MicroAire LipoTower System

Instructions for Use

MICROAIRE®

For Surgery. For Life.™

APPLICABLE PART NUMBERS

REF Number	Description
REF ASP-1021	LipoTower with Aspiration Pump and Tumescent Pump
REF ASP-TUM	Tumescent Pump Module
REF ASP-CBL-1020	Cable - 1020/1025 to LipoTower
REF ASP-CBL-5020	Cable - 5020 to LipoTower
REF ASP-FLTR	Biofilter and Tubing Assembly
REF ASP-RNG-1200	Canister Ring 1200cc
REF ASP-RNG-2000	Canister Ring 2000cc
REF ASP-TB-VAC	Tubing - Vacuum (Non-Sterile)
REF ASP-TB-TUM	Luer Single-Use Tumescent Infiltration Tubing, Single-Spike, 10 Pak
REF ASP-FOOT-1	Foot Pedal
REF ASP-SHLF-1	Shelf
REF PAL-650	Power-Assisted Liposuction Handpiece
REF 1020	PAL Electric Power Console
REF 1025	Instrument Power Console
REF 5020	Electric Power Console for PAL
REF 5025	Electric Power Console for MicroAire Instruments
REF PAL-1200	Liposuction Tubing (12-foot)
REF 1006-PALE	PAL Instrument Cable for REF 1020/1025
REF 5006-PAL	PAL Instrument Cable for REF 5020/5025

INTENDED USE

The MicroAire LipoTower System is a device intended for aesthetic body contouring.

INDICATIONS FOR USE

The MicroAire LipoTower System is indicated for use in the following surgical specialties when the fragmentation, emulsification and aspiration of soft tissue is desired:

- Neurosurgery
- Gastrointestinal and Affiliated Organ Surgery
- Urological Surgery
- Plastic and Reconstructive Surgery
- General Surgery
- Orthopedic Surgery
- Gynecological Surgery
- Thoracic Surgery
- Laparoscopic Surgery

The MicroAire LipoTower System is indicated for use when the fragmentation, emulsification, and aspiration of subcutaneous fatty tissues for aesthetic body contouring is desired.

SYMBOL DEFINITIONS

 TYPE B EQUIPMENT

 ATTENTION SEE INSTRUCTIONS FOR USE

 DO NOT LUBRICATE

 DO NOT IMMERSE

 ELECTROSTATIC SENSITIVE DEVICE

 PRODUCT CATALOG NUMBER

 DO NOT REUSE

 MANUFACTURER

 DATE OF MANUFACTURE (YYYY-MM)

 SERIAL NUMBER

 RELATIVE HUMIDITY LIMITS

 ATMOSPHERIC PRESSURE LIMITS

 TEMPERATURE LIMITS

 UL LISTING

INTRODUCTION

This document, MicroAire LipoTower System - Instructions For Use (IFU), is intended to describe the procedures required to safely operate, clean and maintain the REF ASP-1020, the REF ASP-1021.

The operation, maintenance, cleaning and sterilization procedures for the PAL-650 Power Assisted Lipoplasty Handpiece, the 1020/1025 Standard Electric Console and the 5020/5025 Electric Console are described in their respective IFUs. This IFU addresses primarily the operation, maintenance cleaning and sterilization procedures applicable to the MicroAire LipoTower System.

The MicroAire LipoTower System can be configured to meet the requirements of an individual surgeon. See SETUP section for details on system configuration.

WARNINGS / CAUTIONS / NOTES

Throughout this IFU, the following terms are used to identify operational hints as well as precautions that will help avoid accidental injury to patients or personnel, or to prevent damage to delicate powered instruments.

WARNING: Used to indicate that the safety of patients and hospital personnel could be involved.
CAUTION: Used to point out special procedures or precautions that must be complied with to avoid damaging an instrument.
NOTE: Used to point out the easiest means of carrying out the techniques.

WARNING: Explosion hazard. Do not use in the presence of flammable anesthetics or oxygen.

WARNING: The MicroAire LipoTower System is heavy, weighing approximately 190 pounds. Use the proper equipment to lift the system if required.

WARNING: Flat shelving capacity – 6.8 kg (15lb) maximum safe capacity. Do not exceed.

WARNING: Tumescent pole capacity - 3kg (6.6lb) maximum safe capacity per hook. Do not exceed.

WARNING: Do not transport cart with anything on shelves or hooks. Remove all items from cart before unlocking casters.

WARNING: Do not modify any accessory. Failure to comply may result in patient and or operating room staff injury and equipment damage.

WARNING: Use only MicroAire-approved accessories. Use of other unapproved accessories may result in increased emissions or decreased immunity of the system and will void your warranty.

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: Grounding reliability can only be achieved when the equipment is connected to an equipment receptacle marked "Hospital Only" or "Hospital Grade."

WARNING: Disconnecting the supply cord will isolate the system from the supply mains on all poles simultaneously.

WARNING: Inspect tubing and suction canisters for wear or damage before use.

WARNING: Risk of fire. Use only MicroAire cables to connect to this device.

WARNING: Electric shock. Do not remove cover; refer servicing to qualified personnel only.

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

WARNING: Casters must be locked to prevent movement during normal use when a canister containing fluid is installed on the canister rack. Do not roll or tilt the cart in this condition because fluid could spill onto the cart causing a hazardous situation.

WARNING: ESD (Electromagnetic environment – guidance): Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. If ESD-related issues are experienced during use, it may be necessary to use antistatic materials (e.g., anti-static mat) or to increase the relative humidity of the surrounding environment.

