HALL® MicroFree™ Battery Handpiece Instruction Manual

High Speed Drill: PRO8000SB
Medium Speed Drill: PRO8100SB
Sagittal Saw: PRO8200SB
Oscillating Saw: PRO8300SB
Reciprocating Saw: PRO8400SB
Wire Driver: PRO8600SB

CONMED

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Record the Model and Serial Numbers of the handpieces, and date received. Retain for future reference.

Handpiece Model No. _____ Serial No. _____ Date_____
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1.0 INTRODUCTION

It is recommended that personnel study this manual before attempting to operate, clean, or sterilize this or associated equipment. The safe and effective use of this equipment requires the understanding of and compliance with all warnings, precautionary notices, and instructions marked on the product, and included in this manual. This equipment is designed for use by medical professionals completely familiar with the required techniques and instructions for use of the equipment.

1.1 Operating Principle

The HALL® MicroFree™ Battery Handpieces are powered by the HALL® Small Bone Lithium Power Unit (L3500SB) to provide force to the accessory (burs, blades, drill bits, wires or attachment) for bone cutting, shaping, drilling and soft tissue resection with the drills, or bone cutting, shaping, or resection with the saws. The HALL® MicroFree™ Battery Handpieces are controlled by an activation lever on the handpiece.
Consult the associated HALL® Small Bone Lithium Power Unit (L3500SB) instruction insert prior to operating this equipment.

1.2 Indications for Use

The HALL® MicroFree™ High Speed Drill Battery Handpieces (PRO8000SB) and their accessories perform cutting of soft tissue and bone. The fields of application include: orthopedic, arthroscopic, plastic/reconstructive, oral/maxillofacial and spinal procedures.

The HALL® MicroFree™ Medium Speed Drill, Sagittal Saw, Oscillating Saw and Reciprocating Saw Battery Handpieces (PRO8100SB, PRO8200SB, PRO8300SB and PRO8400SB) and their accessories perform cutting of soft tissue and bone. The fields of application include: orthopedic, arthroscopic, plastic/reconstructive, and oral/maxillofacial procedures.

The HALL® MicroFree™ Wire Driver Handpiece (PRO8600SB) performs pinning and driving wires in arthroscopic, orthopedic, reconstructive, total joint arthroplasties, large/small bone trauma, large/small bone osteotomies, oral/maxillofacial and spinal procedures.

1.3 Intended Use

Same as Indications for Use above.

1.4 Contraindications

None

1.5 Warnings and Precautions

Do not bypass this section. It contains warnings and precautions that must be thoroughly understood before operating any of the equipment. Lack of understanding or adherence to these warnings and precautions may result in injury or even death to the patient.

The words **WARNING, PRECAUTION,** and **NOTE** carry special meanings and they must be read carefully.

WARNING: A warning contains critical information regarding serious adverse reactions and potential safety hazards that can occur in proper use or misuse of the equipment. Failure to observe the information or procedures presented in a Warning may result in injury or other serious adverse reactions to the patient and/or surgical staff.

PRECAUTION: A precaution contains instructions for any special care to be exercised by the practitioner for the safe and effective use of the equipment. Failure to observe the information or procedures presented in a Precaution may result in damage to the equipment.

NOTE: A note is added to provide additional focused information. This information has no critical effect on the patient or equipment.

1.5.1 Warnings

1. Eye protection is recommended when operating equipment. Eye injury may result.
2. It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of the equipment and its associated accessories.
3. Do not use equipment if, upon receipt, package is opened, damaged, or shows any signs of tampering.
4. Do not use equipment in the presence of flammable anesthetics, gases, disinfecting agents, cleaning solutions, or any material susceptible to ignition due to electrical sparking.
5. Do not use sterile equipment beyond the expiration date listed on the label. Sterility of the product cannot be assured beyond the expiration date.
6. Handpieces are supplied non-sterile. Clean and sterilize prior to each use.
7. Do not contact the moving parts on the handpieces. Injury to the operator may occur.
8. Continually check handpiece for overheating. If overheating is sensed, immediately discontinue use and return equipment for service. Overheating of the blade, bur or wire may cause damage to the blade, bur or wire and may cause burns or thermal necrosis.
9. While handpiece is not in use do not place on patient/surgical drapes. Place handpiece on mayo stand.
10. Do not immerse the equipment in fluids. Immersion may render the device inoperable.
11. Failure to follow the specified service interval could result in reduced instrument performance or overheating of the handpiece. Overheating can lead to possible burn injury to the patient or medical personnel. Rotation of handpiece usage per day will assist with proper performance. (Refer to section "**3.5 Maintenance Schedule**").
12. Do not attach, insert or remove accessories or attachments while the handpiece is operating. Injury to the operator and/or damage to the equipment may occur. Place the HALL Small Bone Lithium Power Unit safety mechanism in the "safe" position prior to installation or removal of items.
13. Avoid contact with cutting tip of blade or bur when locking into handpiece. Tips are sharp and may cause injury.
14. After use, blades, burs, wires and tubing sets may be a potential biohazard and should be handled and disposed in accordance with acceptable medical practice and applicable local and national requirements.
15. Do not use burs for plunge cutting. Injury or damage may occur.
16. Disposable blades, burs and wires are supplied sterile and are for single-use only. Do not re-sterilize or reuse. The ability to effectively clean and re-sterilize these single use devices has not been established and subsequent re-use may adversely affect the performance, safety and/or sterility of the devices.
17. When using the HALL MicroFree Sagittal Saw (PRO8200SB), placing excessive bending or twisting force on the sagittal saw blade may cause the collet to open and release the saw blade. Do not use saw blades to pry, remove bone grafts, or as a leverage point. Patient or user injury could occur.
18. Bur guards should always be checked before use. To reduce the risk of injury, prior to surgery, spin the bur guard on a bur. If the bur guard spins freely, the bearing is still good. Otherwise, the bur guard must be sent for repair immediately. DO NOT USE. Overheating can occur if bur guard bearings are worn or not kept clean.
19. Do not operate the drills without the appropriate bur guard and collet locked. Always use a bur of the proper length. The tip of the bur guard should cover the safe line on the bur, if applicable. Without the stabilization that the proper guard provides, the bur can break and be propelled with great force.
20. Loss of use of the MicroFree Handpiece due to battery depletion does not create a hazardous situation.

21. The PRO8600SB HALL MicroFree Wire Driver Handpiece is fully cannulated. When using wires with dual sharp tips, ensure the collet is positioned such that the proximal tip of the wire is angled away from the gripping hand to prevent punctured gloves or injury to hand.

