REF 7800 Battery Sternum Saw

Instructions for Use

MICROAIRE®

For Surgery. For Life.™

Model REF 7800 Battery Sternum Saw
REF 7800-002 Sternum Guard & Accessories
Instruction Manual

APPLICABLE PARTS
REF 7800

INTENDED USE
Multi-purpose, modular, powered instrument system intended for use in general, orthopedic, plastic and trauma surgery.

INTRODUCTION
This manual has been written to help describe the procedures required to keep the MicroAire REF 7800 Battery Sternum Saw 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.

NOTE: Used to point out the easiest means of carrying out techniques.

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

CAUTION: Used to point out special procedures or precautions that must be followed to avoid damaging the system/instruments.

GENERAL WARNINGS

WARNING: The REF 7800 Battery Sternum Saw must never be used without the REF 7800-002 sternum guard securely in place and properly oriented with the MicroAire REF ZR-032M or ZR-033M sternum saw blade.

WARNING: Replace battery pack only with a MicroAire REF 6640-710, REF 7505-710, or REF 7500-620 battery.

WARNING: Explosion Hazard. Not suitable for use in the presence of flammable anesthetics or oxygen.

WARNING: Electric Shock. Do not remove cover, return to factory for servicing.

WARNING: Medical electrical equipment may be affected by electromagnetic interference. It should be installed and used in accordance with the electromagnetic compatibility information provided herein.

WARNING: Portable and mobile RF communications equipment can affect medical electrical equipment.

WARNING: Prior to use, system components should be inspected and operated to detect any damage or malfunction. Do not use if damage is apparent.

WARNING: Always point the handpiece away from the patient and surgical team when testing.

WARNING: If the handpiece will not securely hold the saw blade or sternum guard, discontinue use and return the instrument to the factory for service.

WARNING: Check Safety Lock and Trigger before operating the handpiece. If the trigger should stick in the depressed "ON" position, do not use the handpiece. Immediately remove the battery. Return the instrument to the factory for service. Always use the Safety Lock when the instrument is not running.

WARNING: Check that the battery is fully seated and locked.

WARNING: Disconnect battery in the event of continuous running.

WARNING: No modification of this equipment is allowed.

WARNING: Operating Duty Cycle is 1 minute on, 2 hours off.

WARNING: Irrigation must be applied to the cutting accessory when cutting bone in order to keep bone temperature within safe limits. Cutting without irrigation may cause unsafe temperatures leading to bone necrosis.

WARNING: Use of the REF 7800 Sternum Saw adjacent to or stacked with other equipment should be avoided be cause it could result in improper operation. If such use is necessary, the REF 7800 Sternum Saw and the adjacent equipment should be observed to verify that they are operating normally.

WARNING: Portable RF communications equipment should be used no closer than 30 cm (12 inches) away from any part of the REF 7800 Sternum Saw. Otherwise degradation of the performance of the REF 7800 could result.

WARNING: Use of Battery Packs other than those specified in the List of Compatible Accessories could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: REF 7800 Sternum Saw has been tested for use in the vicinity of High Frequency Electrosurgical / Electro coagulation equipment. Use of such equipment in close proximity to the REF 7800 Sternum Saw may cause unintended interruptions or unintended motion of durations up to 1 second. Place the Instrument on a safe surface when not in use. Do not place powered Instruments on the patient when not in use. Avoid entwining HF surgical cables with powered instruments.

WARNING: The following items should be periodically inspected for signs of damage and repaired or replaced as needed to ensure continued safety with regard to electromagnetic disturbances over the life of the system:

- Check that the Battery Connection base, the rear end cap and the front of the instrument remain securely connected to the main instrument body.
- Check for damage to the battery pack housings.

CAUTION: Do not run the handpiece without the saw blade.

CAUTION: Disconnect battery from handpiece before loading or unloading the saw blade.

CAUTION: Leaving a battery pack attached to a handpiece when not in use may accelerate battery drain.

