PAL®
BY MICROAIRE

In-Service Manual

Power-Assisted Liposuction System

PAL® by MicroAire

Power-Assisted Liposuction System In-Service Manual

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PAL® System Care and Maintenance

All personnel should become familiar with the equipment prior to use in a procedure. Such personnel may include:

- central processing
- members of surgical team
- bioengineering department

All MicroAire power equipment should be inspected and tested in accordance with the facility's bioengineering policy. The bioengineering department should document the service.

System Overview

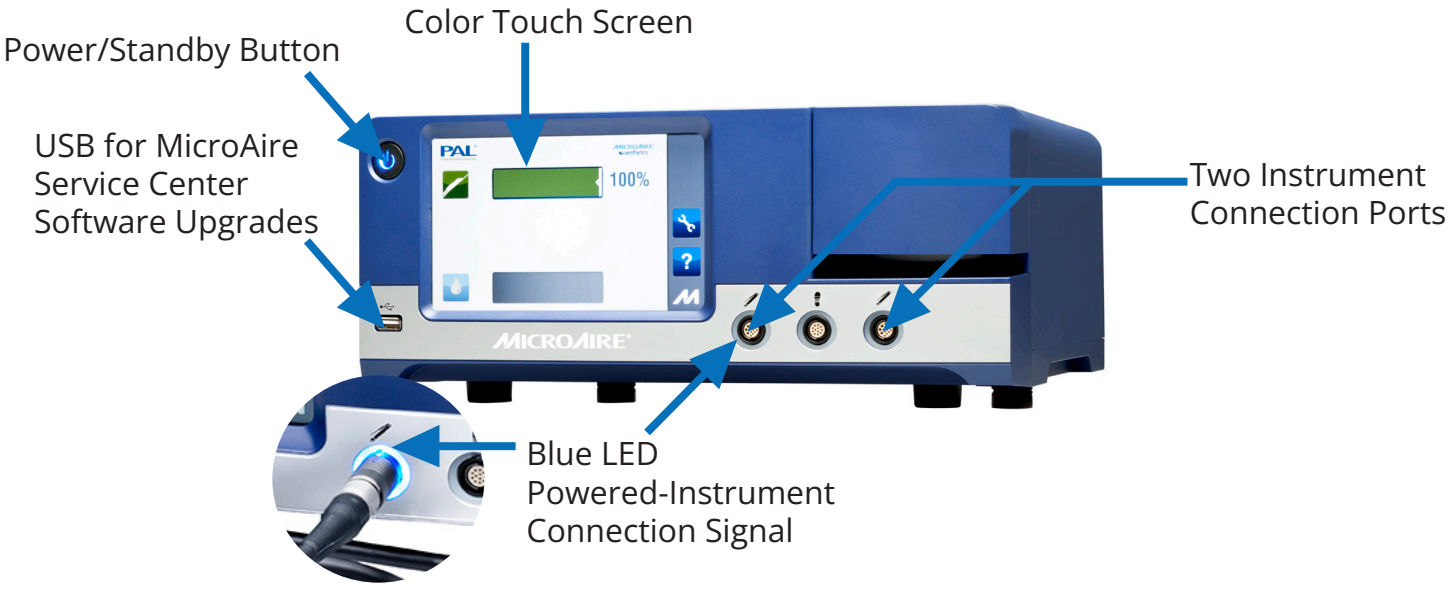
1. 5020 Electric Console
2. PAL-750 (or PAL-650) Electric Handpiece
3. 5006-PAL Cable

5020 Electric Console

Features:

- Operates single or dual instruments
- Pressure sensitive touch screen – this is not a smart device and needs pressure to activate
- Simple "plug and play" setup
- Intuitive Graphical User Interface

For more information, please reference Electric Instrument Control Console Instruction for Use (IFU) "IM-5020"



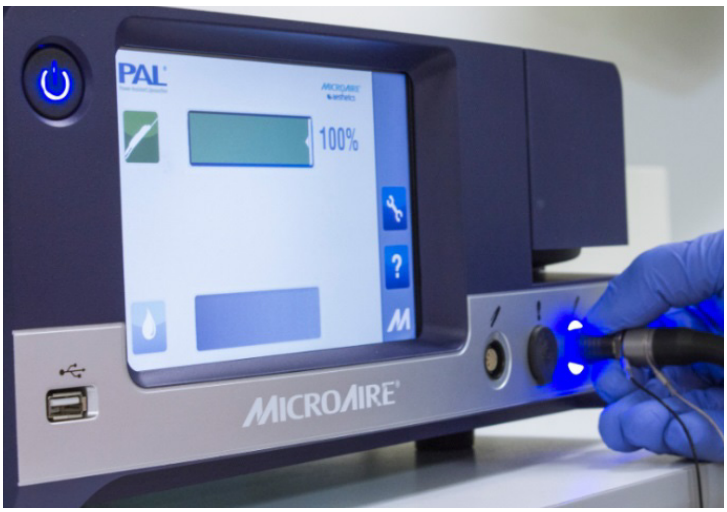
PAL-750 Electric Handpiece

Featuring adjustable reciprocation with a 3.2mm stroke and up to 4,000-5,000 cycles/minute.

For more information, please reference the PAL System IFU “IM-PAL-650”.

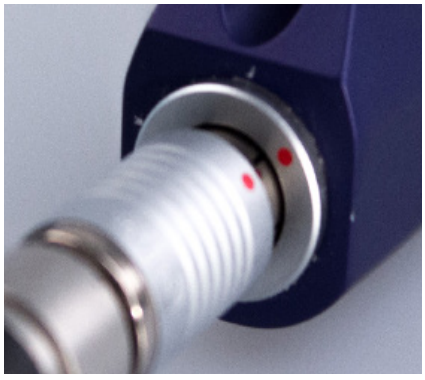
Installation/Set Up

Before initial set up of the PAL system, read and understand the provided Instructions for Use (IFU).



1. Inspect Handpiece, Console, Cable and Cannulas for corrosion, damage, excessive wear and residual moisture prior to each use.
2. Ensure the Console is placed on a stable, flat surface protected from fluid exposure and accidental damage.
3. Attach the electrical connection cable from the back of the Console to a wall outlet, and allow the Console to boot up.

Cable Insertion

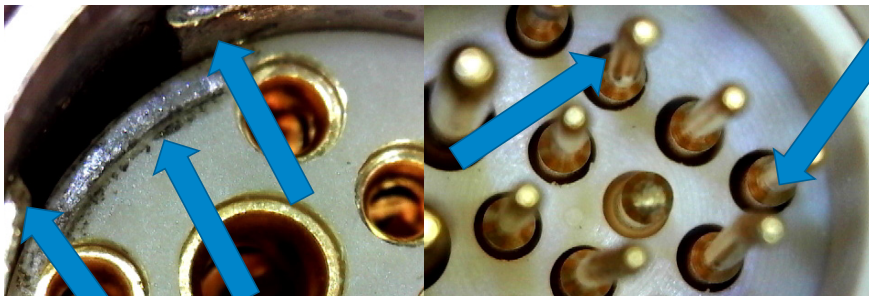


1. Align the indexing dots of the Cable with those on the Handpiece and Console before connecting.
2. Do not twist the cables into position; this will damage the connections and may prevent the Cable from attaching to the Handpiece or Console.

Damaged Cable Connectors

Damaged Pins or Contacts:

- Indicates misalignment and/or twisting of the Cable when inserted or removed from the PAL Handpiece or Console.
- Any indication of damaged, corroded or bent pins should prompt return of product for evaluation by MicroAire.



PAL® System Cleaning and Sterilization

PAL Cleaning and Sterilization Chart

1. Each PAL Handpiece comes with a laminated cleaning & sterilization chart.
2. Always ensure that the cleaning & sterilization instructions are **posted** and are **followed**.