WARNING: EFT (Electromagnetic environment – guidance): Mains power quality should be that of a typical commercial or hospital environment. If EFT-related issues are experienced during use, the use of power-line filtering may be necessary to ensure proper operation in the presence of large power-line transients.

WARNING: Do not block cooling vents. Maintain 50mm MIN clearance.

CAUTION: This device is designed to contour the body by removing localized deposits of excess fat through small incisions and subsequently transfer the tissue back to the patient.

CAUTION: Do not leave cannulas in patient when not in use.

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 and tissue transfer.

CAUTION: Results of this procedure will vary depending on 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: Federal Law restricts this device to sale by, or on the order of, a physician (or properly licensed practitioner).

CAUTION: See "PAL-650 Instrument System Instruction Manual" for detailed information on the PAL-650 handpiece.

CAUTION: See "Model 1020 Standard Electric Console Instruction Manual" for detailed information on the Model 1020 Standard Electric Console. See "Model 5020 Standard Electric Console Instruction Manual" for detailed information on the Model 5020 Standard Electric Console.

CAUTION: Do not use this device to aspirate surgical smoke from devices such as cauterizers, lasers, electrosurgical instruments or ultrasonic units. Doing so may clog the biofilter.

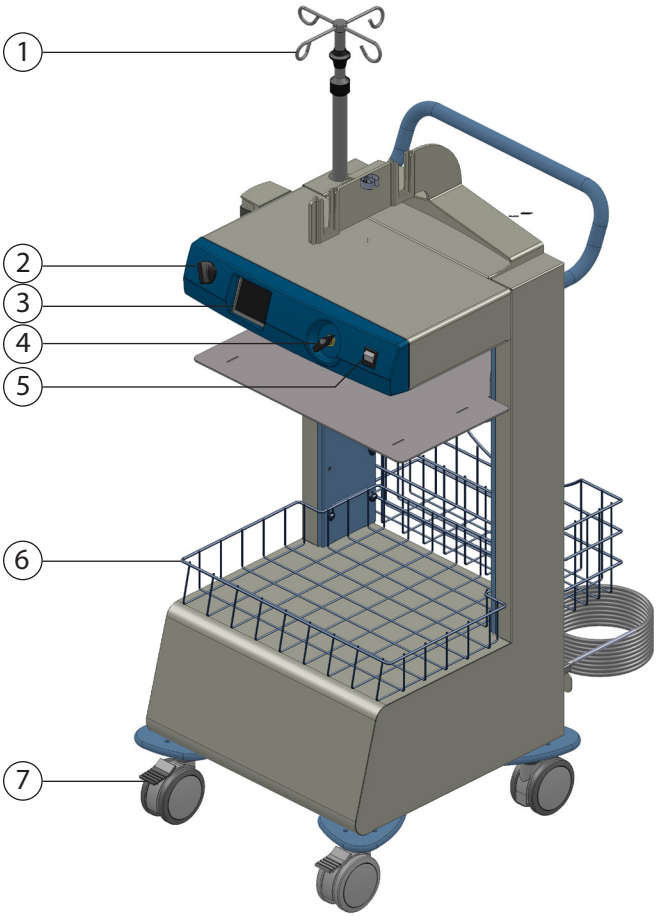
NOTE: This device is intended only for the aspiration of tissue or fluid from the body. The tissue product collected by this device shall only be used with FDA exempt/cleared/approved devices for any further use other than disposal.

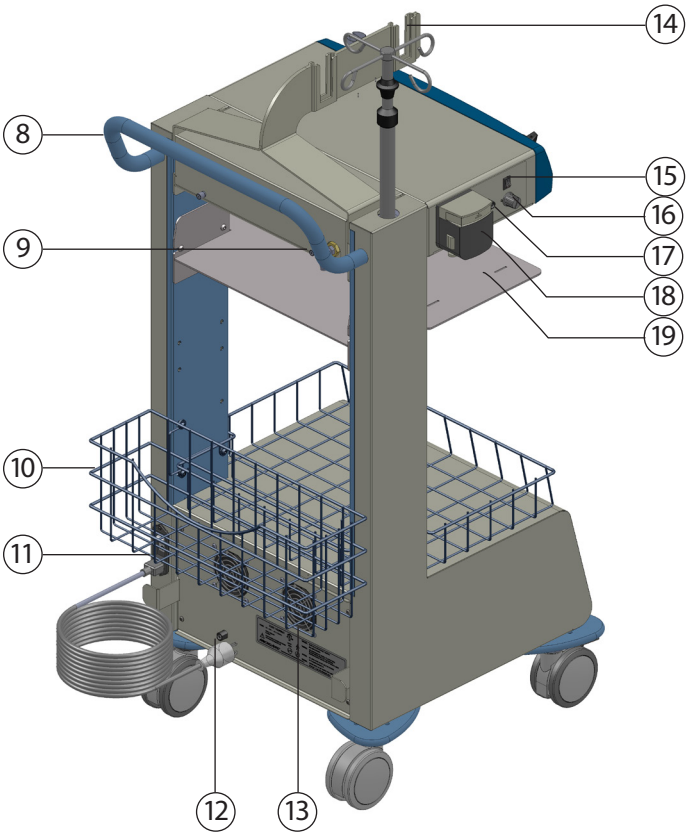
NOTE: All personnel involved with the operation, cleaning, maintenance and cleaning of the REF ASP-1020, -1021, should become familiar with the power equipment before it is set up for use in any procedure. Personnel that are trained should include, but not be limited to, central processing personnel, members of the surgical team, and the bioengineering department.