1.5.2 Precautions

1. United States Federal law restricts sale of this device to or on the order of a physician.
2. This device should only be used in compliance with its intended use.
3. Handle all equipment carefully. If any equipment is dropped or damaged in any way, return it immediately for service.
4. Use only associated CONMED approved equipment and accessories. Using unapproved accessories may result in improper operation, and may result in non-compliance to medical standards.
5. The warranty becomes void and the manufacturer is not liable for direct or resulting damage if:
   - The device or the accessories are improperly used, prepared or maintained;
   - The instructions in the manual are not adhered to;
   - Non-authorized persons perform repairs, adjustments or alterations to the device or accessories.
6. There are no user-serviceable parts inside. No modification of this equipment is allowed.

7. Prior to each use, perform the following:
   - Ensure all accessories are correctly and completely attached. (Refer to Section "**2.2 Assembly/Installation Instructions**").
   - Perform the required Preoperative Functional Tests for the equipment and accessories. (Refer to Section "**2.4 Preoperative Functional Test**").
8. Clean and sterilize all equipment and associated accessories according to instructions for use. (Refer to section "**3.1 Cleaning Information**", section "**3.2 Disinfection Information**" and section "**3.3 Sterilization Information**").
9. Handpieces are factory sealed. Do not disassemble as this may void the warranty.
10. Always inspect for bent, dull or damaged blades or burs before each use. Do not attempt to straighten or sharpen. Do not use if damaged.
11. After each use, thoroughly clean the handpiece, attachments and accessories. (Refer to Section "**3.0 MAINTENANCE**").
12. Do not stall handpieces, damage can occur.
13. Do not operate the oscillating saw or reciprocating saw without a blade locked securely in place. Damage to the handpiece may occur.
14. Never lock the drill collet without a bur inserted. Damage to the collet may result.
15. Different saw blade designs and blade features can produce varying cutting efficiencies. For example: shorter fine-toothed blades will cut hard bone more efficiently than shorter coarse-toothed blades.
16. Do not use PRO8600SB HALL MicroFree Wire Driver Handpiece to remove wires that are firmly embedded in bone. When using the PRO8600SB Wire Driver to remove a wire, ensure wire rotates when handpiece is activated. Discontinue handpiece activation if wire does not rotate to prevent damage to wire and/or handpiece.
17. HALL C-wires (Catalog numbers 5050 series) are recommended for use with the PRO8600SB HALL MicroFree Wire Driver Handpiece.

1.6 Environmental Directives

WEEE Directive [2002/96/EC] on Waste Electrical and Electronic Equipment. This statement only applies to European countries with regard to the Waste Electrical and Electric Equipment (WEEE) European Directive.

The WEEE symbol on the product or its packaging indicates that this product must not be disposed of with other waste. Instead, it is your responsibility to dispose of your waste equipment by handing it over to a designated collection point for the recycling of Waste Electrical and Electronic Equipment. The separate collection and recycling of your waste equipment at the time of disposal will help conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment. For more information about where you can drop off your medical equipment at the end of its useful life for recycling, please contact CONMED.

1.7 Product Photographs and Drawings

The pictures in this manual are for reference only. Items shown may not represent the actual product. However, procedural steps are identical, unless otherwise specified. When necessary, the actual pictures will be represented.

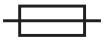
1.8 Symbol Definitions

1.8.1 Product Symbols

SAFE	Safe Mode	LOCK	Collet Lock Position
RUN	Run Mode		Indicates Handpiece should not be Immersed in any fluid.

1.8.2 Warnings and Information Symbols

REF	Catalog Number	SN	Serial Number
	Manufacturer		Date of Manufacture
	Consult Instructions for Use		Refer to Instruction Manual/Booklet (for critical safety instruction)
	Caution		DEHP Symbol
EC REP	Authorized Representative in the European Community	CE	CE Mark of Conformity
Rx ONLY	Prescription Only: Federal Law restricts this device to sale by or on the order of a physician		No User Service Recommended. Refer servicing to qualified CONMED service personnel
	Non Sterile	STERILE	Sterile
STERILE EO	Sterile - Sterilized Using EO	STERILE R	Sterile - Sterilized Using Irradiation
	Do Not Steam Sterilize		Do Not Sterilize
	Do Not Resterilize		Do Not Reuse (for Single Use Only)
	Do Not Use Oil		Do Not Use for Plunge Cutting
	Eye Protection Required		Biohazard Risk
	Do Not Immerse	QTY	Quantity
	Type B Applied Part		Type BF Applied Part
	UL Classification Mark		UL Recognized Components

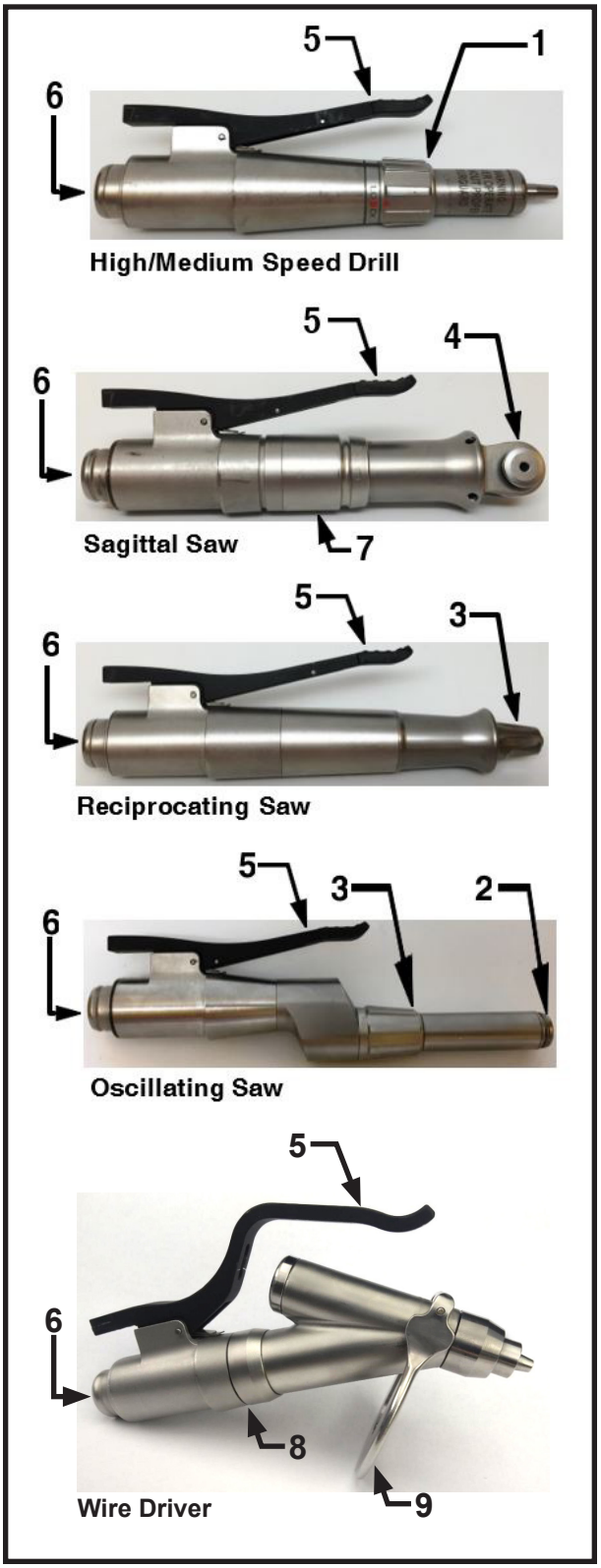
	Rating Fuse		Fuse Location
	Alternating Current		Protective Earth Ground
	Equipotentiality (Equipment Potential)		Non-Ionizing Electromagnetic Radiation (RF Symbol)
	Temperature Limitation		Humidity Limitation
	Atmospheric Pressure Limitation		Use by Date
	Fragile		This Side Up
	Do Not Use if Package is Damaged		Keep Dry
	Warning: Corrosive Substance		Warning: Electrical Hazard/High Voltage
	Waste Electrical and Electronic Equipment (WEEE) Symbol. Regarding European Union end-of-life of product, indicating separate collection for electrical and electronic equipment		
 Lithium	Recycle. Batteries contain materials which must be recycled or disposed of properly. The disposal of batteries as municipal waste is prohibited. Dispose or recycle in accordance with your local, state and governmental regulations. In the U.S. call 1-866-426-6633, or outside the U.S. contact your local CONMED representative for additional information on battery disposal or recycling.		

