MicroAire PAL System
Instructions for Use

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中文 (Chinese)
本明的中文本可在网上 www.microaire.com/resources/instructions-for-use
**APPLICABLE PART NUMBERS***

<table>
<thead>
<tr>
<th>REF Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>REF CAP-600E</td>
<td>Washer Disinfector Cap</td>
</tr>
<tr>
<td>REF PAL-650</td>
<td>PAL Electric Handpiece</td>
</tr>
<tr>
<td>REF ASP-INF-XXXXX-R</td>
<td>Luer Multi-Use Tumescent Infiltration Cannula</td>
</tr>
<tr>
<td>REF PAL-INF-XXXXX-R</td>
<td>PAL Multi-Use Tumescent Infiltration Cannula</td>
</tr>
<tr>
<td>REF PAL-RXXX</td>
<td>PAL Multi-Use Aspiration Cannula</td>
</tr>
<tr>
<td>REF PAL-RXXXB</td>
<td>PAL Multi-Use Bent Aspiration Cannula</td>
</tr>
<tr>
<td>REF PAL-XXX</td>
<td>PAL Single-Use Aspiration Cannula</td>
</tr>
<tr>
<td>REF PAL-XXXB</td>
<td>PAL Single-Use Bent Aspiration Cannula</td>
</tr>
<tr>
<td>REF PAL-XXXT</td>
<td>PAL Single-Use Turbo Aspiration Cannula</td>
</tr>
<tr>
<td>REF PAL-700</td>
<td>PAL Single-Use Luer Lock Adapter</td>
</tr>
<tr>
<td>REF PAL-730</td>
<td>PAL Wand - Cannula Handpiece</td>
</tr>
<tr>
<td>REF PAL-500</td>
<td>PAL Sterilization Case</td>
</tr>
<tr>
<td>REF PAL-900</td>
<td>PAL Single-Use Aspiration Tubing (9 foot), 6 PK</td>
</tr>
<tr>
<td>REF PAL-1200</td>
<td>PAL Single-Use Aspiration Tubing (12 foot), 5 PK</td>
</tr>
<tr>
<td>REF PAL-INF-TB</td>
<td>PAL Single-Use Tumescent Infiltration Tubing, Single-Spike, 10 PK</td>
</tr>
<tr>
<td>REF ASP-INF-TB</td>
<td>Luer Single-Use Tumescent Infiltration Tubing, Single-Spike, 10 PK</td>
</tr>
<tr>
<td>REF 1006-PALE</td>
<td>PAL Electric Handpiece Cable</td>
</tr>
<tr>
<td>REF 5006-PAL</td>
<td>PAL Electric Handpiece Cable</td>
</tr>
<tr>
<td>REF 1020</td>
<td>Standard Electric Console</td>
</tr>
<tr>
<td>REF 5020</td>
<td>Electric Power Console</td>
</tr>
</tbody>
</table>

*See [www.microaire.com](http://www.microaire.com) for cannula part numbers and specifications.

**INTENDED USE**

The MicroAire PAL System is indicated for assisting the surgeon with the removal of tissue or fluid from the body during general surgical procedures including suction lipoplasty for the purpose of aesthetic body contouring.

**INDICATIONS FOR USE**

The MicroAire PAL System, which consists of the PAL Electric Handpiece (REF PAL-650), PAL Wand Manual Handpiece (REF PAL-730), PAL Cable (REF 5006-PAL) and Electric Power Console (REF 5020), is intended to infiltrate tumescent fluid and subsequently remove tissue or fluid from the body during general surgical procedures including suction lipoplasty. These procedures are performed to treat a variety of conditions, including, but not limited to:

- Localized deposits of subcutaneous fat
- Gynecomastia
- Lipomas
- Lymphedema
INTRODUCTION
This document, MicroAire PAL System Instructions For Use (IFU), is intended to describe the procedures required to safely operate, clean and maintain the MicroAire PAL System.

DUTY CYCLE
PAL-650: The PAL Electric Handpiece is designed to operate for up to 20 minutes of continuous use with intermittent operation over a period of 2 hours.

<table>
<thead>
<tr>
<th>Power Output kW – Kilowatts</th>
<th>Vibration Exposure ahv(m/s²)</th>
<th>Uncertainty K (m/s²)</th>
<th>LPA (dB(A))</th>
<th>Noise Emission Value LC,peak (dB(C))</th>
<th>LWA (dB(A))</th>
<th>Mass Weight (kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.065</td>
<td>3.77</td>
<td>1.5</td>
<td>&lt;70</td>
<td>-</td>
<td>-</td>
<td>0.5</td>
</tr>
</tbody>
</table>
TERMS

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

CAUTION Used to indicate procedures that must be followed to avoid damaging an instrument.

NOTE Used to indicate the easiest means of carrying out the techniques.

WARNING: Proper setup of device is critical to safe operation.

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

WARNING: This device will not, in and of itself, produce significant weight reduction.

WARNING: This device should be used with extreme caution in patients with chronic medical conditions, such as diabetes; heart, lung, or circulatory system disease; or obesity.

WARNING: The volume of blood loss and endogenous body fluid loss may adversely affect intra and/or postoperative hemodynamic stability and patient safety. The capability of providing adequate, timely replacement is essential for patient safety.

WARNING: Sterilizers vary in design and performance parameters. Verify cycle parameters against the written instructions of the sterilizer and container manufacturers.

WARNING: Only use MicroAire infiltration tubing, REF PAL-INF-TB, and aspiration tubing, REF PAL-900 or REF PAL-1200; Using other tubing may result in tubing failure and unfavorable results.

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

CAUTION: See IM-5020 Instruction Manual for detailed information on the 5020 electric console.

CAUTION: This device is designed to contour the body by removing localized deposits of excess fat through small incisions.

CAUTION: Use of this device is limited to those physicians who, by means of formal professional training or sanctioned continuing medical education (including supervised operative experience), have attained proficiency in suction lipoplasty.

CAUTION: Results of this procedure will vary depending upon patient age, surgical site, and experience of the physician.

CAUTION: Results of this procedure may or may not be permanent.

CAUTION: The amount of fat removed should be limited to that necessary to achieve a desired cosmetic effect.

CAUTION: All reusable components of the device must be sterilized and all disposable components replaced before using the device system on another patient.

CAUTION: DO NOT twist or force the cable pins into the receptacles. Doing so can bend the pins.

NOTE: All personnel should become familiar with the equipment before it is setup 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.
SYSTEM SETUP

Make sure unit functions properly prior to use. If not, contact MicroAire for service repair.

1. Inspect the handpiece, console, cable and cannulas for damage, corrosion or excessive wear.

2. Inspect sterile disposable items to make sure packaging is not damaged.

3. Attach the electrical connection cable from the back of the Console (REF 5020) to a wall outlet.

4. To attach the Cable (REF 5006-PAL) from the Console to the PAL Handpiece (REF-PAL-650), locate the end of the Cable with the tethered end caps. With the white dot on the Cable facing upward, insert the Cable into either of the two Cable receptacles on the front of the Console. Attach the other end of the Cable to the PAL Handpiece by aligning the red dot on the Cable with the red dot on the Handpiece.

   **CAUTION:** DO NOT twist or force the Cable pins into the receptacles. Doing so can bend the pins.

5. To attach a sterile Cannula (REF PAL-INF-XXXXX-R, REF PAL-RXXX, REF PAL-RXXXB, REF PAL-XXX, REF PAL-XXXB, or REF PAL-XXXT) to the PAL Handpiece (REF PAL-650 or REF PAL-730), place the thumb-throttle of the PAL Handpiece in the SAFE position (PAL-650 only). Slide the small end of PAL Tubing (REF PAL-INF-TB, REF PAL-900, or REF PAL-1200) onto the end of the Cannula (Figure A). Attach the square opening of the Cannula hub onto the corresponding square shaft of the PAL Handpiece, with the Tubing on the bottom of the Handpiece (Figure B). Secure the Tubing along the underside of the PAL Handpiece by pushing the Tubing into the groove on the bottom of the PAL Handpiece (Figure C).

6. For Infiltration, connect the spiked end of the Tubing (REF PAL-INF-TB) to a source of tumescent infiltration solution, usually an IV bag.

7. For Aspiration, connect the large end of the Tubing (REF PAL-900 or REF PAL-1200) to a collection canister.

8. To operate the powered reciprocation of the PAL Handpiece, gently slide the thumb-throttle from SAFE to RUN. Use the thumb-throttle to adjust the speed of reciprocation during the procedure; use the Console to set the maximum speed. The PAL Handpiece is designed to operate at full speed for most procedures.