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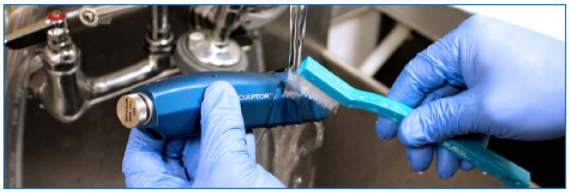
CLEANING AND STERILIZATION

CLEAN (CAP ON)

- Connect CAP-600E or Cable to keep liquid out.
- Scrub with warm water, a soft brush and pH neutral detergent, then rinse.*
- ***Do not immerse. Do not put nose of handpiece into water stream.***



STERILIZE (CAP OFF)

- Remove CAP-600E or Cable to allow steam to penetrate handpiece.
- Full dry cycle is required to prevent corrosion and to ensure proper performance.
- Cool slowly at room temperature. ***Never run while warm.***
- Inspect carefully to ensure all moisture is completely removed.**

Cycle Type	Dynamic-Air-Removal	Gravity-Displacement
Pulses	4	—
Set Point Temperature	132° C / 270° F	121° C / 250° F
Exposure Time	4 minutes	30 minutes
Dry Time	20 minutes	20 minutes

*More information can be found in the PAL-650 Instruction Manuals. Additional languages available at www.microaire.com.
**Residual moisture can result in error messages and functional issues.

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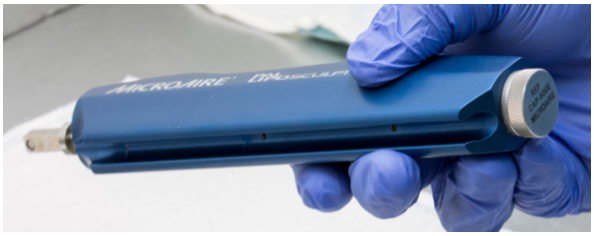
PAL System Cleaning

- Universal precautions for handling contaminated materials should be observed at all times.
- Do not immerse Cable or Handpiece.
- Use only cleaning solutions of a mild pH. Do not use cleaning solutions with chlorine or chloride as the active ingredient as these are corrosive to stainless steel.
- It is recommended that the devices shall be cleaned within 30 minutes of end-of-use to minimize the potential for organic material to dry on the devices.
- DO NOT lubricate or oil the PAL Handpiece. Lubrication may damage the internal motor mechanism. Also take special precautions to avoid the use of cleaners that contain lubricants.

For more information, please reference the PAL System IFU “IM-PAL-650”.

PAL Handpiece Cleaning

ALWAYS connect CAP-600E or PAL Cable to the PAL Handpiece prior to manual cleaning.
ONLY CAP-600E is sufficient to prevent water intrusion with an automated washing system.



PAL Cable Cleaning

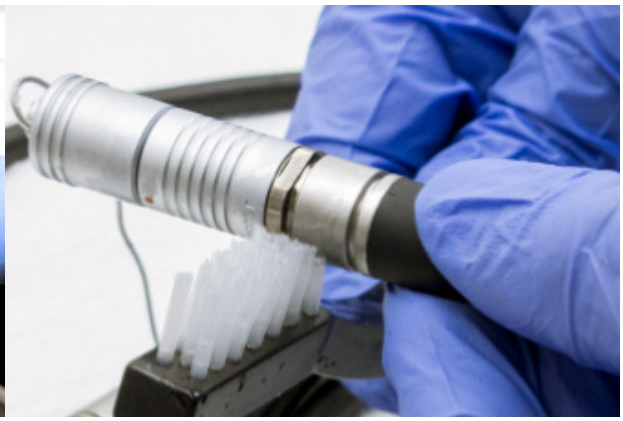
ALWAYS install washer caps on 5006-PAL Cable prior to cleaning to ensure electrical contacts are protected.

Cleaning

Refer to the PAL System Instructions for Use (IFU) for cleaning parameters, as any deviation from these parameters may result in inadequate cleaning of PAL Handpiece and Cable.