2.0 SYSTEM INSTALLATION AND OPERATION

2.1 Product Description

2.1.1 Handpiece Descriptions

1. **Bur Lock Collar** — Rotate to lock or unlock a bur.
2. **Blade Collet** — Holds the blade in place.
3. **Blade Lock Collar** — Rotate to open or lock the blade collet.
4. **Collet Lock Mechanism** — Locks a blade into place.
5. **Activation Lever** — Depress to operate the handpiece.
6. **HALL Small Bone Lithium Power Unit Connector** — The HALL Small Bone Lithium Power Unit (REF L3500SB) connects here to provide power to the handpiece.
7. **Collet Indexing Lock** — locks collet at 45° increments.
8. **Collet Indexing** — Indexes collet at 22.5° increments (total 225°).
9. **Collet Lever** — Pull to load or release wire.



NOTE: Do not allow saline to enter into the connector and HALL Small Bone Lithium Power Unit. Damage may occur to the handpiece.

2.2 Assembly/Installation Instructions

2.2.1 HALL Small Bone Lithium Power Unit Installation

To attach the HALL Small Bone Lithium Power Unit:
1. Put HALL Small Bone Lithium Power Unit in “SAFE” mode.
2. Ensure pins and sockets on HALL Small Bone Lithium Power Unit and handpiece are completely dry prior to connecting.
3. Insert the handpiece into the HALL Small Bone Lithium Power Unit.
4. Push together until fully seated and a click is heard and/or felt.

NOTE: Do not force the handpiece into the HALL Small Bone Lithium Power Unit. This may bend the pins and damage the handpiece.

To remove the HALL Small Bone Lithium Power Unit:
1. Put HALL Small Bone Lithium Power Unit in “SAFE” mode.
2. Pull HALL Small Bone Lithium Power Unit and handpiece apart.

2.2.2 HALL Bur Guard Assembly Instructions

2.2.2.1 Bur Guards

These instructions apply to following Guards:
- Medium Bur Guard (1375-012/1375-012P)
- Long Bur Guard (1375-011/1375-011P)
- Extra-Long Bur Guard (1375-023/1375-023P)

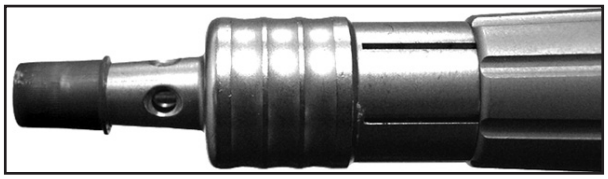
To install a bur guard:
1. Slide the appropriate bur guard over the end of the drill.
2. Ensure it is seated completely.

Prior to installing a bur, but only while using the 1375-012/1375-012P Medium Bur Guard, it is recommended that a SmartGuard® Protector Sleeve (1375-112) be attached. Reference the associated insert that comes packaged with the SmartGuard for additional information.

NOTES:
- **SmartGuard Protector Sleeves are designed to be attached to the Medium Bur Guard during surgical applications. They are intended to be used as a heat-sensing and insulating device that changes color from PURPLE (SAFE to use bur guard) to PINK (REPLACE bur guard) to indicate over-heating of the attached bur guard.**
- **Overheating might occur if bearings are worn or are not kept clean. If overheating occurs while a SmartGuard Protector Sleeve is attached to the Medium Bur Guard, the SmartGuard Protector Sleeve will change color from PURPLE to PINK. Immediately discontinue use of the bur guard to prevent possible injury to the patient and/or operator. Replace the bur guard and return original bur guard for service.**
- **Under prolonged use or intense cutting, the tip of the SmartGuard Protector Sleeve may turn PINK while the rest of the sleeve retains its PURPLE color. If more than 50% of the SmartGuard Protector Sleeve turns PINK, discontinue use immediately to prevent possible injury to the patient and/or operator. Replace the bur guard and return original bur guard for service.**

To attach a SmartGuard Protector Sleeve:

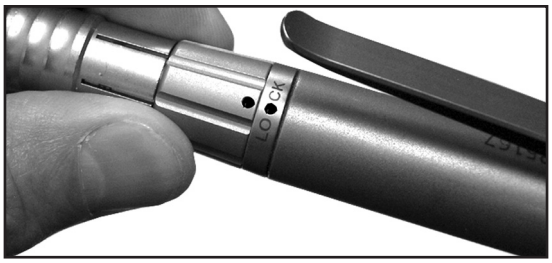
1. Remove the SmartGuard Protector Sleeve from its sterile packaging within the sterile field.
2. Press-fit the SmartGuard Protector Sleeve onto the end of the associated bur guard until fully seated (see figure below).



3. After the SmartGuard Protector Sleeve is attached, install a bur.

To remove the SmartGuard Protector Sleeve:

1. Remove the bur.



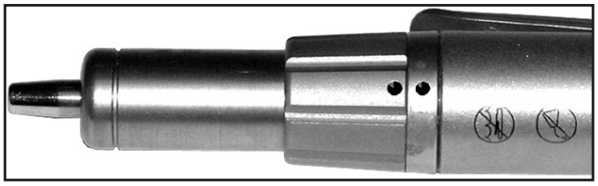
2. Grasp the tabs of the SmartGuard Protector Sleeve between the thumb and forefinger and pull.
3. Discard the used SmartGuard Protector Sleeve properly.

2.2.3 Bur Installation and Removal

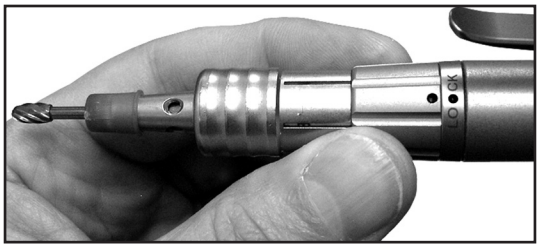
NOTE: Always ensure HALL Small Bone Lithium Power Unit is in "SAFE" mode prior to installing or removing bur from drill.

To install a bur:

1. Select a proper length bur for the guard.
2. Twist the bur lock counter-clockwise to the unlocked position.



3. Insert the bur to the safe line or until the bur seats completely if no safe line is observed.
4. Lock the bur in place by twisting the bur lock clockwise until the red indicator dots are aligned.



5. Always pull on the bur to ensure bur is fully locked in position.

To remove bur:

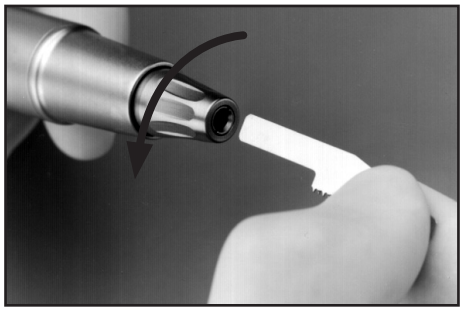
Twist the bur lock counter-clockwise to the unlocked position and remove bur.

2.2.4 Reciprocating Saw Blade and Rasp Installation and Removal

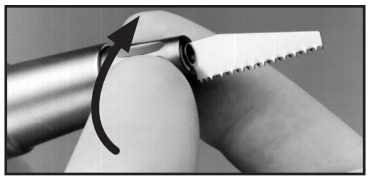
NOTE: Always ensure HALL Small Bone Lithium Power Unit is in "SAFE" mode prior to installing or removing blade from Reciprocating Saw.

To insert a blade:

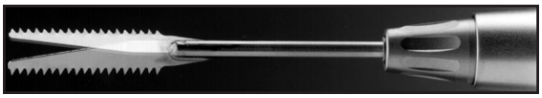
1. Twist the blade locking collar counter-clockwise and insert the shank of the blade or rasp into the collet. Ensure the blade or rasp is fully seated.



2. Twist the blade lock collar clockwise and tighten securely.



Round shank blades or rasps can be seated at any position within a 360° range. Flat blades must be aligned with the slot in the collet.



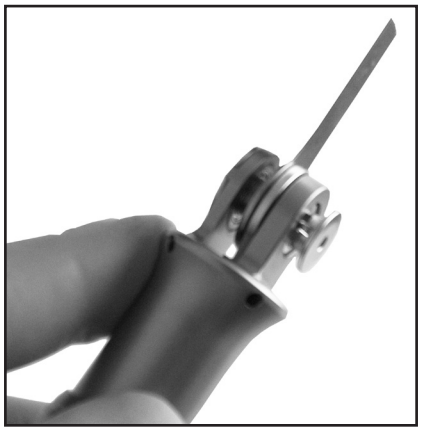
To remove blades or rasps:
Twist the blade lock collar counter-clockwise and remove the blade.

2.2.5 Sagittal Saw Blade Installation and Removal

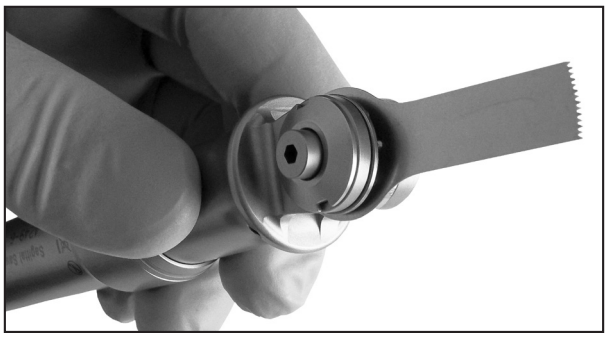
NOTE: Always ensure HALL Small Bone Lithium Power Unit is in "SAFE" mode prior to installing or removing blade from Sagittal Saw.

To Attach Blades:

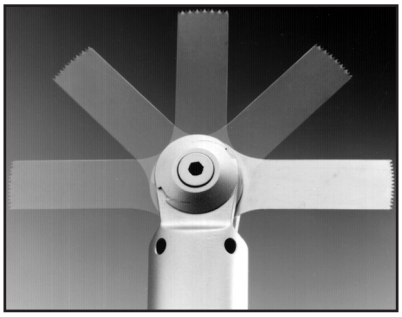
1. Depress the collet lock mechanism to open the collet. Position the blade on the pins inside the collet.



2. Depress the opposite side of the handpiece collet area to lock the blade into position. An audible click should be heard.



3. Blades may be positioned at 45° intervals within a 180° arc.



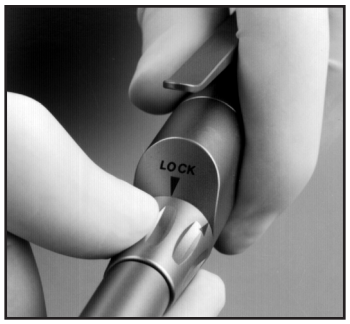
4. Verify the blade is securely attached by activating the handpiece. To remove saw blades: Depress the collet lock mechanism and remove the blade.

2.2.6 Oscillating Saw Blade Installation and Removal

NOTE: Always ensure HALL Small Bone Lithium Power Unit is in "SAFE" mode prior to installing or removing blade from Oscillating Saw.

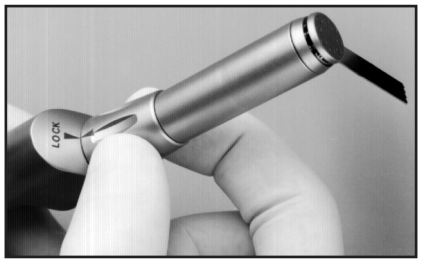
To attach saw blades:

1. Ensure the blade lock collar is in the open position until the arrows are no longer aligned.

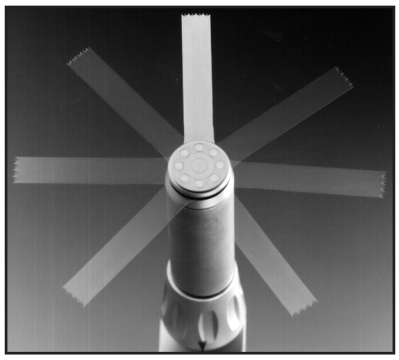


2. Check collet pins for debris, damage, or wear. Do not use if noted.
3. Position the blade on the pins inside the collet.

4. Twist the blade lock collar and align the arrows in the “LOCK” position to secure the blade.



5. Blades may be positioned at 45° intervals within a 360° circumference of the collet.



6. Verify the blade is securely attached by briefly activating the handpiece.

To remove saw blades:
Twist the blade lock collar until the arrows are no longer aligned in the “LOCK” position and remove the blade.

2.2.7 Wire Driver Wire Installation and Removal

NOTE: Always ensure HALL Small Bone Lithium Power Unit is in “SAFE” mode prior to installing or removing wire from Wire Driver handpiece.

NOTE: HALL MicroFree Wire Driver Handpiece can accommodate wires ranging between 0.028” – 0.062” (0.71 – 1.57 mm).

NOTE: Position of Collet Lever may limit travel distance of Activation Lever in some orientations. This may limit speed of the handpiece.

NOTE: Index handpiece collet prior to inserting wire. Do not index handpiece collet if wire is protruding through the activation lever.

To insert wire:
1. Index collet to desired position.
2. Pull back Collet Lever.
3. Insert wire into the handpiece to the desired position.
4. Release Collet Lever to retain wire.
5. Repeat steps 2-4 to reposition wire.

To remove wire:
1. Pull back Collet Lever.
2. Remove wire from handpiece.

2.3 Operating Instructions

PRECAUTION: Discontinue use if overheating is sensed in handpiece during operation. ⚠

2.3.1 Drill Operation

NOTE: Operation of a drill (PRO8000SB, PRO8100SB) without a bur locked in place is considered a failure mode. If the handpiece is activated for several seconds without a bur in place, the handpiece will not run. Operation cannot be initiated until a bur is locked in place.

To operate the handpiece after the guard and bur are attached:
1. Adjust the lever extension to the desired position by pulling the lever extension in and out of the lever.
2. Place the “SAFE/RUN” Slide on the HALL Small Bone Lithium Power Unit in the “RUN” position.
3. Depress the handpiece Activation Lever.

2.3.2 Reciprocating Saw Operation

To activate the handpiece:
1. Adjust the lever extension to the desired position by pulling the lever extension in and out of the lever.
2. Place the “SAFE/RUN” Slide on the HALL Small Bone Lithium Power Unit in the “RUN” position.
3. Depress the handpiece Activation Lever.
4. Place the HALL Small Bone Lithium Power Unit back in the “SAFE” position.
5. Retighten the blade locking collar.

2.3.3 Sagittal Saw Operation

To activate the handpiece:
1. Adjust the lever extension to the desired position by pulling the lever extension in and out of the lever.
2. Place the “SAFE/RUN” Slide on the HALL Small Bone Lithium Power Unit in the “RUN” position.
3. Depress the handpiece Activation Lever.

To index the head:
1. The sagittal saw head can be indexed at 45 degree increments.
2. Pull the collet indexing lock back.
3. Rotate the head to the desired 45 degree increment.
4. Release the collet indexing lock.

2.3.4 Oscillating Saw Operation

NOTE: Lever does not extend with this handpiece.
To activate the handpiece:
1. Place the “SAFE/RUN” Slide on the HALL Small Bone Lithium Power Unit in the “RUN” position.
2. Depress the handpiece Activation Lever.

2.3.5 Wire Driver Operation

To activate the handpiece:
1. Place the “SAFE/RUN” Slide on the HALL Small Bone Lithium Power Unit in the “RUN” position.
2. Depress the handpiece Activation Lever.

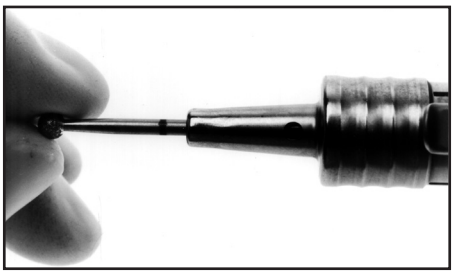
2.4 Preoperative Functional Test

Prior to operating the HALL MicroFree Battery Handpieces, perform the following preoperative tests to verify proper functioning. Any operating difficulties should be reported to your local Sales Representative or CONMED Customer Service.

2.4.1 Bur Guard Functional Test

NOTE: This test excludes the Medium Bur Guard, 1375-012/1375-012P.

1. Remove the guard from the handpiece and insert a bur into the nose of the guard.
2. While holding the bur, spin the guard. The guard should spin freely around the bur shaft without resistance.

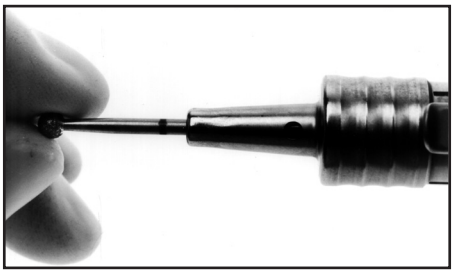


3. Attach the guard and bur to the handpiece.
4. Operate the handpiece for approximately 30 seconds, then stop the handpiece. Once the bur has stopped moving, carefully feel the end of the guard where the guard encases the shaft of the bur for overheating. If overheating is noticed, return guard for service.

2.4.2 Medium Bur Guard (1375-012/1375-012P) Functional Test

Prior to testing, remove the guard from the handpiece. Check for worn bearings:

1. Insert a bur into the nose of the guard.
2. While holding the bur, spin the guard. The guard should spin freely around the bur shaft without resistance.



3. Attach the bur guard to the drill.
4. Attach a SmartGuard Protector Sleeve (1375-112). Reference the associated insert available on the CONMED website.
5. Select a proper length bur for the guard and install a bur.
6. Operate the handpiece for at least 30 seconds. Stop the handpiece and carefully feel the end of the guard where the guard encases the shaft of the bur for overheating. If overheating is noticed, return the guard for service. Or, if the SmartGuard Protector Sleeve changes color from PURPLE to PINK, immediately discontinue use of the bur guard. Replace the bur guard and return original bur guard for service.

2.4.3 Handpiece Functional Test

Before operating the handpiece, check for:

- any loose or missing parts
- any physical damage
- movable parts that do not move freely.

Performance Testing:

1. Assemble the appropriate guard, bur, blade and/or wire according to the assembly instructions.
2. Operate the handpiece for one minute according to the operating instructions. Monitor the handpiece for any of the following:
    - excessive noise
    - excessive vibration
    - handpiece or attachment are hot to the touch during the test procedure or during surgical use.

3.0 MAINTENANCE

3.1 Cleaning Information

3.1.1 Warnings, Precautions and Notes

1. Follow universal precautions for protective apparel when handling and cleaning contaminated instruments.
2. After use (post-operatively) do not allow soiled/contaminated devices to dry prior to pre-cleaning and disinfecting. Clean instruments within 30 minutes after use to minimize the potential of blood and debris drying. Consider covering the re-usable device with a cloth saturated with distilled water to avoid drying of soil.
3. Never clean equipment in an ultrasonic cleaner.
4. Always disconnect the handpiece from the HALL Small Bone Lithium Power Unit prior to cleaning.
5. Always detach accessories from equipment prior to cleaning.
6. Never clean handpieces with bleach, chlorine-based detergents, liquid or chemical disinfectants, or any products containing sodium hydroxide (such as, INSTRU-KLENZ or Buell Cleaner). These products degrade the anodized aluminum coating and may result in reduced handpiece reliability.
7. To prevent corrosion, avoid contact with agents containing iodine or chlorine.

3.1.2 Manual Cleaning Instructions

1. Remove the attachments, HALL Small Bone Lithium Power Unit and disposables from the handpieces.
2. Thoroughly scrub the handpiece and attachments with a clean, soft brush dampened with a mild, pH-balanced detergent. Ensure the blade locking collet on the oscillator and reciprocator handpieces is in the open position. Remove all traces of blood, debris and stains.
3. To clean the cannulated section of the handpiece and attachment, feed the wire end of a cleaning brush through the cannulation of the handpiece or attachment. Pull the brush completely through and repeat until all debris is removed.
4. Manipulate all moving parts of the handpiece and attachments to ensure all debris is removed. If not, clean again until all debris is removed.
5. Keeping the nose of the handpiece pointed downward, rinse under tap water (minimum temperature of 25°C/77°F) for a minimum of 30 seconds using a minimum of 6 liters to remove all traces of soap. Rinse all attachments likewise.
6. Flush all surfaces free of tap water with distilled/deionized water (minimum temperature of 25°C/77°F) for a minimum of 20 seconds using a minimum of 4 liters of distilled/deionized water. Ensure handpiece is visibly free of detergent or cleaning residues.
7. Gently shake the equipment free of water and wipe the surfaces with a clean, lint-free towel.
8. For cleaning instructions of the HALL Small Bone Lithium power unit, refer to instructions of use.

3.1.3 Automated Cleaning Instructions

HALL MicroFree Battery Handpieces are suitable for use in washer/sanitizers. They are designed with advanced materials and sealing technologies and are individually tested to ensure the prevention of ingress of fluids during use and cleaning. MicroFree handpieces have an Ingress Protection rating of IPX6, IPX8 and IPX9, ensuring they are suitably protected against water intrusion.

1. Under running water, remove all traces of blood and debris.
2. Load handpiece in washer/sanitizer and operate according to machine manufacturer’s instructions. It is recommended to use a neutral pH cleaner. Only use approved solutions for cleaning powered instruments according to the manufacturer’s recommendations. Ensure all collet mechanisms are in the open position.
3. Run washer/sanitizer according to the manufacturer’s specifications. A dry cycle is recommended but not required.

3.2 Disinfection Information

NOTE: CaviCide® Spray Ready-to-use or a comparable disinfection solution of PH between 11.0 and 12.49 are highly recommended by CONMED. However, the use of alternative methods of disinfection or disinfection agents outside the scope of this document may be suitable for disinfecting the devices. Alternate disinfection methods must be validated by the end user.

3.2.1 Manual Disinfection Instructions

1. Spray the device thoroughly with CaviCide® Spray Ready-to-use disinfectant.
2. Ensure the device remains wet for a minimum of ten (10) minutes by spraying the device as needed with the CaviCide® Spray Ready-to-use.
3. Rinse under running deionized water for a minimum of one (1) minute.
4. Thoroughly dry all surfaces of the device using a sterile, lint free wipe, changing wipes when necessary to ensure the device is completely dry.

3.2.2 Automated Disinfection Instructions

1. Place device in an automated washer disinfector filled with purified water.
2. Run thermal rinse cycle at 194˚F (90 ˚C) for five (5) minutes.
3. Let device cool before handling.
4. Removed device from washer and thoroughly dry the device with a sterile lint free wipe.

3.3 Sterilization Information

3.3.1 Warnings, Precautions and Notes

1. The use of disinfecting solutions for an exterior instrument wipe will not sterilize the equipment and is not recommended.
2. Do not sterilize equipment or accessories using Ethylene Oxide (EtO).
3. Do not sterilize equipment or accessories using a STERIS system or by comparable sterilization methods.
4. Do not sterilize equipment or accessories in cold sterilants like CIDEX.
5. Always detach accessories from equipment prior to sterilization.
6. Do not use equipment while warm. Allow adequate time for cooling prior to use. Cool by exposure to room temperature. Operation of equipment that is not completely cool or dry may decrease performance and/or reliability.
7. When sterilizing equipment and attachments in a system sterilization tray, use the recommended sterilization parameters in its instruction manual.
8. Do not “Peel Pack” handpieces for sterilization. Sterilization in a sealed pouch traps moisture which can cause damage.
9. Attachments or handpieces with collet mechanisms must be sterilized with the collet fully open.
10. A minimum dry cycle according to the Sterilization Instructions must be run on all equipment and attachments every time the product is sterilized. Failure to use a dry cycle on the products may lead to reduced product performance or premature product failure.
11. In instances where a facility does not have the ability to perform Pre-vacuum sterilization with dry cycles that correspond for the recommendations above, we recommend that the handpiece be dried in a dry heat sterilizer at 250°F (121°C) after sterilization, once a day for two hours. This process will eliminate moisture that may have built up during previous gravity sterilization cycles. Following this process should ensure optimum performance of the handpiece.

Refer also to Section “**1.5 Warnings and Precautions**”.