NOTE: The MicroAire LipoTower System should only be used with compatible FDA cleared tubing, handpieces and cannulas.

NOTE: The MicroAire LipoTower System has been tested for sound level and does not exceed 70 dB(A).

DESCRIPTION





1. **IV/TUMESCENT POLE**
2. **CONTROL SWITCH**
   - Determines the source of ON/OFF functions of the vacuum pump.
     - BYPASS - Vacuum pumps stay on.
     - PAL CONTROL - Vacuum pumps are on when PALhandpiece is on. This requires a BNC cable (REF ASP-CBL-1020, or REF ASP-CBL-5020) to be connected. (See Figure 4).
     - FOOT SWITCH CONTROL - Vacuum pumps are on when footswitch is activated.
3. **LCD SCREEN**
   - Displays vacuum pressure and Tool settings.
4. **VACUUM PRESSURE ADJUSTMENT**
   - MAX - For maximum vacuum turn clockwise.
   - MIN - For minimum vacuum turn counter-clockwise.
5. **STANDBY SWITCH**
   - ON (|) allows pumps to be activated by the Control Switch.
   - STANDBY (**o**) turns vacuum pumps off.
6. **STORAGE BASKET**
7. **LOCKING CASTERS**
8. **PUSH HANDLE**
9. **MAIN VACUUM CONNECTION**
10. **REAR STORAGE BASKET**
11. **POWER INLET AND MAINS DISCONNECT SWITCH**
12. **FOOT SWITCH CONNECTION**
13. **COOLING FANS**
    - Do not block cooling fans or system may overheat.
14. **CANISTER RACK**
    - Designed to securely hold wall-mount style aspiration canisters or wall-mount style canister rings.
15. **TUMESCENT PUMP ON/OFF SWITCH**
16. **TUMESCENT PUMP SPEED ADJUSTMENT KNOB**
17. **TUMESCENT PUMP FOOT SWITCH CONNECTION**
18. **TUMESCENT PUMP MODULE**
    - Standard on model ASP-1021 only. To add module, use REF ASP-TUM.
19. **SHELF**
    - Supports MicroAire electric consoles (REF 1020/1025, REF 5020/5025)

TECHNICAL DESCRIPTION

The MicroAire LipoTower System is Class I, Type B equipment, designed for continuous operation. It should not be used in the presence of flammable anesthetics. This equipment is rated IPX0 and provides no protection against the ingress of solids or liquids.

This equipment provides suction for health care facilities and is not intended for use in the field or during transport.

Rating: 100-120V ~ 60 Hz 1200VA
Output: 360VA

Maximum suction: 27-29 inHg (685.8-736.6 mmHg) at sea level
Maximum continuous run time: 90 minutes

SETUP

WARNING: To avoid personal injury, always ensure that the system is disconnected from applicable energy sources before starting any procedure in this section.

CAUTION: Some components may be Electrostatic Sensitive. Observe precautions for handling Electrostatic Sensitive Devices.

1. LOCKING AND UNLOCKING CASTERS

1. The front casters can be locked by depressing the brake tab that is connected to the caster. *(Figure 1)*
2. The front casters can be unlocked by lifting the brake tab that is connected to the caster. *(Figure 2)*

NOTE: Casters should be locked during set up and operation.

Figure 1 - Lock the casters

Figure 2 - Unlock the casters

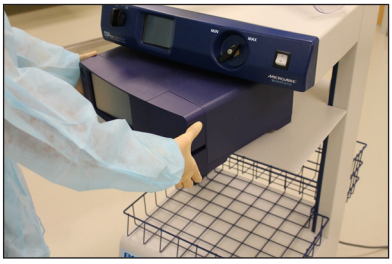


Figure 3 - Install optional console

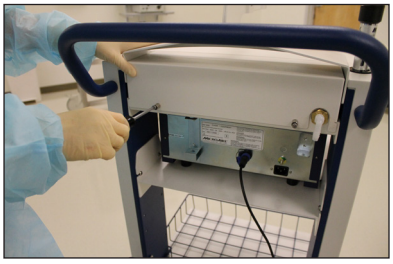


Figure 4 - Unscrew back-cover screws

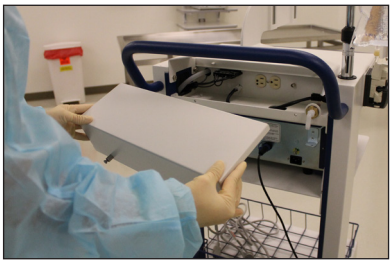


Figure 5 - Remove back panel

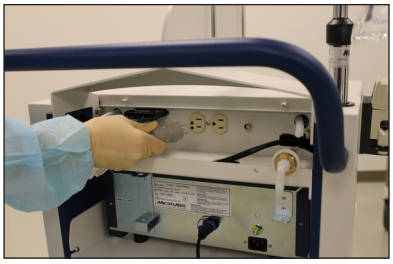


Figure 6 - Plug console into outlet

2. CONNECTING A MICROAIRE POWER CONSOLE FOR PAL SYSTEM (OPTIONAL)

1. Place Electric Console (REF 1020/1025 or REF 5020) on the shelf. *(Figure 3)*
2. Remove the back cover panel on the upper rear of the cart by loosening the two retaining screws. *(Figures 4 and 5)*
3. Manuever the electrical cord from the REF 1020/1025 or REF 5020 through the cable opening and connect it to the hospital grade outlet on the back of the cart. *(Figure 6)*
4. Manuever the BNC cable from the REF 1020/1025 or REF 5020 through the cable opening and connect it to the port on the back of the cart. *(Figure 7)*
5. Replace the rear cover and tighten the two retaining screws.

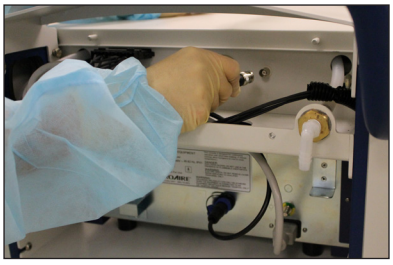


Figure 7 - Attach BNC connector

CAUTION: The Hospital Grade Receptacle has maximum current limit of 3A. Do not exceed.

CAUTION: This panel is in place for safety. Only UL-approved, PAL-related MicroAire cables are to be used to connect to the receptacles within the system. Ensure cover is securely attached before connecting power.

INSTALLING THE IV/TUMESCENT POLE

1. Insert the IV/Tumescent Pole into the receptacle on the top of the cart, in the rear left corner. Make sure that the sheathed wires within the recptacle are positioned toward the front of the cart while lowering the pole carefully into position. *(Figure 8)*
2. Turn the pole clockwise to thread it into position, and stop turning when it is snug.

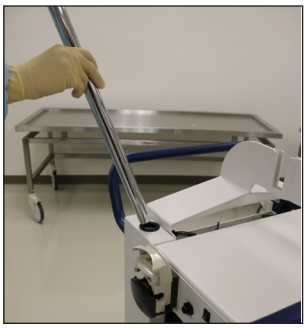


Figure 8 - Install IV Pole

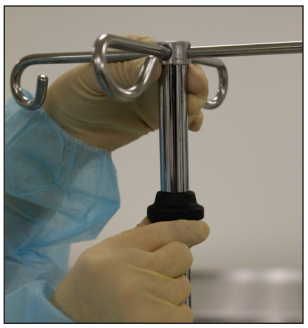


Figure 9 - Adjust pole height

ADJUSTING THE HEIGHT OF THE IV/TUMESCENT POLE

1. Move the locking collar upwards; then the pole can be adjusted up or down. The pole will stay in position once the locking collar is released. *(Figure 9)*

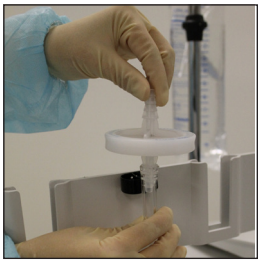


Figure 10 - Install Biofilter

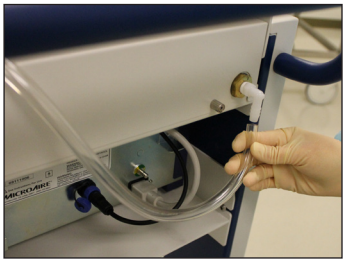


Figure 11 - Connect vacuum

CONNECTING THE BIOFILTER

1. Locate the small black Tubing Clip on the side of the Canister Rack.
2. Push the Biofilter tube into the Tubing Clip so it is secured in place with the Biofilter resting upon the clip, with the tubing exiting downward. *(Figure 10)*
3. Guide the loose end of the Biofilter tubing toward the rear of the cart, beneath the Canister Rack, and connect it to the Main Vacuum Connection. *(Figure 11)*

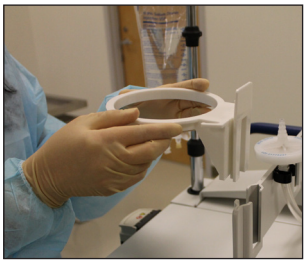


Figure 12 - Install waste canister rings

Figure 13 - Insert canister

ATTACHING WASTE CANISTERS

1. Locate the Canister Rack on the top of the cart. Slide one or more Waste-Canister Rings (REF ASP-RNG-1200 or REF ASP-RNG-2000) into any of the four available canister slots. These slots also accept various wall-mount style waste canisters. *(Figure 12)*
2. Insert appropriately sized Waste Canister into Ring. *(Figure 13)*
3. Connect Waste Canister to the Biofilter using REF ASP-TB-VAC Non-Sterile Vacuum Tubing. *(Figure 14)*

Figure 14 - Connect short tube from canister to filter

WARNING: Use only canisters that are rated appropriately for the vacuum pressure that will be used.

CONNECTING FOOT SWITCHES

1. Connect a Foot Switch to the lower rear of the cart to control the ON/OFF function of the vacuum pumps when the CONTROL SWITCH is set to FOOT SWITCH. (*Figure 15)*
2. Connect a Foot Switch to the Tumescent Pump module on the side of the cart, (where applicable) to control the ON/OFF function of the Tumescent Pump when the Tumescent Switch is in the ON position. (*Figure 16)*

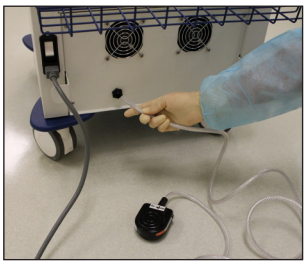


Figure 15 - Connect Foot Switch to rear of cart to control vacuum pumps

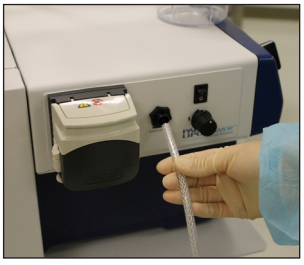


Figure 16 - Connect Foot Switch to side of cart to control infiltration

CONNECTING A SALINE/FLUID BAG TO THE TUMESCENT POLE

1. Hang a sterile saline/fluid bag onto the Tumescnt Pole by carefully inserting the bag's hanging-grommet onto one of the four hooks on the Tumescent Pole *(Figure 17 and 18)*. Up to four bags can be hung at one time, with one on each hook.

Figure 17 - Attach saline/fluid bag to the Tumescent Pole


Figure 18 - Make surethe bag is securely attached to the hook.

WARNING: Ensure that saline bags are properly secured to the hook.
WARNING: Tumescent pole maximum safe weight capacity is 3kg (6.6lb) per hook. Do not exceed.

CONNECTING INFILTRATION TUBING

1. Attach sterile, single-spike infiltration tubing (REF ASP-TB-TUM) to the saline/fluid bag according to the instructions for the saline/fluid bag.
2. Lift the lid on the Tumescent Pump located on the side of the cart. *(Figure 19)*
3. Locate the soft silicone section of infiltration tubing and place it into the open pump, ensuring that the outward flow of fluid is exiting the pump towards the front of the cart. *(Figure 20)*
4. Close the lid on the Tumescent Pump to compress the Infiltration Tubing within the pump.

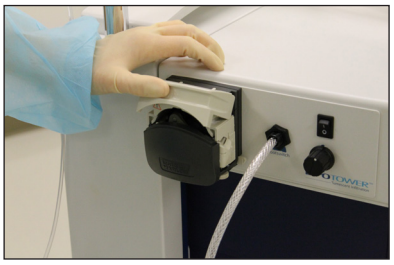


Figure 19 - Open the Tumescent Pump

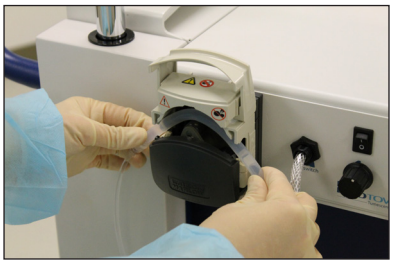


Figure 20 - Insert Infiltration Tubing

OPERATION

WARNING: Prior to use, all MicroAire Power Assisted Lipoplasty System subsystem manuals should be reviewed for important warnings and instructions for use.

WARNING: Prior to use, all system components should be inspected to detect any damage, excessive wear, corrosion or malfunction. DO NOT use if any potential problems become apparent. Contact MicroAire for resolution.

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

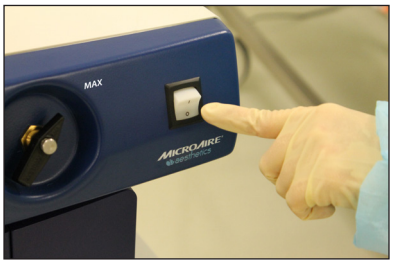


Figure 21 - Standby switch

POWERING UP THE SYSTEM

1. Before plugging the wall outlet power cord into a hospital-grade wall outlet, ensure that the STANDBY switch on the front of the cart is in the "STANDBY" (**o**) position. *(Figure 21)*
2. Insert the electrical cord into the POWER INLET, located on the lower left of the rear of the cart *(Figure 22)*. Plug the power cord into an appropriate hospital-grade wall outlet.
3. To power up the MicroAire LipoTower System, push the Mains Power Disconnect Switch to the "ON" (|) position *(Figure 22)*. A visible light on the STANDBY switch will now be illuminated.
4. Push the STANDBY switch to the "ON" (|) position. An audible sound from the cooling fans will indicate that the MicroAire LipoTower System is powered up.

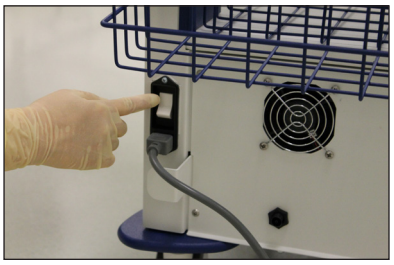


Figure 22 - Power inlet and Mains Disconnect switch

TUMESCENT INFILTRATION CONTROLS

1. Turn on the Tumescent Pump using the ON/OFF switch on the side of the cart. *(Figure 23)*
2. Adjust the speed/flow rate of the pump by turning the Speed Adjustment Knob. Flow rate is increased by turning the knob clockwise, and speed is decreased by turning the knob counterclockwise *(Figure 24)*

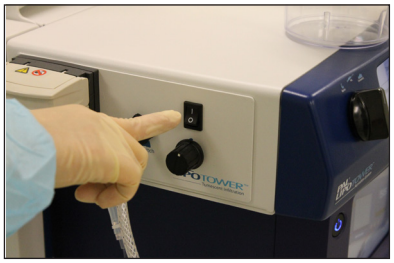


Figure 23 - Tumescent Pump ON/OFF

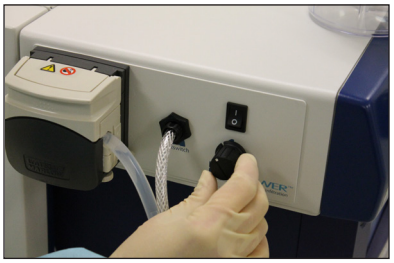


Figure 24 - Speed Adjustment knob

ASPIRATION CONTROLS

1. The 3-WAY CONTROL SWITCH controls the ON/OFF status of the MicroAire LipoTower System vacuum pumps. *(Figure 25)*

- BYPASS (left position) makes the vacuum pumps continuously active;
- PAL (middle position) places the ON/OFF status of the pumps under the control of the throttle of the MicroAire PAL handpiece;
- FOOT SWITCH (right position) places the ON/OFF status of the pumps under the control of a foot switch.

Figure 25 - Three-Way Control Switch

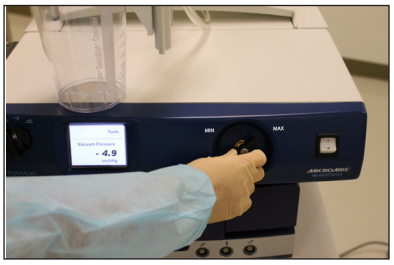


Figure 26 - Vacuum Pressure Knob

NOTE: If "FOOT SWITCH" is selected, ensure that the foot switch cable is securely connected to its receptacle located on the lower rear of the MicroAire LipoTower System. Ensure that the foot switch pedal is located within reach of the operator.

2. The VACUUM PRESSURE ADJUSTMENT knob controls the amount of suction pressure. Vacuum pressure is displayed on the LCD screen. Suction is increased by turning the knob clockwise towards MAX, and suction is decreased by turning the knob counterclockwise towards MIN. *(Figure 26)*

LCD TOUCH SCREENS

BOOT-UP SCREEN

The MicroAire logo will appear while the system is starting up. After boot-up, the screen will automatically advance to the home screen.

HOME SCREEN

This screen displays vacuum pressure, and an option to select the Tools screen. *(Figure 27)*

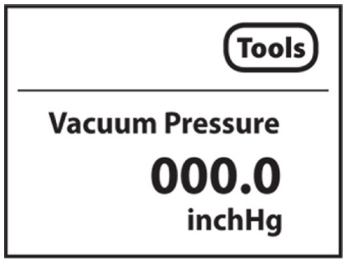


Figure 27 - Home Screen

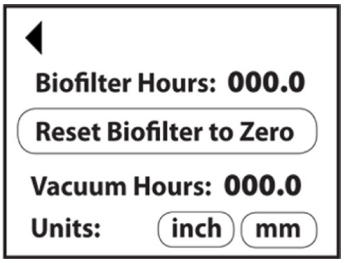


Figure 28 - Tools Screen

TOOLS SCREEN

This screen shows the number of hours used by the Biofilter, a button to reset the Biofilter to Zero, the number of total hours used by the vacuum pump, and buttons to select the unit of measurement. *(Figure 28)*

- Reset the biofilter hour meter by selecting RESET BIOFILTER TO ZERO.
- Select preferred units of measurement by choosing "INCH" or "MM."
- To return to the Main Screen, select the Back icon (left-facing arrow).

NOTE: The vacuum hour meter is not resettable, it represents total time used by the vacuum pumps.

MONITORING

Primary monitoring of the MicroAire LipoTower System status will be accomplished by observing progress at the procedure site of the patient. Secondary monitoring of the MicroAire LipoTower System status will be accomplished by periodic viewing of the tumescent fluid bags, the Tumescent Measuring Device (where applicable), the vacuum pressure as displayed on the LCD screen, and by viewing the waste canisters, to verify functionality as well as volume of aspirant.

CAUTION: Waste canisters should be replaced when 90% full. Overfilling may result in aspirant matter getting into, and contaminating, the MicroAire LipoTower System.

Once the MicroAire LipoTower System is powered up, and its appropriate cables, tubing, waste canisters and biofilter properly connected, and its mode of operation selected, and once the REF PAL-650 or PAL-600 and the REF 1020/1025 or REF 5020 have been properly powered and connected in accordance with their respective IFUs, surgical procedures can be started.

CAUTION: Before use, verify that the MicroAire LipoTower System functions properly. If not, contact MicroAire for resolution.

ADDITIONAL SET UP AND INSTALLATION (OPTIONAL)

INSTALLING THE TUMESCENT MODULE

1. Turn off power and disconnect main power by unplugging power cord.
2. Locate the Tumescent Bay cover on the left side of the cart. Remove the the two retaining screws and slide the cover towards the back of the cart to disengage the clip that is near the front of the cart. Remove cover. *(Figure 29)*
3. Locate the electrical connector harness on the pump module and connect it to the corresponding electrical connector within the bay. *(Figure 30)*
4. Insert the Tumescent Module (REF ASP-TUM) into the tumescent bay by inserting the pump module and then sliding it towards the front of the cart to engage the retaining clip. *(Figure 31)*
5. Insert the two retaining screws to secure the module in the bay. Do not tighten the screws until both are in place, to allow for adjusting the levelness of the module. *(Figure 32)*
6. Align the slot on the peristaltic pump head with the drive shaft, then attach the pump head. *(Figure 33)*
7. Rotate the pump head clockwise until it clicks into place. *(Figure 34)*

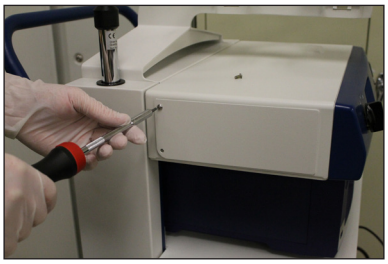


Figure 29 - Remove screws and slide cover towards the back of the cart.

Figure 30 - Connect the electrical harness.

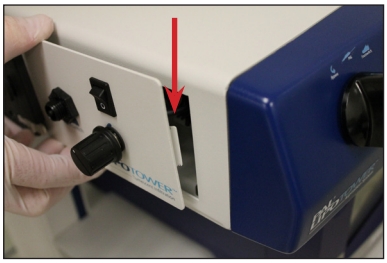


Figure 31 - Insert the module. Slide it rightward to engage retaining clip.

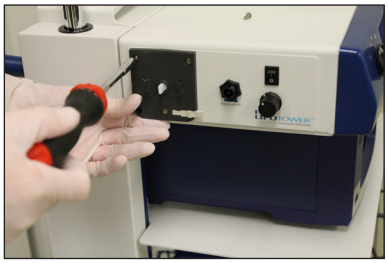


Figure 32 - Replace retaining screws.

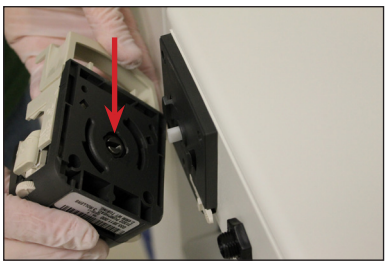


Figure 33 - Align the slot on the pump head with the drive shaft.

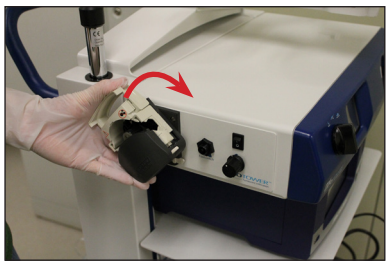


Figure 34 - Rotate the pump head clockwise until it clicks into place.

INSTALLING AN EXTRA SHELF

1. Turn off power and disconnect main power by unplugging power cord.
2. Insert the shelf from the front of the cart toward the rear and line up the bolt holes.
3. Insert the four bolts and use a 5/32" Allen wrench to tighten the bolts until they are snug.

TROUBLESHOOTING

DIFFICULTY INSERTING CABLES

- Align connectors and receptacles carefully.
- Make sure that all markings on cable plugs are aligned with matching markings on receptacles.
- If difficulty persists, contact MicroAire Customer Service for additional troubleshooting and repair.

THE MICROAIRE LIPOTOWER SYSTEM WILL NOT POWER UP

- Position the MAINS DISCONNECT SWITCH, located on the rear of the MicroAire LipoTower System to the OFF position. Ensure that the power cord is fully seated in the wall outlet. Position the MAINS DISCONNECT SWITCH to the ON position.
- Verify that the STANDBY switch is in the ON position.
- If the unit is still not operating properly, contact MicroAire Customer Service for additional troubleshooting and repair.

FOOT SWITCH WILL NOT OPERATE

- Ensure that the foot switch connection tube is fully seated in its receptacle at the lower rear of the MicroAire LipoTower System.
- Ensure that the vacuum pump CONTROL SWITCH is in the FOOT SWITCH position.
- If the foot switch still does not operate properly, contact MicroAire Customer Service for additional troubleshooting and repair.

VACUUM PRESSURE IS INSUFFICIENT

- Ensure all aspiration canisters and aspiration lines are properly connected and not kinked, and all aspiration canister lids are properly installed, with no clogged filters.
- Check the biofilter to ensure it is not clogged.
- Ensure that all applicable component connections are secure (the foot switch, REF PAL-650 handpiece, REF 1020/1025 and REF 5020 electric console); and that the 3-WAY CONTROL SWITCH is properly set.
- If vacuum pressure is still insufficient, contact MicroAire Customer Service for additional troubleshooting and repair.

MICROAIRE LIPOTOWER SYSTEM CIRCUIT BREAKER IS TRIPPED

- Check the biofilter to ensure it is not clogged.
- Cycle the MAINS DISCONNECT SWITCH to the OFF position and then to the ON position.
- If the Circuit Breaker trips again, contact MicroAire Customer Service for additional troubleshooting and repair.

CLEANING AND STERILIZATION

WARNING: The MicroAire LipoTower System should never be sterilized, immersed, or washed.

Before cleaning, the MicroAire LipoTower System should be unplugged. External surfaces of the device should be carefully wiped down with a disinfectant after each procedure, and at the beginning of each day. Care should be taken not to drip fluid into any equipment openings.

WARNING: If any fluid or solid material is drawn into the vacuum pump, the equipment must be serviced.

PREVENTIVE MAINTENANCE

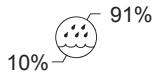
The MicroAire LipoTower System requires the following preventive maintenance:

- The BIOFILTER ASSEMBLY should be replaced after approximately every 25 procedures, or sooner if performance is reduced by clogging. If the BIOFILTER ASSEMBLY shows any moisture inside the filter or in the tubing beyond the filter, it should be changed immediately.
- Replace with MicroAire part REF ASP-FLTR and reset the hour meter in the TOOLS window of the LCD screen.
- All MicroAire equipment should be inspected and tested periodically in accordance with the user facility's bioengineering policy. Such service should be documented within the bioengineering department, and on the equipment (evidenced by an appropriate sticker).

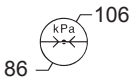
WARNING: Repairs or alterations to MicroAire products made by anyone other than MicroAire or an authorized MicroAire repair agent, will void the product's warranty.

ENVIRONMENTAL PARAMETERS

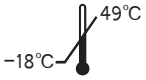
OPERATING CONDITIONS



Relative humidity limits



Atmospheric pressure limits



Temperature limits

WARNING: If there is condensation present on the MicroAire LipoTower System, DO NOT use it. Wait for the unit to come to room temperature and for condensation to evaporate before use.

WARNING: If the MicroAire LipoTower System is operated at high elevation or low atmospheric pressure, aspiration performance may be adversely affected.

NOISE LEVEL EXPOSURE LIMITS

The A-weighted emission sound pressure level of the MicroAire LipoTower System operating under normal conditions does not exceed 70 dB(A).

SHIPPING AND STORAGE CONDITIONS

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

STORAGE: Device 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.

REPAIR AND WARRANTY

MICROAIRE REPAIR SERVICE

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

Telephone	800-722-0822	Mailing Address	MicroAire Surgical Instruments LLC
Fax	800-438-6309		3590 Grand Forks Boulevard
Email	inquiry@microaire.com		Charlottesville, VA 22911, U.S.A.

DO NOT disassemble or attempt to service the equipment. It can only be serviced by MicroAire, or an authorized MicroAire repair agent. Unauthorized service will void the warranty.

RETURN PROCEDURE

The MicroAire LipoTower System is field-repairable only, and should not be returned to the factory.

WARRANTY

MicroAire Surgical Instruments warrants its LipoTower System 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 environments, 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

Follow local regulations for proper disposal.

IEC 60601-1-2 COMPLIANCE SUMMARY

CAUTION: The MicroAire LipoTower system needs to be installed and put into service according to the EMC information provided in this Instructions for Use manual. Portable and mobile RF communications equipment can affect medical electrical equipment. The MicroAire LipoTower System may be interfered with by other equipment with CISPR emission requirements.

CAUTION: The pin of the BNC connector of the MicroAire LipoTower System should not be touched and connection to this port should not be made unless ESD precautionary procedures are used.

CAUTION: Electrostatic Discharge (ESD) can damage electronic equipment. Under certain conditions, ESD may build up on your body or an object and then discharge into another object. To prevent ESD damage, you should discharge static electricity from your body before interacting with the MicroAire LipoTower System. You can protect against static-electricity discharge from your body by touching a metal grounded object before you interact with anything electronic. It is recommended that all staff involved with this device receive an explanation of the ESD warning symbol and training in ESD precautionary procedures.

CAUTION: The use of accessories and cables other than those specified in the Accessories list of this Instructions for Use manual may result in increased emissions or decreased immunity of the equipment or system.

CAUTION: The MicroAire LipoTower system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system must be observed to verify normal operation in the configuration in which it will be used.

Table 1 (IEC 60601-1-2 Table 201)

Guidance and manufacturer's declaration – electromagnetic emissions		
The MicroAire LipoTower system is intended for use in the electromagnetic environment specified below. The customer or the user of the MicroAire LipoTower system should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
Radio Frequency (RF) Emissions CISPR 11	Group 1	The MicroAire LipoTower system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The MicroAire LipoTower system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 2 (IEC 60601-1-2 Table 202)

Guidance and manufacturer's declaration – electromagnetic immunity			
The MicroAire LipoTower system is intended for use in the electromagnetic environment specified below. The customer or the user of the MicroAire LipoTower system should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±2 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±1.65 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
	±1 kV for input/output lines	±1 kV for input/output lines	
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±1 kV line to line ±2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% *U*T (>95% dip in *U*T) for 0.5 cycle 40% *U*T (60% dip in *U*T) for 0.1 sec 70% *U*T (30% dip in *U*T) for 0.5 sec <5% *U*T (>95% dip in *U*T) for 5 sec	<5% *U*T (>95% dip in *U*T) for 0.5 cycle Deviation allowed for devices whose kVA rating is greater than 1kVA 70% *U*T (30% dip in *U*T) for 0.5 sec <5% *U*T (>95% dip in *U*T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MicroAire LipoTower system requires continued operation during power mains interruptions, it is recommended that the MicroAire LipoTower system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: *U*T is the a.c. mains voltage prior to the application of the test level.			

Table 3 (IEC 60601-1-2 Table 204)

Guidance and manufacturer's declaration – electromagnetic immunity			
The MicroAire LipoTower system is intended for use in the electromagnetic environment specified below. The customer or the user of the MicroAire LipoTower system should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the MicroAire LipoTower system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = (3.5/3)\sqrt{P}$ 150 kHz to 80 MHz $d = (3.5/3)\sqrt{P}$ 80 MHz to 800 MHz $d = (7/3)\sqrt{P}$ 800 MHz to 2.5 GHz ...where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and (d) is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
Superscript a: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the MicroAire LipoTower system is used exceeds the applicable RF compliance level above, the MicroAire LipoTower system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MicroAire LipoTower system. Superscript b: Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 4 (IEC 60601-1-2 Table 206)

Recommended separation distances between portable and mobile RF communications equipment and the MicroAire LipoTower system			
The MicroAire LipoTower system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MicroAire LipoTower system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MicroAire LipoTower system as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = (3.5/3)\sqrt{P}$	**80 MHz to 800 MHz** $d = (3.5/3)\sqrt{P}$	**800 MHz to 2.5 GHz** $d = (7/3)\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33
For transmitters rated at a minimum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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