Manual Cleaning

1. Prepare neutral enzymatic solution (such as Steris® Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner), per manufacturer's instructions using warm utility water (≥ 49°C).
2. Inspect the proximal end of the Handpiece and the distal end of the Cable for the presence of any soil and contaminants. Wet a brush (such as Sklar® 10-1650) with warm utility water (≥ 49°C). Brush the proximal end of the Handpiece and the distal end of the Cable for 1 – 2 minutes to agitate and remove any soil or contaminants.
3. Wipe the Handpiece and Cable using a lint-free wipe wetted with warm utility water (≥49°C) for a minimum of 30 seconds, until no visible soil or contaminants remain. Pay particular attention to Handpiece and Cable connections. Replace soiled wipes as necessary.
4. Wet a brush (such as Sklar® 10-1650) with the prepared cleaning solution. Brush the Handpiece and Cable for 2 – 5 minutes, until no visible soil or contaminants remain. Pay particular attention to crevices. Toggle the Handpiece ON/STAND-BY switch multiple times to clean the crevices on both sides of the switch. Do not immerse the Cable or Handpiece.
5. Wipe the Handpiece and Cable using a lint-free wipe wetted with warm utility water (≥49°C) for a minimum of 30 seconds, until no visible soil or contaminants remain. Pay particular attention to crevices.
6. Dry the Handpiece and Cable with a clean, lint-free cloth.



Automated Cleaning

1. Prepare neutral enzymatic solution (such as Steris® Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner), per manufacturer's instructions using warm utility water (≥ 49°C).
2. Inspect the proximal end of the Handpiece and the distal end of the Cable for the presence of any soil and contaminants. Wet a brush (such as Sklar® 10-1650) with warm utility water (30°-40°C). Brush the proximal end of the Handpiece and the distal end of the Cable for 1 – 2 minutes to agitate and remove any soil or contaminants.
3. Wet a brush (such as Sklar® 10-1650) with the prepared cleaning solution. Brush the Handpiece and Cable for 1 – 2 minutes, until no visible soil or contaminants remain. Pay particular attention to crevices. Where applicable, toggle the Handpiece ON/STAND-BY switch multiple times to clean the crevices on both sides of the switch. Do not immerse Handpiece or Cable.
4. Load the device(s) into a washer-disinfector. Recommended Washer/Disinfector Cycle is in the PAL System IFU "IM-PAL-650".
5. Dry the Handpiece and Cable with a clean, lint-free cloth.

For more information, please reference the PAL System IFU "IM-PAL-650".

Preparing for Sterilization

- Prior to sterilization, caps **MUST BE REMOVED**. Remove the cap or Cable from the Handpiece AND the washer caps from the Cable.
- Caps or Cables connected to a device during sterilization will impede the drying process and result in residual moisture left inside of the Handpiece or Cable.
- All multi-use components of the device must be sterilized and all disposable components replaced before using the system on another patient.
- Sterilizers vary in design and performance parameters. Verify that the cycle parameters of the sterilizer meet the parameters outlined in the sterilization instructions in the PAL System IFU "IM-PAL-650".

Technique for Removal of Cap from Cable

The collar must be pulled back on the Cable to release the locking tabs prior to the release of cap.

- Only hold the metal parts of the Cable during cap removal.
- Pull in a straight line to remove the cap; do NOT twist or pull at an angle.

Packaging

Once cleaned and inspected, the Handpiece, Cable or Cannula can be wrapped individually in a standard FDA cleared medical grade steam sterilization wrap (such as Cardinal Health® Convertors® Bio-Shield® Sterilization Wraps - supplier part #4040). The wrap should be large enough to contain the device without stressing the packaging.

For more information, please reference the PAL System IFU "IM-PAL-650".

Steam Sterilization

- All sterilization cycles require a **MINIMUM DRY CYCLE** exposure time of **20 MINUTES**.
- This is a **minimum requirement** and should be increased accordingly until **ALL evidence of moisture has been removed** from the device and packaging.

ALWAYS RUN A COMPLETE DRY CYCLE

- Never shorten the dry cycle, this may result in service interruptions related to residual moisture and corrosion that may not be visible during examination.
- Always allow the PAL Handpiece and Cable to cool slowly at room temperature. Attempting use prior to cooling may result in lost functionality and/or damage the system.