3.3.2 Inspection Recommendations

1. Inspect device prior to sterilization.
2. Generally, unmagnified visual inspection under good light conditions is sufficient. All parts of the device should be checked for visible soil and/or corrosion.
3. Functional checks should be performed where possible.
4. Mating devices should be checked for proper assembly.
5. Ensure moving parts move freely. When necessary, lubricate moving parts with HALL Blitz® Instrument Cleaner (M105A) or equivalent. Remove any excess lubrication.
6. Remove and replace damaged instruments/containers.

3.3.3 Sterilization Instructions

Steam sterilization is safe and effective and has no contraindications for sterilizing this equipment. Handpieces and attachments may be processed in a pre-vacuum steam sterilizer (Steam Pre-vacuum) or in a gravity (downward) displacement sterilizer (Steam Gravity).

1. Individually wrap handpiece and accessories. In the United States, use FDA-cleared sterilization wrap.
2. Follow the recommended minimum sterilization exposure times listed below.
3. Use the recommended tray parameters in its instruction manual when sterilizing handpieces and attachments in a system sterilization tray.
4. The instructions provided have been validated as being capable of preparing the HALL MicroFree Battery Handpiece for re-use. It remains the responsibility of the processor to ensure that the processing is actually performed using equipment, materials and personnel in the processing facility to achieve the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

Recommended sterilization exposure times are as follows:

Table 1: Sterilization Parameters of HALL MicroFree Battery Handpieces without a System Sterilization Tray in the United States

Method	Temperature	Exposure	Dry Cycle
Steam Pre-Vacuum	270°F (132°C)	3 minutes	8 minutes
Steam Pre-Vacuum	270°F (132°C)	4 minutes	8 minutes
Steam Pre-Vacuum	273°F (134°C)	3 minutes	8 minutes
Steam Gravity	250°F (121°C)	30 minutes	8 minutes

Table 2: Sterilization Parameters of HALL MicroFree Battery Handpieces without a System Sterilization Tray outside the United States

Method	Minimum Temperature	Maximum Temperature	Minimum Exposure	Maximum Exposure	Minimum Dry Cycle	Maximum Dry Cycle
Steam Pre-Vacuum	273°F (134°C)	278°F (137°C)	3 minutes	18 minutes	8 minutes	No maximum
Steam Gravity	250°F (121°C)	-	30 minutes	-	8 minutes	No maximum

3.4 Troubleshooting

Table 3: Troubleshooting Guide

Symptom	Possible Cause	Corrective Action
Handpiece does not operate.	• Handpiece faulty. • Power unit safety is in the safe, or off position. • Twist collet not in the fully locked position. • Handpiece not fully seated in power unit.	• Return for service. • Move safety to the appropriate operating position. • Twist collet to the fully locked position. • Securely connect handpiece to power unit.
Handpiece Overheats	• Worn bearings in the bur guard, or collet. • Moisture in the handpiece.	• Refer to section "**2.4.1 Bur Guard Functional Test**". If resistance is noticed, return bur guard for service. If no resistance is noticed, return for service. • Resterilize the handpiece according to sterilization parameters and drying times. (Refer to section "**3.3.1 Warnings, Precautions and Notes**").

3.5 Maintenance Schedule

Regular and proper maintenance of your equipment is the best way to protect your investment. It is essential that you have your equipment serviced as scheduled in order to retain its optimum performance and reliability, which will reward you with safer, less problematic product performance over time.

The equipment is not field repairable. Your CONMED authorized service department is the most knowledgeable about this equipment and its accessories and will provide competent and efficient services. Service at CONMED at the recommended service interval is mandatory to keep your product warranties in effect. Any services and/or repairs done by any unauthorized repair facility may result in reduced performance of the equipment or equipment failure. (Refer to Section "**5.0 CUSTOMER SERVICE**").

The HALL MicroFree Battery Handpieces (PRO8000SB, PRO8100SB, PRO8200SB, PRO8300SB, PRO8400SB, PRO8600SB) and Attachments shall be returned every 12 months for servicing.

The Bur Guards shall be returned every 6 months for servicing.

4.0 TECHNICAL SPECIFICATIONS

Medical electrical equipment complies with and was tested with respect to electric shock, fire, electromagnetic compatibility, mechanical and other specified hazards only, in accordance with:

- ANSI/AAMI ES60601-1: 2005 (R2012) and A1:2012 and C1:2009 (R2012) and A2:2010 (R2012), Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.
- CAN/CSA C22.2 No. 60601-1:14, Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.
- IEC60601-1-2:2014, Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances — Requirements and tests

4.1 Product Technical Specifications

4.1.1 Handpieces

HALL® MicroFree™ High Speed Drill (PRO8000SB):	
IEC Classification:	Internally Powered, Applied Part Type BF
Mode of Operation:	Intermittent Loading
Maximum Speed (Nominal):	70,000 rpm
Torque:	2 in. oz.
Bur Pull Out Force:	Exceeds 10.0 lbs. (4.5 kg)
Length:	5.21 in. (13.23 cm)
Diameter:	0.90 in. (2.29 cm)
Weight:	7.5 oz. (213 g)
Acoustic Noise:	88.1 dBC
Duty Cycle (once daily):	10 seconds ON, 10 seconds OFF (3x) 30 seconds ON
Ingress Protection	IPX6/IPX8/IPX9

HALL® MicroFree™ Medium Speed Drill (PRO8100SB)	
IEC Classification:	Internally Powered, Applied Part Type BF
Mode of Operation:	Intermittent Loading
Maximum Speed (nominal):	25,000 rpm
Torque:	6 in. oz.
Bur Pull Out Force:	Exceeds 10.0 lbs. (4.5 kg)
Length:	5.0 in. (12.7 cm)
Diameter:	0.90 in. (2.29 cm)
Weight:	6.6 oz. (187 g)
Acoustic Noise:	74.2 dBC
Duty Cycle (once daily):	10 seconds ON, 10 seconds OFF (3x) 30 seconds ON
Ingress Protection	IPX6/IPX8/IPX9

HALL® MicroFree™ Sagittal Saw (PRO8200SB)	
IEC Classification:	Internally Powered, Applied Part Type BF
Mode of Operation:	Intermittent Loading
Max Speed:	25,000 cpm
Stroke:	4° arc
Length:	5.0 in. (12.7 cm)
Diameter:	0.90 in. (2.29 cm)
Weight:	7.5 oz. (213 g)
Acoustic Noise:	86.2 dBC
Duty Cycle (once daily):	30 seconds ON, 20 seconds OFF (4x)
Ingress Protection	IPX6/IPX8/IPX9