CAUTION: Make sure the tip of the sternum saw blade is inside the foot of the sternum guard and does not strike any part of the sternum guard. Improper alignment of the sternum guard with the saw blade can cause damage to the sternum saw or saw blade.

CAUTION: If the handpiece will not hold the saw blade or sternum guard securely, discontinue use and return to the factory for service.

CAUTION: Check Safety Lock and Trigger before operating the handpiece. If the trigger should stick in the depressed "ON" position, do not use the handpiece. Immediately remove the battery. Return the instrument to the factory for service. Always use the Safety Lock when the instrument is not running.

CAUTION: Check that the battery is fully seated and locked.

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

CAUTION: Disconnect sternum guard, battery, and saw blade prior to sterilization. Batteries must be sterilized separate from the handpiece and sternum guard.

CAUTION: DO NOT run instruments while warm. Cool by exposure to room temperature.

CAUTION: DO NOT immerse in liquid to cool.

CAUTION: 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

NOTE: Disconnect sternum guard, battery, and saw blade prior to sterilization. Batteries must be sterilized separately.

NOTE: The REF 7800 Sternum Saw is suitable for use in hospitals and surgery centers. These systems should not be used near Magnetic Resonance Imaging equipment.

NOTE: The emissions characteristics of this product make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). If it is used in a residential environment (for which CISPR 11 Class B is normally required) this equipment might not offer adequate protection to radio frequency communication services. The user might be required to take mitigation measures, such as relocating or re-orienting the equipment.

NOTE: Mailing address is located on back cover.

MARKINGS

Name	Ref# (ISO 7000)[2]	Symbol	Description	Use Standard
Refer to Instruction Manual / Booklet	ISO-7010 M002		• Indicates a MANDATORY action for the user to consult the Instructions For Use (IFU). • Symbol must be blue, as shown.	IEC 60601-1:2005[1]
Consult Instructions For Use (IFU)	1641		Indicates the need for the user to consult the Instructions For Use (IFU). Not required in conjunction with the Caution symbol, if applicable.	ISO 15223-1:2012[1]
Caution	0434A / 0434B		Indicates the need for the user to consult the Instructions For Use (IFU) for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the device itself.	ISO 15223-1:2012[1]
UL symbol	N/A		MEDICAL-GENERAL MEDICAL EQUIPMENT AS TO ELECTRIC SHOCK, FIRE, AND MECHANICAL HAZARDS ONLY. IN ACCORDANCE WITH ANSI/AAMI ES 60601-1 (2005) + A1 (2012) + CAN/CSA C22.2 No. 60601-1 (2014) | Control Number: E494242	UL
Type B Applied Part	5840		Indicates a medical device complying with the specified requirements of IEC 60601-1 to provide protection against electric shock, particularly regarding allowable patient leakage current and patient auxiliary current.	IEC 60601-1:2005[1]
Locked	5569		To identify on a control that a function is locked or to show the locked status.	IEC 60878:2015[1]
Unlocked	5570		To identify on a control that a function is not locked or to show the unlocked status.	IEC 60878:2015[1]
Do Not Expose to Stray Magnetic Fields	N/A		Indicates a medical device that is not to be exposed to stray magnetic fields.	N/A
Authorized Representative in the European Community	N/A		Indicates the authorized representative in the European Community. This symbol shall be accompanied by the name and address of the authorized representative, adjacent to the symbol.	ISO 15223-1:2012[1]
Serial #	2498		• Indicates the manufacturer's serial number so that a specific medical device can be identified. • Per EN980:2008, the SN symbol may be used without surrounding box.	ISO 15223-1:2012[1]
Lot / Batch Code	2492		Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1:2012[1]
REF (Catalog #)	2493		• Indicates the manufacturer's catalog number so that the medical device can be identified. • Per EN980:2008, the REF symbol may be used without surrounding box.	ISO 15223-1:2012[1]
Sterile	2499		Indicates a medical device that has been subjected to a sterilization process. Use of the Sterile symbol requires a use-by date (see Use-By Date symbol).	ISO 15223-1:2012[1]
Sterilized using Irradiation (gamma)	2502		Indicates a medical device that has been sterilized using irradiation (gamma). Use of the Sterile symbol requires a use-by date (see Use-By Date symbol).	ISO 15223-1:2012[1]
Non-Sterile	2609		• Indicates a medical device that has not been subjected to a sterilization process. This symbol should only be used to distinguish between identical or similar medical devices sold in both sterile and non-sterile conditions. • Also indicates a medical device that is provided non-sterile but must be sterilized prior to use.	ISO 15223-1:2012[1]
Temperature Limitation	0632		Indicates the temperature limits to whichthe medical device can be safely exposed. The upper and lower limits to temperature shall be indicated adjacent to the upper and lower horizontal lines.	ISO 15223-1:2012[1]