9. To remove the Cannula from the PAL Handpiece, stop the reciprocation by sliding the thumb-throttle to the SAFE position. Pull the Tubing out of the groove on the underside of the PAL Handpiece. Press the colored tab on the Cannula hub to release the Cannula from the shaft, and slide the Cannula off of the PAL Handpiece.

**Figure A- Attach PAL tubing to cannula**  
**Figure B - Attach hub to PAL Handpiece**  
**Figure C - Push tubing into PAL Handpiece**
PAL HANDPIECE AND CABLE CLEANING AND STERILIZATION INSTRUCTIONS

WARNING: Universal precautions for handling contaminated materials should be observed at all times.

CAUTION: DO NOT lubricate or oil the PAL Handpiece. Lubrication may damage the internal motor mechanism. Also take special precautions to avoid the use of cleaners that contain lubrication.

CAUTION: DO NOT immerse the PAL Handpiece in fluid.

CAUTION: Use only cleaning solutions that are mild pH, unless they are indicated for use with anodized aluminum and surgical instruments.

CAUTION: DO NOT utilize cleaning agents with chlorine or chloride as the active ingredient is corrosive to stainless steel.

CAUTION: DO NOT utilize cleaning agents that are phenol based.

CAUTION: The PAL Handpiece and Cable are sterilized by steam, using either a gravity displacement or pre-vacuum autoclave sterilizer.

CAUTION: DO NOT sterilize the console or its power cord.

WARNING: Sterilizers vary in design and performance parameters. Verify cycle parameters against the written instructions of the sterilizer and container manufacturers. Pre-vacuum sterilization is the preferred method of sterilization for the PAL Handpiece because it allows for rapid sterilization of the internal components.

Limitations on Reprocessing
Repeated processing, according to the instructions below, has minimal effect on the PAL Handpiece. End of life is determined by wear and damage due to use.

1. **At 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: It is recommended that instruments be cleaned within 30 minutes of end use to minimize the potential for organic material drying on the instrument prior to cleaning.

2. **Preparation for Decontamination**
   a. Remove all inserted surgical accessories (cannula, tubing, etc.) from the handpiece. Single-use surgical accessories should be discarded after use, handling them as any contaminated accessory is handled.
   b. Disassemble instruments and accessories.
   c. For Automated Cleaning, install the Washer Cap REF CAP-600E. (PAL-650 only)
   d. For Manual Cleaning, install the Washer Cap REF CAP-600E or the Electric Cable (REF 5006-PAL)

3. **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.

4. **Cleaning: Automated**
   a. Load the medical devices into the Washer Disinfector. Avoid contact between devices (movement during washing could cause damage and washing action could be obstructed). DO NOT overload the trays.
   b. The minimum recommended Washer/Disinfector cycle is listed in the chart at the top of the next page:
<table>
<thead>
<tr>
<th>#</th>
<th>Title</th>
<th>Detergent</th>
<th>Minutes</th>
<th>Temp</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pre-Wash</td>
<td>Mild pH Enzymatic*</td>
<td>4</td>
<td>&lt;= 50 °C (122 °F)</td>
</tr>
<tr>
<td>2</td>
<td>Rinse</td>
<td>None</td>
<td>1**</td>
<td>&lt;= 50 °C (122 °F)</td>
</tr>
<tr>
<td>3</td>
<td>Wash</td>
<td>Mild pH</td>
<td>4</td>
<td>&gt; = 60 °C (140 °F)</td>
</tr>
<tr>
<td>4</td>
<td>Drain for 1 minute minimum</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Rinse</td>
<td>None</td>
<td>2**</td>
<td>&gt; = 60 °C (140 °F)</td>
</tr>
<tr>
<td>6</td>
<td>Drain for 1 minute minimum</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Thermal Disinfect</td>
<td>None</td>
<td>10</td>
<td>&gt; = 93 °C (200 °F)</td>
</tr>
<tr>
<td>8</td>
<td>Drain for 1 minute minimum</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* 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:** Washers/Disinfectors should comply with the requirements of ISO 15883. They should be properly installed and be regularly tested in accordance with ISO 15883.

5. **Cleaning: Manual**
   a. Clean the handpiece thoroughly with warm (> 60 °C / 140 °F) water, pH neutral enzymatic detergent, and a soft brush. Scrub the handpiece with a brush, paying close attention to instrument crevices.
   b. Rinse thoroughly under running (< 50 °C / 122 °F) water for a minimum of 2 minutes. If possible, use distilled water for the final rinse.

6. **Disinfection**
   Disinfection is only acceptable as an adjunct to full terminal sterilization for reusable surgical instruments. See sterilization section above.

7. **Drying**
   Wipe off any water from the handpiece with a soft lint-free towel. An air gun can also be used to dry the handpiece.

8. **Maintenance, Inspection and Function Testing**
   a. Remove the Washer Cap or Electric Cable from the handpiece. (PAL-650 only)
   b. Carefully inspect each device to ensure that all visible blood and soil has been removed.
   c. Visually inspect for damage and/or wear.
   d. Check the action of moving parts to ensure smooth operation throughout the intended range of motion.
   e. Where instruments form part of a larger assembly, check that the devices assemble with mating components.

**NOTE:** If concerns are noted that may compromise the function of the device, please contact MicroAire.

9. **Packaging**
   a. 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. (ASTM/AAMI ST79, EN ISO 17665-1)
   b. 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 ST79, EN ISO 17665-1).
10. Sterilization
Steam sterilize using one of the following cycles:

a. Pre-Vacuum Steam Sterilization for a single instrument or in a sterilization tray:
   Full cycle with 3-minute exposure time at 134-137 °C (273-279 °F), 8 minute minimum heated dry time
   - OR -
   Full cycle with 4-minute exposure time at 132-135 °C (270-275 °F), 8 minute minimum heated dry time

b. Gravity Displacement Steam Sterilization for a single instrument:
   Full cycle with 30-minute exposure time at 132 - 135 °C (270-275 °F), 8 minute minimum heated dry time.

c. Gravity Displacement Steam Sterilization for in a sterilization tray:
   Full cycle with 35-minute exposure time at 132 - 135 °C (270-275 °F), 8 minute minimum heated dry time.


NOTE: DO NOT use instruments when they are still warm. They need to cool down to room temperature. Cool by exposure to room temperature. DO NOT soak instruments in liquid to cool them down or wrap cold towels around them.

NOTE: DO NOT process powered surgical instruments in equipment that uses peracetic acid as a liquid sterilant.

NOTE: Ethylene Oxide (EtO) is NOT recommended for powered surgical instruments because lengthy aeration time is needed to assure that no ethylene oxide is left in the internal mechanisms or on the surface of the instrument.

11. 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, and temperature/humidity extremes.

12. Additional Information
   a. Sterile instrument packages should be examined closely prior to opening to ensure that there has been no loss of package integrity.

   b. “Flash” Gravity-Steam
      1.) “Flash” sterilization: Surgical centers that wish to steam sterilize patient care items for immediate use shall at a minimum follow the requirements as outlined in ANSI/AAMI ST79, EN ISO 17665-1. Reduction of bioburden and removal of gross soil are essential steps in preparing an item for sterilization by any method. Please follow the steps for decontamination of the instrument prior to any sterilization process including “flash” sterilization. The processed items must be transferred immediately, using aseptic technique, from the sterilizer to the actual point of use. There is NO storage or shelf life of flash-sterilized items because of the probability of contamination after the sterilizer door is opened and the items are removed. When performed correctly, flash sterilization is safe and effective for sterilization of medical devices (AAMI ST79, EN ISO 17665-1).

      2.) Re-usable surgical instruments with moving parts require a dry cycle to keep the product functioning appropriately. “Flash” Gravity-Steam sterilization with NO dry time is NOT recommended as a normal process of sterilization.

      3.) Instrument/Accessory ONLY Exposure
         Time = Full cycle with 11-minute exposure time
         Exposure Temperature = 270-275 °F (132-135 °C)
         Minimum Dry Time = 8 minutes
         Materials - UNWRAPPED ONLY
MULTI-USE CANNULA CLEANING AND STERILIZATION INSTRUCTIONS

CAUTION: DO NOT sterilize single-use cannula. The connector will warp or crack.

WARNING: Universal precautions for handling contaminated materials should be observed at all times.

CAUTION: DO NOT utilize cleaning solutions that are not mild pH, unless they are approved for use with anodized aluminum and surgical instruments.

CAUTION: DO NOT utilize cleaning agents with chlorine or chloride as the active ingredient is corrosive to stainless steel.

CAUTION: DO NOT utilize cleaning agents that are phenol based.

CAUTION: MicroAire powered surgical instruments (including multi-use cannulae) are normally sterilized by steam, using either a gravity displacement or pre vacuum autoclave sterilizer.

WARNING: Sterilizers vary in design and performance parameters. Verify cycle parameters against the written instructions of the sterilizer and container manufacturers. Pre vacuum sterilization is the preferred method of sterilization for powered surgical instruments because it allows for rapid sterilization of the internal components.

CAUTION: Automatic cleaning is NOT recommended.

CAUTION: Usage beyond maximum intended re-use will reduce performance and increase wear on handpiece.

WARNING: Failure to comply with maximum intended re-use may result in injury to patients and health care professionals.

WARNING: Multiple-use cannulas should not be used for procedures in which tissue is harvested for reinjection.

Limitations on Reprocessing

Multiple–use Cannulas are intended for limited re-use with a maximum intended re-use of 15-20 cases when processed according to the instructions below.

1. At Point of Use
   Disassemble the cannulae from the instrument and disposable tubing. Remove excess body fluids and tissue with a disposable, non-shedding wipe and place cannulae in a basin with warm water and a mild detergent. Body fluids and tissue should not be allowed to dry on cannulae prior to cleaning.

   NOTE: It is recommended that instruments be cleaned within 30 minutes of end use to minimize the potential for organic material drying on the instrument prior to cleaning.

2. Preparation for Decontamination
   Locate the appropriate sized soft bristled cylindrical brush and/or stylet. Stylets are commonly used in smaller diameter cannulae where the inner lumen is too small to fit a cylindrical brush. The brush and/or stylet should be long enough to easily reach the tip of the cannula. The bristles of the brush should be wide enough to fill the lumen but still be able to move freely.

3. Preparation of Cleaning Agent
   Prepare mild pH enzyme cleaning agents at the maximum use-dilution and temperature recommended by the manufacturer. Determination of cleaning agents shall be by local or country regulations.
4. Cleaning: Automated

a. Fully submerge the cannulae in the enzymatic cleaning agent. Using a syringe, flush the cannulae with enzyme cleaning agent and water to remove debris and any blockages.

b. Clean the inside diameter of each cannula shaft (lumen), while still submerged in the enzymatic cleaning agent, using the appropriate sized soft bristled cylindrical brush and/or stylet. The inside diameter of each cannula is to be cleaned until no visible debris comes out of the tip of each cannula or out of the back of each cannula where the brush and/or stylet is inserted.

c. Load the cannulae into the washer-disinfector.

d. Connect cannulae to the rinsing ports of the washer-disinfector. If there is no direct connection, place the cannulae directly on injector jets or in injector sleeves of the injector basket. Arrange cannulae so that the cannulations are not horizontal and openings are oriented downwards (to assist drainage). Avoid contact between devices (movement during washing could cause damage, and the washing action could be obstructed).

e. The minimum recommended washer-disinfector cycle is listed in the chart below:

<table>
<thead>
<tr>
<th>#</th>
<th>Title</th>
<th>Detergent</th>
<th>Minutes</th>
<th>Temp</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pre-Wash</td>
<td>Mild pH Enzymatic*</td>
<td>4</td>
<td>&lt;= 50 °C (122 °F)</td>
</tr>
<tr>
<td>2</td>
<td>Rinse</td>
<td>None</td>
<td>1**</td>
<td>&lt;= 50 °C (122 °F)</td>
</tr>
<tr>
<td>3</td>
<td>Wash</td>
<td>Mild pH</td>
<td>4</td>
<td>&gt;= 60 °C (140 °F)</td>
</tr>
<tr>
<td>4</td>
<td>Drain</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Rinse</td>
<td>None</td>
<td>2**</td>
<td>&gt;= 60 °C (140 °F)</td>
</tr>
<tr>
<td>6</td>
<td>Drain</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Thermal Disinfect</td>
<td>None</td>
<td>10</td>
<td>&gt;= 93 °C (200 °F)</td>
</tr>
<tr>
<td>8</td>
<td>Drain</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Dry</td>
<td>None</td>
<td>6</td>
<td>&gt;= 100 °C (212 °F)</td>
</tr>
</tbody>
</table>

* 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:** Washers/Disinfectors should comply with the requirements of ISO 15883. They should be properly installed and be regularly tested in accordance with ISO 15883.

f. Upon completion of the washer-disinfection cycle, remove the cannulae from the washer-disinfector. Visually inspect each cannula inner shaft, outer shaft, hub and all recessed features to ensure all visible blood and debris has been removed. If blood or debris remains, repeat the entire automatic cleaning process.

5. Cleaning: Manual with Ultrasonic

a. Using a syringe, flush the inside diameter of each cannula shaft (lumen) with the enzymatic cleaning agent and soak the cannulae for 20 minutes in the enzymatic cleaning agent.

b. Scrub the hub and exterior cannula shaft with a soft bristled brush while submerged in the enzymatic cleaning agent until all visible debris has been removed from the exterior surfaces.
c. Clean the lumen of each cannula using the appropriate sized soft bristled cylindrical brush and/or stylet, while submerged in the enzymatic cleaning agent. A syringe may be used to aid in cleaning the lumens. The inside diameter of each cannula is to be cleaned until no visible debris comes out of the tip of each cannula or out of the back of each cannula where the brush and/or stylet is inserted.

d. Place the cannulae in an ultrasonic bath (40 kHz) for an additional 20 minutes in enzymatic cleaning agent. Ensure that the instruments are completely immersed in cleaner.

e. Remove cannula from bath and rinse all items thoroughly under running (<50 °C / 122 °F) water for a minimum of 2 minutes.

f. Use a syringe to flush the lumen of the cannulae with lukewarm tap water. If possible, use distilled water for the final rinse.

g. Upon completion of the manual cleaning, visually inspect each cannula inner shaft, outer shaft, hub and all recessed features to ensure all visible blood and debris has been removed. If blood or debris remains, repeat the entire manual cleaning process.

6. Disinfection
   Disinfection is only acceptable as an adjunct to full terminal sterilization for Multi-Use surgical instruments. See sterilization section below.

7. Drying
   Wipe off any water from the cannula with a soft lint-free towel. An air gun can also be used.

8. Maintenance, Inspection and Function Testing
   a. Carefully inspect each device to ensure that all visible blood and debris has been removed.
   b. Visually inspect for damage and/or wear.
   c. Check the action of moving parts to ensure smooth operation throughout the intended range of motion.
   d. Where instruments form part of a larger assembly, check that the devices assemble with mating components.

   NOTE: If concerns are noted that may compromise the function of the device, please contact your MicroAire representative.

9. Packaging
   a. 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 ST79, EN ISO 17665-1).
   b. 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 ST79, EN ISO 17665-1).

10. Sterilization
    Steam sterilize using one of the following cycles:

    a. Pre-Vacuum Steam Sterilization for a single device or in a sterilization tray:
       Full cycle with 4-minute exposure time at 132-135 °C (270-275 °F), 20 minute minimum heated dry time

    b. Gravity Displacement Steam Sterilization for a single device or in a sterilization tray:
       Full cycle with 35-minute exposure time at 132 - 135 °C (270-275 °F), 15 minute minimum heated dry time
ENVIRONMENTAL PARAMETERS

OPERATING CONDITIONS

SHIPPING AND STORAGE CONDITIONS

SERVICE AND REPAIR INFORMATION

IN HOSPITAL SERVICE

All MicroAire power equipment should be inspected and tested periodically in accordance with the facility’s bioengineering policy. Such service should be documented within the bioengineering department.

Repairs or alterations to MicroAire products made by anyone other than MicroAire or an Authorized MicroAire Repair Facility will void that product’s warranty.

PREVENTATIVE MAINTENANCE

Because of the stressful nature of surgical use, decontamination, and sterilization, MicroAire recommends that the PAL System (PAL-650 Handpiece, 5006-PAL Cable and 5020 Console) be returned to the factory for routine inspection and service at least once a year. There is no charge for service during the warranty period.

TROUBLE SHOOTING

NOTE: PAL Handpieces can run trouble-free for over a decade when properly cleaned and sterilized. The most common cause for repair is improper use of the Washer Disinfector Cap (REF CAP-600E).

**CAP the Cable and PAL Handpiece during cleaning** to prevent liquid water from entering the device. It’s okay to keep the Cable plugged into the PAL Handpiece during manual cleaning as a form of capping.

**UNCAP the Cable and the PAL Handpiece during sterilization** to allow steam to penetrate the device.

**DRY the devices completely using the dry cycle** after sterilization to remove all moisture from within the device. Failure to do so may cause corrosion on the pins and within the motor.

1. Difficulty attaching the Cable
   Align connectors and receptacles carefully. Make sure the white dot is facing upward when connecting the Cable to the Console. Make sure the red dot on the Cable is aligned with the matching red dot on the PAL Handpiece. Never force the cable into a receptacle because this can bend the pins.

2. The handpiece will not start
   a. Check that the Console is plugged in, turned on, and the touchscreen is indicating a connection to the PAL Handpiece.
   b. Check the pins in the Cable and the PAL Handpiece to see if they are bent or corroded.
   c. If the PAL Handpiece does not start, the problem could be in the Handpiece, the Cable or the Console. Return all three system components to MicroAire for a proper diagnosis.
REPAIR SERVICE

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

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

<table>
<thead>
<tr>
<th>Telephone:</th>
<th>FAX:</th>
<th>Email:</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA: 800-722-0822</td>
<td>800-438-6309</td>
<td><a href="mailto:inquiry@microaire.com">inquiry@microaire.com</a></td>
</tr>
<tr>
<td>OUTSIDE USA: +434-975-8000</td>
<td>+434-975-4134</td>
<td><a href="mailto:inquiry@microaire.com">inquiry@microaire.com</a></td>
</tr>
</tbody>
</table>

NOTE: We may be able to solve the problem without physically receiving the equipment.

NOTE: Do not disassemble or attempt to service the equipment.

NOTE: PAL equipment can only be serviced by MicroAire or an Authorized MicroAire Repair Facility.

NOTE: Unauthorized service will void the warranty.

NOTE: If a problem occurs with your PAL System, please return all three system components (PAL-650 Handpiece, 5006-PAL Cable and 5020 Console) because the equipment works as an integrated system. Returning only one or two of the system components may result in a false diagnosis.

NOTE: Original owners (based on serial number registration) may request a loaner system while their system is being repaired. This option is not available to owners of PAL systems from secondary sources.

To return an item for service, follow this procedure:

1. Contact Customer Service for a Return Material Authorization (RMA) number.
   
   **NOTE:** Do not return equipment without an RMA number. This may cause delays in service and problems tracking your return.

2. Clean and sterilize equipment before sending for repair.

3. Along with the items sent for repair, please enclose a description of the problem along with contact information.

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

5. Ship the merchandise by Express Mail, Federal Express or UPS to ensure tracking and to prevent mail delays.

6. Indicate if an estimate of repair costs is needed prior to commencing work on the repair.
WARRANTY

MicroAire Surgical Instruments LLC warrants its instruments to be free from defects in material and workmanship in their manufacture for a period of one year from the original purchase date by the end customer. The warranty is limited to the repair or replacement of the product without charge.

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

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

EXTENDED WARRANTY / SERVICE AGREEMENT

Extended warranties and service agreements are available on MicroAire power equipment. 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 full serviceable condition before being eligible for a service agreement.

DISPOSAL

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 a Manufacturer’s approved WEEE collection facility in Europe. DISTRIBUTOR shall provide on request to MANUFACTURER, the proof of compliance with the European and national provisions regarding the WEEE Directive. Please refer to www.microaire.com/weee for WEEE Compliance Instructions.
THE MICROAIRE PAL SYSTEM IS COVERED UNDER THE FOLLOWING PATENTS

US Patent No. 5911700, 6139518, 6258054
Canadian Patent No. 2,282,516
Brazilian Patent No. PI 9808317-1
Mexican Patent No. 233624
European Patent No. 1 006 895
Austrian Part of EP Patent No. 1 006 895
Belgium Part of European Patent No. 1 006 895
Denmark Part of European Patent No. 1 006 895
Italy Part of European Patent No. 1 006 895
French Part of EP Patent No. 1 006 895
Netherlands Part of European Patent No. 1 006 895
Finland Part of European Patent No. 1 006 895
German Part of European Patent No. 1 006 895
Greece Part of European Patent No. 1 006 895
Luxembourg Part of European Patent No. 1 006 895
Portugal Part of European Patent No. 1 006 895
Spain Part of European Patent No. 1 006 895
Sweden Part of European Patent No. 1 006 895
Swiss Part of EP Patent No. 1 006 895
British Part of European Patent No. 1 006 895
Other International Patents May Apply or Pending