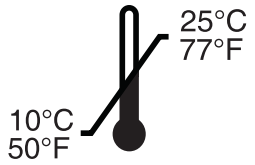
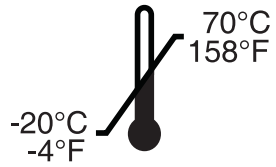
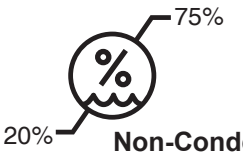
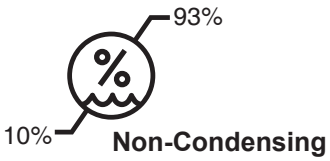
HALL® MicroFree™ Oscillating Saw (PRO8300SB)	
IEC Classification:	Internally Powered, Applied Part Type BF
Mode of Operation:	Intermittent Loading
Maximum Speed (nominal):	25,000 rpm
Stroke:	8° arc
Length:	5.92 in. (15.04 cm)
Diameter:	0.90 in. (2.29 cm)
Weight:	7.6 oz. (217 g)
Acoustic Noise:	87.3 dBC
Duty Cycle (once daily):	10 seconds ON, 20 seconds OFF (4x)
Ingress Protection	IPX6/IPX8/IPX9

HALL® MicroFree™ Reciprocating Saw (PRO8400SB)	
IEC Classification:	Internally Powered, Applied Part Type BF
Mode of Operation:	Intermittent Loading
Maximum Speed (nominal):	17,000 rpm
Stroke:	1/10 in (2.54 mm)
Length:	5.53 in. (14.05 cm)
Diameter:	0.90 in. (2.29 cm)
Weight:	7.9 oz. (221 g)
Acoustic Noise:	88.4 dBC
Duty Cycle (once daily):	20 seconds ON, 30 seconds OFF (3x)
Ingress Protection	IPX6/IPX8/IPX9

HALL® MicroFree™ Wire Driver (PRO8600SB)	
IEC Classification:	Internally Powered, Applied Part Type BF
Mode of Operation:	Intermittent Loading
Maximum Speed (nominal):	2,833 rpm
Wire Diameter Range:	0.028 to 0.062 in (0.71 to 1.57 mm)
Length:	4.8 in (12.2 cm)
Diameter (collet):	0.63 in. (1.6 cm)
Weight:	8.8 oz. (250 g)
Acoustic Noise:	60 dBC
Duty Cycle (once daily):	Insert Wires: 6 seconds ON/20 seconds OFF (x5) Remove Wires: 6 seconds ON/10 seconds OFF (x5)
Ingress Protection:	IPX6/IPX8/IPX9

4.2 Product Environmental Requirements

4.2.1 Environmental Technical Specifications

Environmental Conditions	Operating	Storage and Transport
Temperature:		
Relative Humidity:		
Atmospheric Pressure:		

4.2.2 Electromagnetic Requirements

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the HALL MicroFree Battery Handpieces, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
Use of this equipment near high frequency surgical equipment, and RF shielded rooms for magnetic resonance imaging shall be excluded. Otherwise, degradation of the performance of this equipment could result.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

HALL MicroFree Battery Handpieces are intended for use in the electromagnetic environment specified below. The customer or the user of the HALL® MicroFree™ Battery Handpieces should assure that they are used in such an environment		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF Emissions CISPR 11	Group 1	HALL MicroFree Battery Handpieces use RF energy only for internal functions; therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The emissions characteristics of this equipment make it suitable for use in industrial areas asnd 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 need to take mitigation measures, such as relocating or re-orienting the equipment.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The HALL MicroFree Battery Handpieces are intended for use in the electromagnetic environment specified below. The customer or the user of the HALL MicroFree Battery Handpieces should assure that it is used in such an environment.		
Immunity Test	**IEC 60601 Test Level**	**Electromagnetic Environment Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 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%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Radiated RF IEC 61000-4-3	80 MHz to 2.7 GHz 3 V/m	N/A
Proximity field from wireless transmitters	9 V/m - 28 V/m 15 Specific Frequencies	N/A

Proximity field from wireless transmitters

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity Test Level (V/m)
385	380 – 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1,720	1,700 – 1,990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1,845						
1,970						
2,450	2,400 – 2,570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5,240	5,100 – 5,800	WLAN 802. 11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5,500						
5,785						
NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.						

4.3 Handpieces, Attachments and Accessories

REF	Description
	Bur Guards
1375-011	Long Bur Guard
1375-012	Medium Bur Guard
1375-023	Extra Long Bur Guard
	Precision Bur Guards
1375-011P	Long Bur Guard
1375-012P	Medium Bur Guard
1387-023P	Extra Long Bur Guard
	Power Unit
L3500SB	HALL Small Bone Lithium Power Unit
L3000	Lithium Charger
L3500	Lithium Charger Adaptor
	Handpieces
PRO8000SB	HALL MicroFree High Speed Drill
PRO8100SB	HALL MicroFree Medium Speed Drill
PRO8200SB	HALL MicroFree Sagittal Saw
PRO8300SB	HALL MicroFree Oscillating Saw
PRO8400SB	HALL MicroFree Reciprocating Saw
PRO8600SB	HALL MicroFree Wire Driver
	Miscellaneous
1375-112	SmartGuard Protector Sleeve
5053-124	Cleaning Brush

5.0 CUSTOMER SERVICE

5.1 Assistance and Repair

If you need technical assistance regarding the use or application of this product, or you encounter a problem that requires servicing or repair, contact CONMED Customer Service at 1-866-426-6633 or your CONMED Sales Representative. Outside the U.S. contact your local CONMED Representative.

Report any events involving injuries or malfunctions to the CONMED Regulatory Product Support.

Products returned for repair must have an authorized Service Request (SR) number prominently displayed on the box and included on all paperwork. Refer to this number if making inquiries about the repair status. Please call CONMED Customer Service and provide the following information to obtain an S.R. number prior to returning any product for repair:

5.1.1 Product Number

5.1.2 Serial/Lot Number

5.1.3 Reason for Return

5.1.4 Original Invoice Number

5.1.5 Date of Purchase

5.1.6 Detailed description of the problem

CONMED
Attn.: Customer Service Dept. 11311 Concept Boulevard Largo, Florida 33773-4908 USA

Customer Service		
(within U.S.)	**Phone:**	**1-866-426-6633**
	FAX:	**(727)-399-5256**
(outside U.S.)	**Phone:**	**+1 (727)-392-6464**
	FAX:	**+1 (727)-397-4540**
CONMED Regulatory Product Support		
(within U.S.)	**Phone:**	**1-800-325-5900**
(outside U.S.)	**Phone:**	**+1 (727)-392-6464**

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