Dynamic-Air-Removal Steam Sterilization:

Full cycle with 4-minute exposure time at a minimum temperature of 132°C (270°F), 20 minute minimum heated dry time for individually wrapped devices.

Cycle Type	Dynamic-Air-Removal
Pulses	4
Set Point Temperature	132° C / 270° F
Exposure Time	4 minutes
Dry Time	20 minutes

Gravity-Displacement Steam Sterilization:

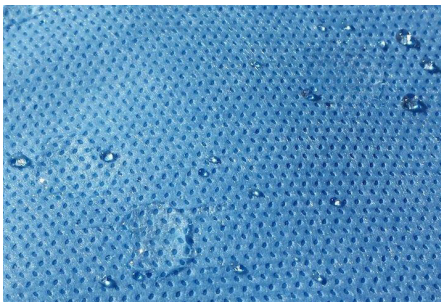
Full cycle with 30-minute exposure time at a minimum temperature of 121°C (250°F), 20 minute minimum heated dry time for individually wrapped devices.

Cycle Type	Gravity-Displacement
Set Point Temperature	121° C / 250° F
Exposure Time	30 minutes
Dry Time	20 minutes

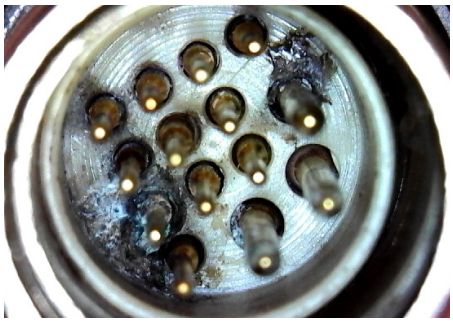
For more information, please reference the PAL System IFU “IM-PAL-650”.

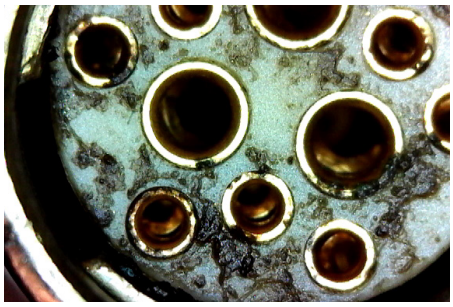
Results of Inadequate Cleaning and Sterilization

