 1) Sterile instrument packages should be examined closely prior to opening to ensure that there has been no loss of package integrity.
 - 2) Do not use instruments when they are still warm. They need to cool down to room temperature.
 - 3) Do not soak instruments to cool them down or wrap cold towels around them.

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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

TROUBLESHOOTING

<u>Problem:</u>	<u>Cause:</u>	<u>Troubleshooting Steps:</u>
Throttle lever will not depress	Debris in trigger assembly	Thoroughly clean and sterilize handpiece
Handpiece does not run when throttle lever is depressed	Throttle lever not in correct position	Rotate stop, resume use
	Handpiece is too hot or cold	Allow to return to room temperature
	Mechanical malfunction	Return to MicroAire for service
	Electrical/magnetic interference present	Turn off all electrical equipment not in use
		Release trigger for one second, resume use
	Gripper lever not first depressed	Depress gripper lever before depressing trigger
Handpiece stalls while in use	Excessive load	Reduce load, release trigger for one second, resume use
	Instrument is too hot	Allow to cool to room temperature
Handpiece runs but Pin/Wire does not rotate	Mechanical malfunction	Return handpiece to MicroAire for service
Pin/Wire/Drill hard to load/unload in handpiece	Incorrect Pin/Wire/Drill size	Use only .71mm - 2mm Pin/Wires/Drill Shanks
	Debris in handpiece collet	Clean and sterilize handpiece
Pin/Wire will not fit in coupler	Incompatible Pin, Wire or Drill	Use MicroAire approved Pin, Wire or Drill
	Debris in handpiece	Clean and sterilize handpiece

WARRANTY, SERVICE AND REPAIR

Warranty

MicroAire Surgical Instruments warrants the 5995U Solo™ Driver 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.

NOTE: Repairs or alterations to MicroAire products made by anyone other than MicroAire or an authorized MicroAire repair facility will void that products 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 servicable 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-Mail:
USA	800-722-0822	800-648-4309	inquiry@microaire.com
Outside USA	434-975-8000	434-975-4134	intlsvvc@microaire.com

NOTE: 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 your return.

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 United States unless specified otherwise.

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.

Power Output, Noise and Vibration Information

Power Output kW - KiloWatts	Vibration Exposure		Noise Emission Value			Mass Weight (kg)
	a_{hv} (m/s ²)	Uncertainty K (m/s ²)	L_{PA} (dB(A))	$L_{C,peak}$ (dB(C))	L_{WA} (dB(A))	
0.05	1.68	1.5	74	-	-	.022



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