The Hall® PowerPro® Electric II Handpieces Instruction Manual

(PRO6100, PRO6125, PRO6135)





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

Handpiece Model No. ______ Serial No _______ Date ______

Handpiece Model No. _____ Serial No ______ Date ______

Handpiece Model No. _____ Serial No ______ Date ______

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1. INTRODUCTION

	1.1	Opera	ting Principle	1
	1.2	Indicat	tions for Use	1
	1.3	Intend	ed Use	1
	1.4	Contra	aindications	1
	1.5	Warnir	ngs and Precautions	2
		1.5.1	Warnings	2
		1.5.2	Precautiwons	3
	1.6	Enviro	nmental Directives	4
	1.7	Produc	ct Photographs and Drawings	4
	1.8	Symbo	ol Definitions	4
		1.8.1	Product Symbols	4
		1.8.2	Warnings and Information Symbols	5
2.				
	2.1	Produ	ct Description	7
		2.1.1	PowerPro Electric II Modular Handpiece (PRO6100)	7
		2.1.2	PowerPro Electric II Oscillator Handpiece (PRO6125)	8
		2.1.3	PowerPro Electric II Reciprocator Handpiece (PRO6135)	9
	2.2	Assem	nbly/Installation Instructions	10
		2.2.1	Handpiece Cord Installation	10
		2.2.2	Connecting and Removing Attachments to the Modular Handpiece	11
		2.2.3	Connecting and Removing Blades to the Oscillator Handpiece	12
		2.2.4	Connecting and Removing Blade to Reciprocator Handpiece	13
	2.3	Opera	ting Instructions	14
		2.3.1	PowerPro Electric II Modular Handpiece (PRO6100) Operation	14
		2.3.2	PowerPro Electric II Oscillator Handpiece (PRO6125) Operation	17
		2.3.3	PowerPro Electric II Reciprocator Handpiece (PRO6135) Operation	18
	2.4	Preop	erative Functional Test	18

3. MAINTENANCE

	3.1	3.1 Cleaning Information	
		3.1.1 Warnings, Precautions and Notes	19
		3.1.2 Manual Cleaning Instructions	
		3.1.3 Washer/Sanitizer Cleaning (Optional)	20
	3.2	Sterilization Information	20
		3.2.1 Warnings, Precautions and Notes	20
		3.2.2 Sterilization Instructions	20
	3.3	Troubleshooting	22
	3.4	Maintenance Schedule	
4.	TEC 4.1	Product Technical Specifications	25
		4.1.1 Handpieces	
	4.2	Product Environmental Requirements	
		4.2.1 Environmental Technical Specifications	
		4.2.2 Electromagnetic Requirements	
	4.3	Handpieces, Attachments and Accessories	
5.	CU	STOMER SERVICE	
	5.1	Assistance and Repair	30

1. 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. Service intervals, as listed in section "3.4 **Maintenance Schedule**", are required to keep the equipment at its optimum operating performance.

1.1 Operating Principle

The PowerPro Electric II Handpieces are electrically powered by CONMED Linvatec surgical consoles to provide rotary, reciprocating, or oscillating force to the accessory (drill bits, saw blades, reamers, drivers or other attachments) for bone cutting, drilling, driving and soft tissue resection. The handpieces use a detachable cable and are controlled by a single activation trigger and safety/direction lever on the handpiece.

1.2 Indications for Use

The PRO6100 PowerPro Electric II Modular Handpiece, and its accessories, perform cutting of soft tissue and bone. The fields of application include: Orthopedic, Arthroscopic, Oral/Maxillofacial, Hand, Foot, and Plastic/Reconstructive surgical procedures.

The PRO6125 PowerPro Electric II Oscillator Handpiece, and its accessories, perform cutting of soft tissue and bone. The fields of application include: Orthopedic, Arthroscopic, Otolaryngological, Oral/Maxillofacial, Hand, Foot, and Plastic/Reconstructive surgical procedures.

The PRO6135 PowerPro Electric II Reciprocator Handpiece, and its accessories, perform cutting of soft tissue and bone. The fields of application include: Orthopedic, Arthroscopic, Hand, Foot, and Plastic/Reconstructive surgical 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.
- 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. Do not excessively bend or kink the handpiece cord. Always inspect cords for signs of excessive wear or damage, or bent, broken or missing pins within the connector(s). If any wear or damage is found, discontinue use and replace handpiece immediately. Using a damaged power cord could possibly cause injury.
- 7. Handpieces are supplied non-sterile. Clean and sterilize prior to each use.
- 8. Do not contact the moving parts on the handpieces. Injury to the operator may occur.
- Continually check handpiece for overheating. If overheating is sensed, immediately discontinue use and return equipment for service. Overheating of the blade or bur may cause damage to the blade or bur and may cause burns or thermal necrosis.
- While handpiece is not in use do not place on patient/surgical drapes. Place handpiece on mayo stand.
- 11. Do not immerse the equipment in fluids. Immersion may render the device inoperable.



12. 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 "3.4 Maintenance Schedule").



- 13. 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 handpiece safety mechanism in the "safe" position prior to installation or removal of items.
- 14. Avoid contact with cutting tip of blade or bur when locking into handpiece. Tips are sharp and may cause injury.
- 15. After use blades, burs 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.



- 16. Do not use burs for plunge cutting. Injury or damage may occur.
- 17. Disposable blades and burs are supplied sterile and are for single-use only. Do not resterilize 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.



- 18. