

MicroAire LipoTower System

Instructions for Use



MICROAIRE®
For Surgery. For Life.™

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APPLICABLE PART NUMBERS

REF Number	Description
REF ASP-1021	LipoTower
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	Vacuum Tubing
REF ASP-FOOT-1	Foot Pedal
REF ASP-SHLF-1	LipoTower Shelf

ACCESSORIES

REF Number	Description
REF ASP-TB-TUM	Single Spike Infiltration Tubing, Luer Lock
REF PAL-650	PAL Electric Handpiece
REF 1020	Standard Electric Console
REF 1025	Instrument Electric Console
REF 5020	Electric Instrument Control Console (PAL)
REF 5025	Electric Instrument Control Console (MicroAire Powered Instruments)
REF PAL-1200	PAL Aspiration Tubing – 12 ft
REF 1006-PALE	PAL 1020 Electric Instrument Cable
REF 5006-PAL	PAL 5020 Electric Instrument Cable

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
	DO NOT LUBRICATE
	DO NOT IMMERSE
	ELECTROSTATIC SENSITIVE DEVICE
REF	PRODUCT CATALOG NUMBER
	DO NOT REUSE
	MANUFACTURER
	DATE OF MANUFACTURE (YYYY-MM)
SN	SERIAL NUMBER
	UL LISTING
	ATTENTION: READ ALL WARNINGS AND PRECAUTIONS IN INSTRUCTIONS FOR USE
LOT	BATCH CODE
	CONSULT INSTRUCTIONS FOR USE
	NON-IONIZING ELECTROMAGNETIC RADIATION
R_x Only	PRESCRIPTION ONLY
	BYPASS
	PAL
	FOOT PEDAL

INTRODUCTION

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

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

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.

MICROAIRE LIPOTOWER SYSTEM CAUTIONS AND WARNINGS

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: IV/Tumescent pole maximum capacity is 3kg (6.6lb) 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: This device will not, in and of itself, produce significant weight reduction.

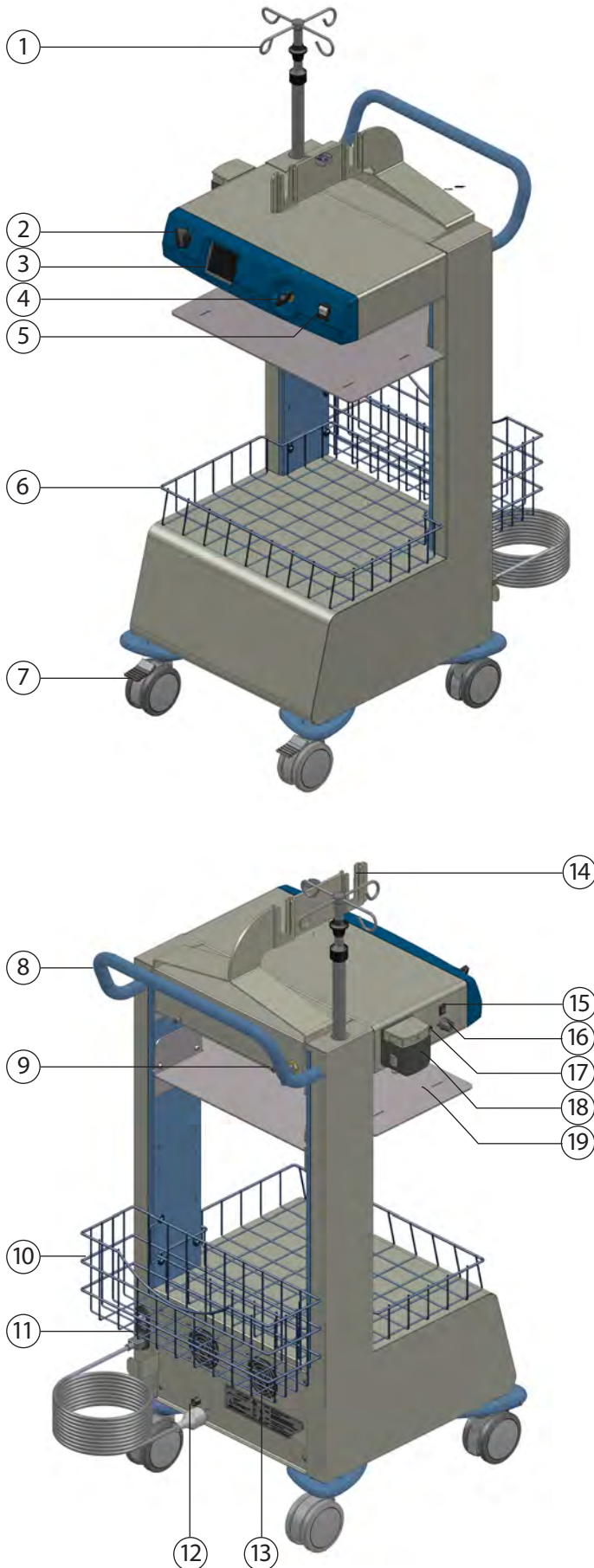
WARNING: This device should be used with extreme caution in patients with chronic medical conditions, such as diabetes, heart, lung or circulatory system disease or obesity.

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 a hospital grade 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:** Risk of fire. Use only MicroAire cables to connect to this device.
- WARNING:** Risk of 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:** Do not block cooling fans. Maintain a minimum of 50mm clearance.
- WARNING:** Prior to use, all associated MicroAire device and accessory Instructions for Use documents should be reviewed.
- WARNING:** Prior to use, all system components and accessories should be inspected to detect any damage, excessive wear, corrosion, or malfunction. If potential problems are found do not use. Contact MicroAire Customer Service for resolution.
- WARNING:** The MicroAire LipoTower System should never be sterilized, immersed or washed.
- CAUTION:** 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., antistatic mat) or to increase the relative humidity of the surrounding environment.
- CAUTION:** 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.
- 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 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:** Federal Law (USA) restricts this device to sale by, or on the order of, a physician, Rx, (or properly licensed practitioner).
- 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.
- CAUTION:** It is recommended that the MicroAire LipoTower System shall not be used adjacent to or stacked with other equipment. 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.
- CAUTION:** Prior to use, verify that the LipoTower System and accessories assemble and function properly. If assembly or functionality is compromised, contact MicroAire Customer Service.
- CAUTION:** The use of accessories and cables other than those specified in the Accessories list of this Instructions for Use document may result in increased emissions or decreased immunity of the equipment or System.
- CAUTION:** The MicroAire LipoTower System must be installed and put into service according to the EMC information provided in this document. Portable and mobile RF communications equipment can affect medical electrical equipment. This device 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 the user's body or an object and then discharge into another object. To prevent ESD damage, all personnel should discharge static electricity from the body before interacting with the MicroAire LipoTower System. This can be accomplished by touching a metal grounded object before interacting with anything electronic. It is recommended that all personnel involved with the device receive an explanation of the ESD warning symbol and training in ESD precautionary procedures.
- 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, maintenance, and cleaning of the REF ASP-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 for the vacuum pumps.
 - BYPASS - Continuous vacuum.
 - PAL CONTROL - Vacuum pumps are activated when the PAL handpiece is activated. This requires a BNC cable (REF ASP-CBL-1020, or REF ASP-CBL-5020) to be connected. (See Figure 4).
 - FOOT PEDAL CONTROL - Vacuum pumps are on when foot pedal is activated.

3. LCD SCREEN

- Displays vacuum pressure and Tools settings.

4. VACUUM PRESSURE ADJUSTMENT

- MAX - For maximum vacuum turn clockwise.
- MIN - For minimum vacuum turn counterclockwise.

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 PEDAL CONNECTION

13. COOLING FANS

WARNING: Do not block cooling fans. Maintain a minimum of 50mm clearance.

14. CANISTER RACK

- Designed to securely hold wall-mount style suction canisters or wall-mount style canister rings.

15. TUMESCENT PUMP ON/OFF SWITCH

16. TUMESCENT PUMP SPEED ADJUSTMENT KNOB

17. TUMESCENT PUMP FOOT PEDAL CONNECTION

18. TUMESCENT PUMP MODULE

19. SHELF

- Supports MicroAire electric consoles (REF 1020/1025, REF 5020/5025)

TECHNICAL DESCRIPTION

The MicroAire LipoTower System is Class II, 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
Vacuum Flow Rate: 3.0 SCFM (0.08 m³/min)

SETUP

WARNING: To avoid personal injury, always ensure that the system is disconnected from applicable energy sources before starting system setup.

CAUTION: Some components of the MicroAire LipoTower 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.

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. Maneuver 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. Maneuver 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. Ensure cover is securely attached before connecting power.

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

CAUTION: Only UL-approved, PAL-related MicroAire cables are to be used to connect to the receptacles within the system.



Figure 1 - Lock the casters



Figure 2 - Unlock the casters



Figure 3 - Install optional console



Figure 4 - Unscrew back-cover screws

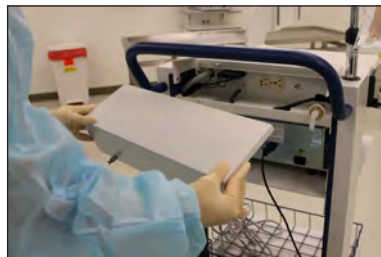


Figure 5 - Remove back panel



Figure 6 - Plug console into outlet



Figure 7 - Attach BNC connector

INSTALLING THE IV/TUMESCENT POLE

1. Insert the IV/Tumescent Pole into the receptacle located at the rear left corner on the top of the cart. Make sure that the sheathed wires within the receptacle 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. Stop turning when the pole 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)*

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, and 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 10 - Install Biofilter



Figure 11 - Connect vacuum

ATTACHING WASTE CANISTERS

1. Locate the Canister Rack on the top of the cart. Slide one or more 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 suction canisters. *(Figure 12)*
2. Insert appropriately sized canister into Ring. *(Figure 13)*
3. Connect a suction canister to the Biofilter using MicroAire Non-Sterile Vacuum Tubing (REF ASP-TB-VAC). *(Figure 14)*



Figure 12 - Install waste canister rings



Figure 13 - Insert canister

WARNING: Use only suction canisters that are rated appropriately for the vacuum pressure that will be used. MicroAire does not provide nor recommend suction canisters.

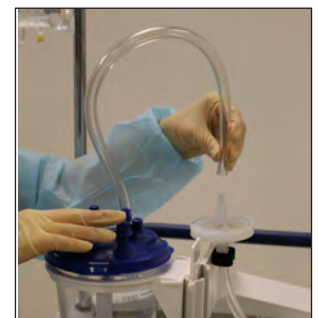


Figure 14 - Connect short tube from canister to filter

CONNECTING FOOT PEDALS

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



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



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

CONNECTING A SALINE/FLUID BAG TO THE IV/TUMESCENT POLE

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

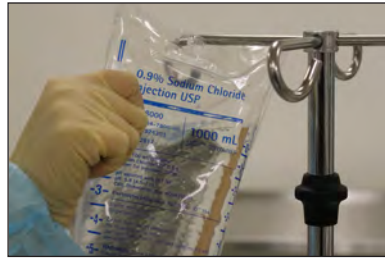


Figure 17 - Attach saline/fluid bag to the IV/Tumescient Pole



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

WARNING: IV/umescent 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 Tumescient Pump located on the side of the cart. (Figure 19)
3. Locate the soft silicone section of the 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)



Figure 19 - Open the Tumescient Pump



Figure 20 - Insert Infiltration Tubing

4. Close the lid on the Tumescient Pump to compress the Infiltration Tubing within the pump.

OPERATION

WARNING: Prior to use, all MicroAire Power Assisted Liposuction System 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. If any potential problems are found contact MicroAire Customer Service for resolution.

WARNING: Eye protection must be worn when operating any power equipment to prevent injury, blindness, or contamination of the eye from patient tissue or body fluids.

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" (○) position. (Figure 21)
2. Insert the electrical cord into the POWER INLET, located on the lower left 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 21 - Standby switch



Figure 22 - Power inlet and Mains Disconnect switch

TUMESCENT INFILTRATION CONTROLS

1. Turn on the Tumescence Pump using the ON/OFF switch on the side of the cart. (Figure 23)

NOTE: If the Tumescence Pump does not activate when the on/off switch is in the ON position, depress the Foot Pedal

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 decreased by turning the Knob counterclockwise (Figure 24)



Figure 23 - Tumescence 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)

- In BYPASS mode (left position) the vacuum pumps are continuously active;
- In PAL mode (middle position) the ON/OFF status of the pumps are controlled by the throttle of the MicroAire PAL handpiece;
- In FOOT PEDAL mode (right position) the ON/OFF status of the pumps is under the control of the Foot Pedal.



Figure 25 - Three-Way Control Switch



Figure 26 - Vacuum Pressure Knob

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.



Figure 27 - HOME Screen

HOME SCREEN

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

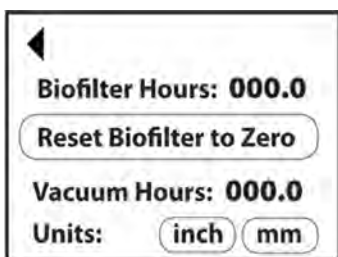


Figure 28 - TOOLS Screen

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).

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 vacuum pressure as displayed on the LCD screen, and by viewing the suction canisters, to verify functionality as well as volume of aspirate.

CAUTION: During the liposuction procedure, suction canisters should be replaced when 90% full. Overfilling may result in contamination of the MicroAire LipoTower System.

CAUTION: Prior to use, verify that the LipoTower System and accessories assemble and function properly. If assembly or functionality is compromised, contact MicroAire Customer Service.

ADDITIONAL SET UP AND INSTALLATION (OPTIONAL)

REPLACING 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 toward the back of the cart. This will 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.
- Ensure 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 PEDAL WILL NOT OPERATE

- Ensure that the Foot Pedal 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 PEDAL position.
- If the Foot Pedal still does not operate properly, contact MicroAire Customer Service for additional troubleshooting and repair.

VACUUM PRESSURE IS INSUFFICIENT

- Ensure all suction canisters and aspiration tubing are properly connected and are not kinked, and all suction 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 Pedal, PAL-650 Handpiece, 1020/1025 and 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 pumps of the MicroAire LipoTower System, 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 50 hours, 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).

ENVIRONMENTAL PARAMETERS

OPERATING CONDITIONS

WARNING: If there is condensation present on the MicroAire LipoTower, do not use the system. 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 ensure 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	800-438-4309		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 repairs service or alterations 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 must be installed and put into service according to the EMC information provided in this document. 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.
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- CAUTION:** Electrostatic Discharge (ESD) can damage electronic equipment. Under certain conditions, ESD may build up on the body or an object and then discharge into another object. To prevent ESD damage, all personnel should discharge static electricity from your body before interacting with the MicroAire LipoTower System. This can be accomplished by touching a metal grounded object before interacting 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 document may result in increased emissions or decreased immunity of the equipment or system.
- CAUTION:** The MicroAire LipoTower System shall not be used adjacent to or stacked with other equipment. 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% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 0.1 sec 70% UT (30% dip in UT) for 0.5 sec <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle Deviation allowed for devices whose kVA rating is greater than 1kVA 70% UT (30% dip in UT) for 0.5 sec <5% UT (>95% dip in UT) 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: UT 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	3 Vrms 150 kHz to 80 MHz	3 Vrms	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: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
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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