Use-By Date	2607		Indicates the date after which the medical device is not to be used. This symbol shall be accompanied by a date to indicate that the medical device should not be used after the end of the month shown. The date is expressed as YYYY-MM (e.g. 2015-11) or YYYY-MM-DD (e.g. 2015-11-29).	ISO 15223-1:2012[1]
Do Not Reuse	1501		Indicates a medical device that is not to be resterilized.	ISO 15223-1:2012[1]
Do Not Use if Package is Damaged	2606		Indicates a medical device that should not be used if the package has been damaged or opened. This symbol may also mean "Do not use if the product sterile barrier system or its packaging is compromised".	ISO 15223-1:2012[1]
Sternum Saw Guard Alignment Arrow	N/A		Indicates alignment of Sternum Saw Guard.	N/A
Humidity Limitation	2620		Indicates the range of humidity to which the medical device can be safely exposed. The humidity limitations shall be indicated adjacent to the upper and lower horizontal lines.	ISO 15223-1:2012[1]
Atmospheric Pressure Limitation	2621		Indicates the range of atmospheric pressure to which the medical device can be safely exposed. The atmospheric pressure limitations shall be indicated adjacent to the upper and lower horizontal lines.	ISO 15223-1:2012[1]
Do Not Immerse in any Liquid	5995		Indicates a medical device that is not to be immersed in any liquid.	IEC 60335-2-15
Do Not Lubricate	N/A		Indicates a medical device that is not to be lubricated.	N/A
Date of Manufacture	2497		• Indicates the date when the medical device was manufactured. The date is expressed as YYYY-MM (e.g. 2015-11) or YYYY-MM-DD (e.g. 2015-11-29). • If the symbol is filled (see Manufacturer symbol), both the date of manufacture and the name/address of the manufacturer may be combined in one symbol.	ISO 15223-1:2012[1]
Manufacturer	3082		• Indicates the medical device manufacturer. This symbol shall be accompanied by the name and address of the manufacturer. The date of manufacture may be combined with this symbol. • When using MicroAire as the manufacturer, use the MicroAire LLC symbol.	ISO 15223-1:2012[1]
CE Mark with NB	N/A	CE 2797	Indicates the European Conformity Mark with Notified Body Number. 2797 is the BSI-NL-registered Notified Body.	Council Directive 93/42/EEC
Prescription	N/A		Caution: Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).	FDA Title 21, Chapter 1, Subchapter H, Part 801.15(F)
Dispose of per WEEE Directive 2012/19/EU	N/A		Indicates a medical device that is not to be disposed of as unsorted municipal waste. Medical device is to be disposed of per WEEE Directive 2012/19/EU.	Council Directive 2012/19/EU
Dispose of per WEEE Directive 2012/19/EU	N/A		Indicates a medical device that is not to be disposed of as unsorted municipal waste. Medical device is to be disposed of per WEEE Directive 2012/19/EU. This symbol is used in place of the above symbol if the product entered the market after 13 August, 2005.	Council Directive 2012/19/EU (Symbol: European Standard EN 50419)
Packaging is Recyclable	1135		Indicates that the marked item or its material is part of a recovery or recycling process.	IEC 60878:2015