Inadequate Dry Cycle

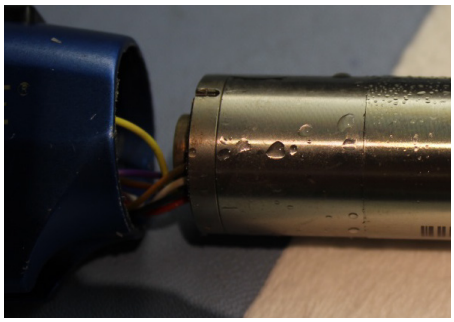


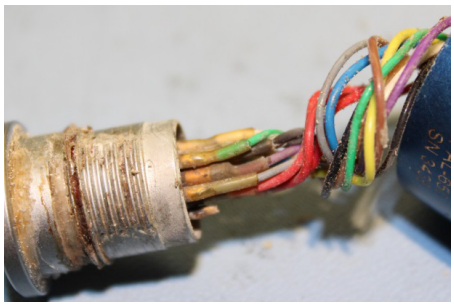
Damaged Contacts from Residual Moisture





The Internal Effects of Improper Cleaning/Drying





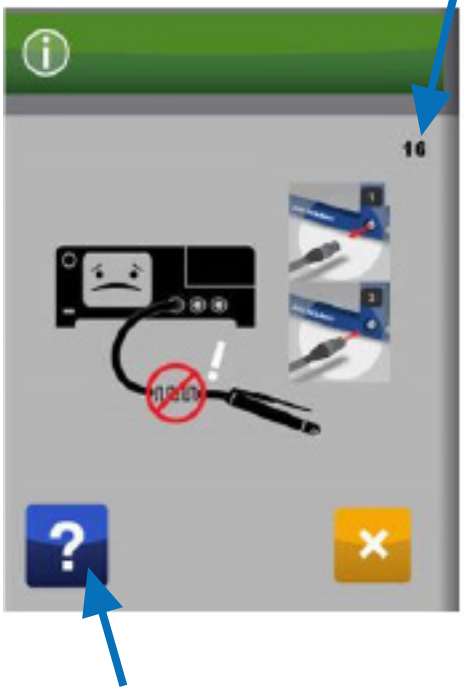
The Impact of Improper Cleaning/Drying

- Moisture induced issues are typically intermittent and can occur at any time the system is in use.
- Moisture and corrosion issues that result from inadequate cleaning/reprocessing are **NOT COVERED UNDER WARRANTY**, resulting in significantly higher repair charges.
- Moisture and corrosion issues **WILL REOCCUR** unless staff responsible for cleaning/reprocessing are informed.

Encountering Diagnostic Codes

Diagnostic Codes

The 5020 Console is equipped with diagnostic functions to address any errors or anomalies detected while using the PAL-750 or PAL-650 Electric Handpiece and 5006-PAL Cable.



Each diagnostic code is assigned a number.

- In this case, the error code number is **16**, and the description is "**Instrument Hall Failure Alert**".
- Many codes provide instructions on what is required to clear the codes; however, most indicate an issue with the system that must be addressed by swapping out that piece of equipment.

Instrument Hall Failure Alert – The Console has detected a failure in the operation of the motor's hall states. Unplug instrument and reconnect to the Console to reset. If Hall errors continue, return instrument and Cable to MicroAire for service.

Press the Icon to clear the Alert.

Press the Icon to exert Alert Help.

Provides explanation of code.

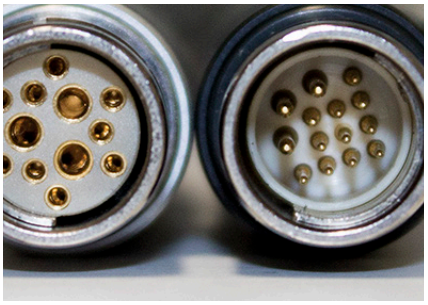
1. With the exception of Temperature, Communication, Stall, or Electromagnetic Interference codes, most of the remaining codes can be an indication of a bad connection.
2. To verify a proper connection, remove the Cable from the Handpiece and from the Console. Inspect the contacts on the Cable, Handpiece, and Console for the following conditions:
   - Moisture
   - Signs of Corrosion
   - Indications of Damaged or Bent Pins
3. Corrosion can impede the electrical signals of your PAL system and may or may not be corrected by detaching and reattaching the cable.
4. Any visible signs of corrosion or damaged/bent pins should prompt return of the product for evaluation by MicroAire.

For more information, please reference the PAL System IFU "IM-PAL-650" and Electronic Instrument Control Console IFU "IM-5020".

Contact Examples

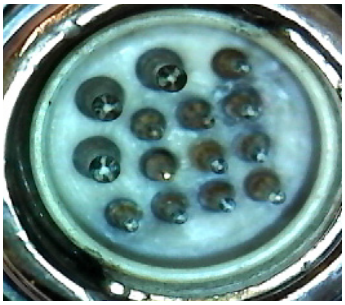
Good Contacts

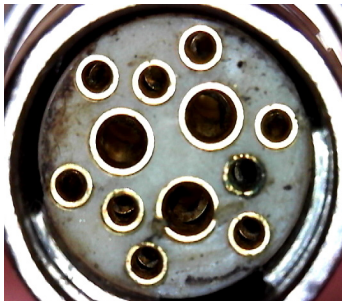
Contacts are clean, reflective, and gold.



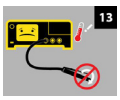
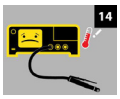
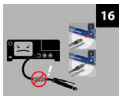
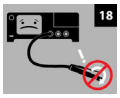
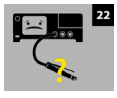
Corrosion in Contacts

Contacts are dirty, non-reflective, and green or black.





Alert Icons and Definitions

ICON	NAME	DEFINITIONS	CAUSES OF PROBLEM
	Error 12 Internal Error	Internal Console Malfunction. Contact MicroAire.	There is a problem internal to the REF 5020 Console. Return the Console for service.
	**Error 13 Internal Temperature Stop**	Temperature of motor drive circuit has exceeded safe levels. Instrument operation will be suspended until the Console circuits cool down.	Continued operation of instrument after receiving Error 14 Alert
	**Error 14 Internal Temperature Warning**	Temperature of motor drive circuit has exceeded normal levels. Instrument shutdown pending.	Operation of the Console at excessive ambient temperatures or duty cycles.
	**Error 16 Bad Hall Sensor**	Invalid Motor Sensor Signal. Instrument Motor Can Not Operate. Contact MicroAire.	The Console is detecting invalid sensor signals. The cause is most often in the instrument or instrument cable, but can also be a sign of a damaged Console. Return all involved instruments, cables and Consoles for service.
	**Error 18 Stall**	Instrument has stalled. Ensure Cutting accessory is not bound up and retry. If problem persists, contact MicroAire.	This can be a sign of overly aggressive technique that binds the cutting accessory. It can also be caused by a mechanically seized instrument, or an open motor connection in the instrument cable.
	Error 21 Irrigator Alert	Indicates a malfunction with the irrigator pump. Check that Irrigation tubing is installed correctly and retry. If problem persists, contact MicroAire.	This occurs when the Irrigation Pump is run with no tubing installed, or if the pump rotor becomes jammed up. Check installation of irrigation tubing and try again.
	**Error 22 Unrecognized Instrument**	Console does not recognize instrument. Check that connector pins are clean and undamaged and retry. If problem persists, contact MicroAire.	This can occur due to problems in either the instrument cable or the instrument itself that result in the instrument type not being recognized by the Console.

For more information, please reference the PAL System IFU “IM-PAL-650” and Electronic Instrument Control Console IFU “IM-5020”.

Duty Cycle, Preventative Maintenance and Repair Services

Duty Cycle

The PAL Electric Handpiece has a duty cycle of two hours on, two hours off. Prolonged usage above and beyond this duty cycle may result in the device feeling warm to the touch. This indicates that the device needs to cool down.

Preventative Maintenance and Warranty

- MicroAire recommends the PAL System (PAL-750/PAL-650 Handpiece, 5006-PAL Cable and 5020 Console) be returned to the factory for routine inspection and service **at least once a year**.
- There is no charge for service during the warranty period.
- 1 year preventative maintenance service is recommended for the PAL-750/PAL-650 Handpiece.
- More frequent PM service may be required depending upon the usage of your PAL Handpiece and Cable.
- Extended warranty coverage is also available for your PAL Handpiece and Console providing it is less than 5 years old. Call Customer Service to decide if extended warranty coverage is right for you.

For more information, please reference the PAL System IFU “IM-PAL-650” and Electric Instrument Console IFU “IM-5020”.

Required Information for Service Needs

1. MicroAire Customer Number.
2. A clear description of why you wish to return your product; preventative maintenance or repair.
3. The part number and serial number of your Console, Cable and PAL Handpiece that was in use at the time of the encountered issue and the diagnostic code.
4. Specific details of the encountered issue and attempts to resolve the matter.
5. The best point of contact regarding the reported issue to avoid delays and to ensure that your service needs are met.

If return of the equipment is required; after providing the required information you will be issued a Return Material Authorization (RMA) number. The RMA number will identify your service request and the repair status. Note the RMA number on the package or packing slip when returning your equipment for evaluation.

Part and Serial Number Location

Part and Serial Number Information on the Console

Part and Serial Number Information on the Cable

Customer Service Contact Information

For service contact our Customer Service Department at:

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

	USA	OUTSIDE USA
Telephone:	800-722-0822	+434-975-8000
Fax:	800-438-4309	+434-975-4134
Email:	inquiry@microaire.com	inquiry@microaire.com

MicroAire Customer Service

For any questions concerning the information in this manual, please contact MicroAire Customer Service:

	Telephone	FAX
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OUTSIDE USA:	+434-975-8000	+434-975-4134

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