

MicroAire[®]

SURGICAL INSTRUMENTS



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Model 1020 Standard Electric Console Instruction Manual

**Model 1020 Standard Electric Console
Instruction Manual**

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Series 1000 Instrument Instructions
See Pages 13-26

PAL-600E Instructions
See Pages 27-29

- INTRODUCTION -

This manual has been written to help describe the procedures required to keep the MicroAire 1020 Standard Electric Console system operating properly.

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

1. **NOTE:** Used to point out the easiest means of carrying out techniques.
2. **WARNING:** Used to indicate that the safety of the patient and hospital personnel could be involved.
3. **CAUTION:** Used to point out special procedures or precautions that must be followed to avoid damaging the system/instrument.

- GENERAL WARNINGS -

- WARNING:** Risk of fire. Replace fuse with 3.15A/250V Slow Blow (SLO).
- WARNING:** Grounding reliability can only be achieved when the equipment is connected to equipment receptacle marked "Hospital Only" or "Hospital Grade".
- WARNING:** Disconnecting the supply cord will isolate the console from the supply mains on all poles simultaneously.
- WARNING:** Risk of fire. Use only MicroAire cables to connect to the instrument.
- WARNING:** Explosion Hazard. Not suitable for use in the presence of flammable anesthetics or oxygen.
- WARNING:** Electric Shock. **DO NOT** remove cover. Refer servicing to qualified personnel only.
- WARNING:** Type BF rating may only be maintained if the instrument is not used to bridge between the patient and ground.
- WARNING:** Use care to ensure that there is no electromagnetic interference between this device and other devices in use.
- CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician.
- NOTE:** All personnel should become familiar with the power equipment before it is set-up for use in any procedure. Personnel inserviced should include, but not limited to, central processing personnel, members of the surgical team, and the bioengineering department.
- NOTE:** Continuous Operation with Short Time Loading. (1 Minute Running, Allow to cool to room temperature).

- CONSOLE MARKINGS -

EXTERNAL:

Ref: 1020

Ratings: 240W



CLASS 1 EQUIPMENT

Attention, See instructions for use. This unit is designed for Continuous Operation with Short-Time Loading. (1 Minute Running, Allow handpiece to cool to room temperature).

Input: 100-230 V~, 50-60 Hz, 240W



Handpiece



Power "OFF"



Speed Indicator



Power "ON"



Speed Control



Type BF equipment.



Reverse Indicator [reserved for future use]



Irrigator

WARNING: Use Only With MicroAire UL Listed Irrigator.



European Conformity Mark



CLASSIFIED BY UNDERWRITERS LABORATORIES, INC. WITH RESPECT TO ELECTRIC SHOCK, FIRE, AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 2601-1, CAN/CSA C22.2 NO. 601-M90

Control Number: 8R91

- INSTRUMENT MARKINGS [REFERENCE ONLY] -



"Safe" or "Lock"

SAFE

Throttle safety lock is engaged



"Run" or "Load"

RUN

Throttle safety lock is NOT engaged

- 1020 STANDARD ELECTRIC CONSOLE -

The Model 1020 Standard Electric Console is designed for use only with MicroAire Powered Instruments. It is compatible with PAL-E, 1000E and 19xx instrument types. The 1020 Console is not intended to be sterile, and should never be sterilized.

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

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

DO NOT use any component if damage is apparent.

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

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

- SYSTEM CHECK, ASSEMBLY, AND OPERATION -

1. Check the console and all cables for signs of damage or wear.
2. Inspect the handpiece for damage, or corrosion, or excessive wear.

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

3. Check all surgical accessories. Make sure that blades, drills, burs, and/or cannulae are not dull or bent, and that they lock correctly into the handpiece.
4. Attach the surgical accessory (blade, bur, drill, cannula) to the handpiece.



5. Starting with the console, plug the wall outlet power cord into the back of the unit. The plug only inserts one way.


6. Plug the handpiece cable into the receptacle located on the front of the console.


NOTE: Be sure to align the red dot on the cable with the red dot on the console receptacle before inserting.


7. Firmly hold the handpiece and insert the handpiece cable into the back of the handpiece. Be sure to match the pins in the cable with the holes in the handpiece receptacle before inserting.

8. Before plugging the console into the wall voltage outlet, check to see that the power switch on the front of the console is in the "OFF" position. Plug the power cord into a Hospital Grade outlet and turn the power switch to "ON" to activate the unit. The console will operate on 100 - 230V~ grounded outlets. Once the unit is turned on, the switch and all LEDs on the front panel will illuminate, and 4 short "beeps" will be heard. If the 4 short "beeps" are not heard, please refer to the Troubleshooting section. When the instrument is ready to run the console will give a single "short beep".

NOTE: The "OFF" position is designated by  and the "ON" position is designated by .

9. Make sure the safety switch on the handpiece is in the  or **SAFE** position. Insert the surgical accessory into the handpiece, making sure it is secure. (Different handpieces have different mechanisms for attaching these components. Please refer to the instructions specific to the handpiece).

a. Make sure that, when the safety lock is on  or **SAFE** it prevents activation of the motor by the hand throttle.

b. Make sure that, when the safety lock is on  or **RUN** it allows activation of the motor by the hand throttle.

c. Make sure that the throttle does not stick in the fully depressed position. If it has any tendency to stick, reclean and resterilize the handpiece. If the handpiece still does not meet the above requirements, return the handpiece for service.

10. With the surgical accessory inserted, test run the instrument in the sterile field for 3 10-second intervals, checking for any indication of irregular noise, or excessive heat or vibration. Irregular grinding noises may indicate impending failure or over heating of the handpiece. If any irregular grinding noises are present, return the instrument for service.

11. Check for excessive heat.

WARNING: Excessive heat is the most likely cause of patient injury. Any power instrument is subject to overheating, especially in the nose section. Even normal operation of the system in a cycle other than 1 minute "ON" and allowing the handpiece to cool to room temperature may cause the handpiece to become hot.

To check for overheating, test run the handpiece for approximately 30 seconds. Periodically monitor the temperature of the nose section. The temperature should not rise above 115°F (46°C) and should not become uncomfortable to touch with gloved fingers. If the instrument temperature exceeds 115°F (46°C) please return it for service.

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


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

- Blood deposits, saline, and bone fragments often enter the forward section of the hand-

piece during operation. Saline causes corrosion, and blood produces restrictive deposits.

- Repeated sterilization removes grease from the bearings, and leaves mineral deposits on moving parts. Regular maintenance is recommended to replace bearings, seals, and "o" rings.

- The force of cutting produces wear on bearings and oscillating mechanisms.

12. To operate the handpiece slide the safety lock to the  or **RUN** position. Gently depress the throttle lever to activate the motor. Fully depress the throttle lever one time to obtain fine speed control.

13. To set the throttle maximum speed at other than 100%:

- Fully depress the throttle of the instrument.
- Use the control knob to set the maximum speed. (Constant LED indicates maximum set point).
- Maximum speed is now set for the desired instrument.

NOTE: The operator set value will be reset to 100% when the instrument is removed.

14. System is ready for use.

- TROUBLESHOOTING -

1. The 1020 Standard Electric Console provides audible signals to aid in troubleshooting possible problems with the console and the instrument being used with it.

- 4 short "beeps" should be heard when the 1020 Console is powered on. If the 4 short "beeps" are not heard, verify the following:
 - the power cord is connected to the console and the power source
 - the power switch is on
 - the power switch LED is lit.

If the power switch LED is not lit, or if it is lit and the 4 short "beeps" are not heard, return the console for service.

- 3 long "beeps" indicate an improper instrument type has been connected to the console. This signal is triggered if MicroAire 6000 series instruments or the 1641 SmartDriver are attached to the 1020. Valid instrument types include the PAL-600E, 1000E and 19xx series instruments. If it is a type that should work, remove and reinstall both ends of the cable. If this does not correct the problem, try another cable or contact MicroAire Customer Service.

- 1 long "beep" followed by 3 short "beeps" indicates a bad motor in the handpiece. Try reconnecting both ends of the cable. If this does not correct the problem, try another cable or contact MicroAire Customer Service.


2. The 1020 Standard Electric Console is equipped with an automatic shut-off feature. If the motor of the handpiece is stalled for more than 2 seconds, the console will turn off power to the handpiece until the throttle is released and depressed again.


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

a. Align connectors and receptacles carefully. Make sure the pins on the cable are aligned with the matching holes in the console or handpiece receptacle. This connection is a tight fit to keep particles from getting inside the handpiece.

b. Make sure the plug is pressed fully into the handpiece and that the "snap lock" is fully engaged.

4. Handpiece will not start.

a. Check that the console is "ON" (the main power switch is in the  position, with the switch illuminated) and the front panel LED's are illuminated.

b. Make sure the throttle is in the  or **RUN** position.


c. Make sure the maximum speed display indicates a maximum speed, and the light over the cable receptacle is illuminated.

d. Replace the handpiece cable.

e. Remove the handpiece and plug a different handpiece into the console and cable. If this handpiece runs properly, then return the faulty handpiece for service.

f. If the handpiece does not run properly, return the system (console, handpieces and cables) for service.

5. Handpiece runs slowly.

a. Check that the safety lock is all the way in the  or **RUN** position.

b. Replace the handpiece cable.

c. Remove the handpiece and plug a different handpiece into the console. If this handpiece runs at the proper speed, return the faulty handpiece for service.

d. If the second handpiece does not run properly, return the system (console, handpieces and cables) for service.

6. Maximum speed set does not function properly.

a. Make sure the lever was depressed in the proper sequence.

b. Try another handpiece in place of the one not adjusting properly.

c. If the second handpiece runs properly, then return the faulty handpiece for service.

d. If the second handpiece does not run properly, return the system (console, handpieces and cables) for service.

- ROUTINE CLEANING/DECONTAMINATION -

- 1020 CONSOLE CLEANING INSTRUCTIONS -

1. Unplug the 1020 Standard Electric Console from the power source.

2. External surfaces of the unit 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 openings on the console


WARNING: The 1020 Console should never be sterilized, immersed, or washed.

- INSTRUMENT CLEANING INSTRUCTIONS -

Dried blood, saline, and other deposits inside the handpiece are a major cause of equipment malfunction. Proper cleaning and inspection prior to sterilization will avoid delays during the surgical procedure.

CAUTION: The handpiece is sensitive to moisture. **DO NOT** immerse the handpiece in saline, disinfectant, or any other liquid. **DO NOT** use an ultrasonic cleaner as ultrasonic cleaning can damage the bearings in the handpieces, potentially resulting in overheating or seizure.

1. Disassemble and transport to the decontamination area.

a. If using the throttle lever handpiece, slide the safety lock to the  or **SAFE** position.

b. Turn the power switch on the console to .

c. Unplug the power cord from the wall outlet and from the back of the console.

d. Disconnect the handpiece cable from the console.

NOTE: The handpiece cable has a mechanical snap-lock mechanism to keep the plugs firmly connected during use. To disconnect, pull on the grooved area of the plug and not on the black plastic strain relief immediately behind it. This protects delicate wire terminations in the connector.

e. Remove all inserted surgical accessories (blades, burs, drills, cannulae) from the handpiece. Disposable surgical accessories should be discarded after use, handling them as any contaminated sharp accessory is handled. Reusable PAL cannulae should be cleaned with a cylindrical cannulation brush, and then processed for reuse. Reuse of surgical cutting accessories (burs, blades, drills) is not recommended.

2. Clean the device immediately, using an appropriate detergent solution.

a. Immediate decontamination protects personnel and prevents transmission of unknown pathogens.

b. Make sure the handpiece cable is connected to the handpiece to keep detergent solution and water out of the motor.

c. Clean the handpiece cable thoroughly with warm water, mild detergent, and a soft brush.

d. Pay vigorous attention to crevices.

3. Use a cannulation brush on cannulated handpieces.

a. Clean the cannulated shaft of wire drivers with the small cylindrical wire driver cannulation brush (9600-063).

b. Remove bur guard from drills.

c. Clean inside drill collets and bur guards with the drill cannulation brush (9600-064).

4. Flush the noses of drills and wire drivers with a Water-Pik or similar device. Flushing removes blood, debris, and saline deposits.

5. Rinse with the handpiece cable connected, rinse components under running water to remove all traces of detergent solution. If possible, use distilled water for the final rinse.

6. Dry.

7. Disconnect the handpiece cable from the handpiece, grasping it firmly on the grooved area of the plug. Be sure to pull straight back on the grooved area of the plug and **DO NOT** pull on the black plastic strain relief immediately behind it. Dry all the components with a lint-free towel.

8. Lubrication of head modules. **DO NOT** lubricate or oil the handpieces. Lubrication will clog the motor and prevent it from starting. Also take special precautions to avoid the use of cleaners that contain lubrication.

9. Accidental immersion. If a handpiece is accidentally immersed in saline, disinfectant, cleaning fluid, or any other corrosive substance, take the following steps to save the handpiece.

a. Totally immerse the handpiece in distilled water for 1 minute to dilute the corrosive fluid. **DO NOT** allow the water to dry in the handpiece.

b. Immediately after soaking, steam sterilize in a prevacuum sterilizer at 270°F (132°C) for 4 minutes followed by an 8 minute drying time. Sterilizing will dry out the handpiece, avoid rusting, and prevent contamination from collecting in the motor.

- INSTRUMENT STERILIZATION INSTRUCTIONS -

MicroAire's powered surgical instruments (including handpieces, and the handpiece cable) are normally sterilized by steam, using either a gravity displacement or prevacuum sterilizer. **DO NOT** sterilize the console or its power cord.

1. Sterilization parameters

Sterilizers vary in design and performance parameters, verify cycle parameters against the written instructions of the sterilizer and container manufacturers. Prevacuum

sterilization is the preferred method of sterilization for powered surgical instruments because it allows for rapid sterilization of the internal components. The following are suggested sterilization parameters for MicroAire's PAL-E and 1000E instruments, using the wrapped or unwrapped method:

a. Prevacuum Steam Sterilization:

4 minutes at 270°F (132°C), 8 minutes drying time.

b. Gravity displacement steam sterilization:

35 minutes at 270°F (132°C), 8 minutes drying time.

NOTE: DO NOT run instruments while warm. Cool by exposure to room temperature. **DO NOT** immerse in liquid to cool.

2. Flash sterilization

Please contact MicroAire for the most up-to-date information on this sterilization method.

3. Ethylene Oxide Sterilization.

Ethylene 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.

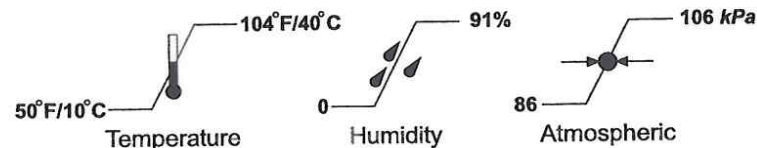
4. Peracetic Acid

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

- ENVIRONMENTAL PARAMETERS -

OPERATING CONDITIONS

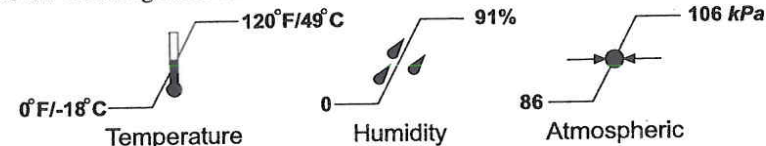
This device has been tested and proven to operate within the following conditions:



WARNING: If there is condensation present on the 1020 Console, **DO NOT** operate the console.

SHIPPING/STORAGE CONDITIONS

This device has been tested and proven to function after repeated exposure to the following 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.

- WARRANTY, SERVICE AND REPAIR -

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

- IN HOSPITAL SERVICE -

All MicroAire equipment should be inspected and tested periodically in accordance with the facility's bio-engineering policy. Such service should be documented within the bio-engineering department.

NOTE: The 1020 Standard Electric Console requires no preventative maintenance.

WARNING: Repairs or alterations to MicroAire products made by anyone other than MicroAire or an Authorized MicroAire Repair Facility will void that product's warranty, and the customer will be responsible for any costs related to returning the product to working condition

- MICROAIRE REPAIR SERVICE -

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

Telephone	Mail	Fax
(800) 538-5561	1641 Edlich Dr.	(434) 975-4126
(434) 975-8000	Charlottesville, VA 22911, USA	

E-Mail repairs@microaire.com

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

To return an item for service, follow this procedure:

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

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

2. Clean and disinfect equipment before sending for repair.

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

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

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

6. Return the merchandise prepaid.

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

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

- PERIODIC INSPECTION -

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

- MICROAIRE PRODUCT LIFESPAN -

The 1020 Standard Electric Console has no inherent wear-out mechanisms and should provide years of reliable service. This life-expectancy is based on the proper handling and care of the console. Any abuse, misuse, or use in other than recommended operating parameters may affect the life of the equipment.

- 1020 CONSOLE WARRANTY -

MicroAire Surgical Instruments LLC warrants its 1020 Standard Electric Console to be free from defects in material and workmanship in their manufacture for a period of 1 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 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 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.

- REFERENCES -

Association for the Advancement of Medical Instrumentation (AAMI)

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Occupational Safety and Health Administration. "Occupational exposure to blood-borne pathogens, final rule." Federal Register 56 (December 6, 1991): 64004-64182.