[1] ISO 15223-1:2012 – "Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements"
[2] ISO 7000/IEC 60417 – "Graphical symbols for use on equipment – Registered symbols"

LIST OF COMPATIBLE ACCESSORIES

Part Number	Description	IFU	Type B Applied Parts
REF ZR-032M	Sternum Saw Blade	IM-7800	Yes
REF 7800-002	Sternum Saw Guard	IM-7800	Yes
REF 6640-710	NiMH Battery Pack	IM-PWRBATT	No
REF 7505-710	Large NiMH Battery Pack	IM-PWRBATT	No
REF ZR-033M	Aggressive Saw Blade	IM-7800	Yes
REF 7500-700	NiMH Battery Charger	IM-7500-700	No
REF 7500-615	Aseptic Battery Housing	IM-ASEPBATT	No
REF 7500-620	Aseptic NiMH Battery Pack	IM-ASEPBATT	No
REF 7500-625	Charging Adapter	IM-ASEPBATT	No
REF 7500-630	Aseptic Transfer Shield	IM-ASEPBATT	No

WARNING: Use of Battery Packs other than those specified in the List of Compatible Accessories could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

ENVIRONMENTAL PARAMETERS (REF 7800, REF 7800-002)

OPERATING CONDITIONS

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

Temperature Humidity Atmospheric

SHIPPING & STORAGE CONDITIONS

This device has been tested and proven to operate after repeated exposure to the following conditions:

Temperature Humidity Atmospheric

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.

TECHNICAL DATA - SPECIFICATIONS

Operating Speed:	12,000 CPM (nominal)
Cutting Stroke:	0.117 in. (3.0 mm)
REF 7800 Handpiece Weight (without battery pack) :	2.65 lb. (1211 g)
REF 6640-710 Battery Weight:	0.95 lb. (431 g)
Battery Voltage:	14.4 volts
Duty Cycle:	1 minute on, 2 hours off.
Rating:	14.4 VDC 225W

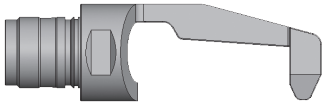
HANDPIECE SAFETY MECHANISMS

Trigger in Upright - "ON" Position

Trigger in "OFF" Position
(Trigger can be turned in either direction to be turned "OFF")

REF 7800-002 STERNUM GUARD

The REF 7800 Battery Sternum Saw requires the use of the included REF 7800-002. The guard can be attached to the handpiece in either a superior or inferior position, depending on the position at which the blade was loaded.



INSTRUMENT COMPONENTS

Features & Descriptions

1. **Blade Locking Collet**
   Insert the REF ZR-032M or ZR-033M Sternum Saw Blade into the blade locking collet by turning the collet in the direction indicated by the arrow, and then inserting the blade.
2. **Sternum Guard Lock / Release Button**
   Depress this button to lock or release the REF 7800-002 Sternum Guard from the handpiece.
3. **Trigger / Safety Lock**
   The REF 7800 Battery Sternum Saw operates at variable speeds and is controlled by depressing the trigger. The instrument is in the OFF position when the trigger is not depressed. As the trigger is depressed the speed increases from 0% - 100%. The trigger also serves as the safety lock for the handpiece (see previous page). After loading the saw blade and attaching the sternum guard and battery, fully depress the trigger and release one time before use.
4. **Battery Release Button**
   Depress this button to remove a battery/power pack from the handpiece. This button does not need to be depressed to load a battery/power pack.

ACCESSORY ATTACHMENT

Battery Attachment

The REF 7800 Battery Sternum Saw must have a fully charged MicroAire REF 6640-710 battery installed before each use. The MicroAire REF 7505-710 and REF 7500-620 batteries may also be used with the REF 7800 Battery Sternum Saw. To attach the battery to the handpiece, place the battery under the base of the instrument with the longer side facing the rear of the instrument. Firmly push the battery into the base of the handpiece until the battery latch clicks into place.

Sternum Guard Attachment

WARNING: DO NOT USE The REF 7800 Battery Sternum Saw without the REF 7800-002 sternum guard securely in place and properly oriented with the MicroAire REF ZR-032M or ZR-033M sternum saw blade.

INSTRUMENT SETUP

CAUTION: Disconnect battery from handpiece before loading or unloading the saw blade.

CAUTION: Battery pack should not be left attached to the handpiece when not in use. This could result in accelerated battery drain.

To insert the REF **ZR-032M or ZR-033M saw blade into the sternum saw handpiece:**

1. Make sure the handpiece trigger is set to the "OFF" position and the safety is "ON" by turning the trigger to one side.
2. If installed, remove the sternum guard from the handpiece by depressing the release button located on the underside of the sternum guard collet.
3. Twist the blade locking collet into the open position by rotating in the direction of the arrows.
4. While holding the blade locking collet in the open position, insert a MicroAire REF ZR-032M or REF ZR-033M saw blade until it is fully seated. The blade may be inserted in the inferior or superior position.
5. Release the blade locking collet; it should automatically spring back into the lock position.

To install the REF **7800-002 Sternum Guard on the sternum saw:**

1. Make sure the handpiece trigger is set to the "OFF" position and the safety is "ON" by turning the trigger to one side.
2. Make sure that the MicroAire REF ZR-032M or REF ZR-033M sternum saw blade is securely installed.
3. Push the sternum guard into the blade/guard collet, over the installed saw blade. The sternum guard may be inserted more easily by depressing the sternum guard lock button as the sternum guard is installed on the handpiece. Make sure that the sternum guard is aligned with the saw blade teeth facing away from the sternum guard. The sternum guard must be completely locked into place prior to use. Use the alignment arrows to make sure the sternum guard is properly aligned with the handpiece.

CAUTION: Make sure the tip of the sternum saw blade is inside the foot of the sternum guard and does not strike any part of the sternum guard. Improper alignment of the sternum guard with the saw blade can cause damage to the sternum saw or saw blade.

Test run the assembled handpiece for a few seconds to make sure that the blade and sternum guard are properly aligned and secure.

1. Move the safety lock to the "OFF" position by turning the trigger back into the vertical position.
2. Run the handpiece by fully depressing the trigger.

WARNING: Always point the handpiece away from the patient and surgical team when testing.

WARNING: If the handpiece will not securely hold the saw blade or sternum guard, discontinue use and return the instrument to the factory for service.

WARNING: Check Safety Lock and Trigger before operating the handpiece. If the trigger should stick in the depressed "ON" position, do not use the handpiece. Immediately remove the battery. Return the instrument to the factory for service. Always use the Safety Lock when the instrument is not running.

WARNING: Check that the battery is fully seated and locked.

WARNING: Disconnect battery in the event of continuous running.

TROUBLESHOOTING

1. Blade will not load into collet:
   a. Make sure that the blade is the MicroAire REF ZR-032M or REF ZR-033M.
   b. Mare sure the blade locking collet is fully turned in the direction indicated by the arrow on the collet.
   c. Attempt to load a different REF ZR-032M or REF ZR-033M blade into the collet. If the second blade cannot be loaded into the collet, return the handpiece for service.

2. Sternum Guard will not lock into handpiece:
   a. Make sure that the sternum guard is the MicroAire REF 7800-002.
   b. Make sure the arrows on the handpiece and guard are aligned properly, and the Guard Lock/Release Button is depressed when attempting to insert the sternum guard.
   c. Attempt to load a different REF 7800-002 sternum guard into the collet. If the second guard cannot be loaded into the collet, return the handpiece for service.

3. Trigger cannot be depressed:
   a. Make sure the trigger is turned to the upright "ON" position (refer to page 6).
   b. Make sure the instrument was properly cleaned and sterilized.
   c. If trigger cannot be depressed, return to factory for service.
   d. DO NOT OIL the handpiece or trigger, as this could damage the instrument.

4. Handpiece does not run when trigger is depressed:
   a. Make sure you have a fully charged MicroAire Battery Pack properly seated in the handpiece base.
   b. Try a different, fully charged battery pack in the handpiece. If the handpiece still does not operate when the trigger is depressed, return the handpiece for service.

5. Battery does not seat properly in handpiece:
   a. Make sure you are using an approved MicroAire battery/power pack (part numbers listed on page 5).
   b. Make sure the longer side of the battery pack is facing the rear of the instrument as shown on page 6.
   c. Attempt to insert another battery pack. If second battery pack will seat properly, return the first battery for inspection. If the second battery pack does not seat properly, return the handpiece and batteries for service.
   d. Make sure the connector pins in the handpiece battery receptacle are not bent. If the pins are bent, return the handpiece for service. **DO NOT** attempt to bend the pins back into place.

6. Handpiece runs slowly:
   a. Make sure you have a fully charged MicroAire Battery Pack properly seated in the handpiece base.
   b. Try a different, fully charged battery pack in the handpiece. If the handpiece still runs slowly when the trigger is depressed, return the handpiece for service.

ROUTINE CLEANING/DECONTAMINATION

7800 INSTRUMENT CLEANING INSTRUCTIONS

1. Remove the battery, sternum guard, and sternum saw blade from the handpiece.
2. Scrub the handpiece, sternum guard, and batteries using warm water, a soft brush, and mild detergent. Scrub the handpiece with the brush, paying close attention to the instrument crevices. Take care to keep the instrument as upright as possible to restrict water from flowing into the battery cavity and contacts of the battery.
3. Rinse all items thoroughly under running water, again paying close attention to the battery cavity by keeping the instrument as upright as possible. Dry the instrument and accessories with a lint-free towel.

INSTRUMENT STERILIZATION INSTRUCTIONS

[see separate Battery Sterilization Instructions in IM-PWRBATT]

MicroAire surgical instruments are normally sterilized using steam autoclaves by either gravity discharge, or pre-vacuum sterilization. The following sterilization processes have been validated based on AAMI Protocols. The exposure times and temperatures are the minimum validated requirements to ensure sterility.

CAUTION: Disconnect sternum guard, battery, and saw blade prior to sterilization. Batteries must be sterilized separate from the handpiece and sternum guard.

HANDPIECE AND STERNUM GUARD – WRAPPED OR UNWRAPPED

1. Steam Sterilization

Steam sterilize using one of the following cycles:

Sterilization Cycle	Instrument	Minimum Time & Temp	Min Heated Dry time
Dynamic Air Removal (Pre-vacuum)	Single Instrument	3 minute full cycle @ 134 – 137°C (273 – 279°F)	8 minutes
		4 minute full cycle @ 132 – 135°C (270 – 275°F)	8 minutes
	Sterilization Tray	3 minute full cycle @ 134 – 137°C (273 – 279°F)	10 minutes
		4 minute full cycle @ 132 – 135°C (270 – 275°F)	10 minutes
Gravity Displacement	Single Instrument	30 minute full cycle @ 132 – 135°C (270 – 275°F)	8 minutes
	Sterilization Tray	45 minute full cycle @ 132 – 135°C (270 – 275°F)	20 minutes

CAUTION: DO NOT run instruments while warm. Cool by exposure to room temperature.

CAUTION: DO NOT immerse in liquid to cool.

2.Flash sterilization

Flash sterilization is not recommended for powered surgical instruments. The REF 7800 Sternum Saw has not been validated for flash sterilization.

3.Ethylene Oxide Sterilization.

Ethylene oxide 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.

Disposal

Follow federal, state and local ordinances governing the proper disposal of medical equipment.

WARRANTY, SERVICE AND REPAIR

Periodic inspection and service is essential to keep MicroAire instruments running properly.

IN HOSPITAL SERVICE

All MicroAire equipment should be inspected and tested periodically in accordance with the facility's bioengineering policy.

CAUTION: 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

If a problem with your equipment should arise, contact MicroAire Customer Service Department:

	Telephone:	**Fax:**	**Email:**
USA:	800-722-0822	800-438-6309	inquiry@microaire.com
Outside USA:	434-975-8000	434-975-4134	intlsvc@microaire.com

NOTE: Mailing address is located on back cover.

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.

7800 BATTERY STERNUM SAW & ACCESSORY WARRANTY

MicroAire Surgical Instruments, LLC warrants its REF 7800 Battery Sternum Saw and the REF 7800-002 Sternum Guard to be free from defects in material and workmanship 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 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.

BATTERY INSTRUCTIONS

Battery Charging
See separate operating instructions provided with the MicroAire UL Classified Battery Charger (REF 7500-700).

Battery Installation
The REF 7800 Battery Sternum Saw handpiece must have a fully charged MicroAire battery pack (REF 6640-710, REF 7505-710 or Aseptic Battery) installed before use. To attach the battery to the handpiece, place the battery under the base of the instrument with the longer side facing the rear of the instrument. Firmly push the battery into the base of the handpiece until the battery latch clicks into place.

Aseptic Battery
The REF 7800 Battery Sternum Saw is designed to operate using the MicroAire Aseptic Battery. The Aseptic Battery uses a non-sterile battery pack REF 7500-620 that is placed in a sterilized System housing REF 7500-615 with locking door, and removes the need to steam sterilize battery packs. See separate instructions provided with the REF 7500-6XX Aseptic Battery System.

CAUTION: Leaving a battery pack attached to a handpiece when not in use may accelerate battery drain.

MICROAIRE BATTERY WARRANTY

MicroAire Surgical Instruments warrants the REF 7505-710 Large Battery Pack and REF 6640-710 Small Battery Pack to be free from defects in material and workmanship for a period of one (1) year from the original purchase date by the end customer. MicroAire warrants the REF 7500-620 Aesptic Battery to be free from defects and workmanship in their manufacture for a period of ninety (90) days 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 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 warranties and/or service agreements are not available on MicroAire batteries.

Part Number		7505 Drill Reamer Battery\Electric	7506 Oscillating Saw Battery\Electric	7507 Reciprocating Saw Battery\Electric
Power Output	kW-KiloWatts	0.0135	0.13	0.13
Vibration Exposure	$a_{hv}(m/s^2)$	4.1	4.1	4.1
	Uncertainty K (m/s^2)	1.5	1.5	1.5
Noise Emission Value	L_{PA} (db(A))	84	84	84
	$L_{C,peak}$ (db(C))	-	-	-
	L_{WA} (dbA))	100	100	100
Mass	Weight (kg)	1.04	1.19	1.16

ELECTROMAGNETIC COMPATIBILITY

NOTE: The 7800 Sternum Saw is suitable for use in hospitals and surgery centers. These systems should not be used near Magnetic Resonance Imaging equipment.

EMC Test & Standard	Test Levels / Limits	Compliance
Mains terminal disturbance voltage (conducted emissions): CISPR 11	Not Applicable for Battery Powered Equipment	Not Applicable
Electromagnetic radiation disturbance (radiated emissions): CISPR 11	CISPR 11 Class A	Complies with Class A Limits
Harmonic distortion: IEC 61000-3-2	Not Applicable for Battery Powered Equipment	Not Applicable
Voltage fluctuations and flicker: IEC 61000-3-3	Not Applicable for Battery Powered Equipment	Not Applicable
Electrostatic discharge immunity: IEC 61000-4-2	Discharge Level (kV) Contact – Direct: + /- 8 Contact – Indirect: +/- 8 Air +/- 2, 4, 8, 15	 Complies Per Note* Complies Per Note* Complies Per Note*
Radiated RF electromagnetic field immunity: IEC 61000-4-3	3V/m 80MHz to 2700 MHz 80% AM at 1 KHz	Complies Per Note*
Immunity to proximity fields from RF wireless communications equipment: IEC 61000-4-3	IEC 60601-1-2 Table 9	Complies Per Note*
Immunity to High Frequency Surgical Equipment: IEC 60601-2-2	Tested for immunity to modern (non-spark gap) HF Surgical Equipment per the guidelines of IEC60601-2-2:2017 Annex BB. Cut Mode at 150 Watts: Coagulate Mode at 70 Watts: The HF Surgical generator was in operation as part of the EM environment for all other immunity tests.	 Complies Per Note* Complies Per Note* See Other Immunity Tests
Electrical fast transient/burst immunity – IEC 61000-4-4 AC mains: I/O SIP/SOP Ports:	Not Applicable for Battery Powered Equipment Series 7000 Instruments have no I/O SIP/SOP Ports	Not Applicable Not Applicable
Surge Immunity: IEC 61000-4-5 Input Power Ports (Line to Line) (Line to Earth)	Not Applicable for Battery Powered Equipment	Not Applicable

ELECTROMAGNETIC COMPATIBILITY

EMC Test & Standard	Test Levels / Limits	Compliance
Immunity to conducted disturbances induced by RF fields (conducted RF disturbance immunity) – AC mains: IEC 61000-4-6 Patient Connected Ports: IEC 61000-4-6	Not Applicable for Battery Powered Equipment	Not Applicable
Power Frequency Magnetic Field Immunity: IEC 61000-4-8	Frequency: 50 Hz or 60 Hz Test Level: 30 A/m	Complies Per Note*
Voltage Dips: IEC 61000-4-11	Not Applicable for Battery Powered Equipment	Not Applicable
Voltage Interruptions Immunity: IEC 61000-4-11	Not Applicable for Battery Powered Equipment	Not Applicable

NOTE *: The 7800 Sternum Saw has no Essential Performance. Compliance with Immunity Testing is defined as a) the instrument will remain functional after the test, and b) the instrument in a standby mode will not run for more than 1 second as a result of the test.

WARNING: Use of the 7800 Sternum Saw adjacent to or stacked with other equipment should be avoided be cause it could result in improper operation. If such use is necessary, the 7800 Sternum Saw and the adjacent equipment should be observed to verify that they are operating normally.

WARNING: Portable RF communications equipment should be used no closer than 30 cm (12 inches) away from any part of the 7800 Sternum Saw. Otherwise degradation of the performance of the 7800 could result.

WARNING: Use of Battery Packs other than those specified in the List of Compatible Accessories could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: 7800 Sternum Saw has been tested for use in the vicinity of High Frequency Electrosurgical / Electro coagulation equipment. Use of such equipment in close proximity to the 7800 Sternum Saw may cause unintended interruptions or unintended motion of durations up to 1 second. Place the Instrument on a safe surface when not in use. Do not place powered Instruments on the patient when not in use. Avoid entwining HF surgical cables with powered instruments.

WARNING: The following items should be periodically inspected for signs of damage and repaired or replaced as needed to ensure continued safety with regard to electromagnetic disturbances over the life of the system:

- Check that the Battery Connection base, the rear end cap and the front of the instrument remain securely connected to the main instrument body.
- Check for damage to the battery pack housings.

NOTE: The emissions characteristics of this product make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). If it is used in a residential environment (for which CISPR 11 Class B is normally required) this equipment might not offer adequate protection to radio frequency communication services. The user might be required to take mitigation measures, such as relocating or re-orienting the equipment.

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EC REP

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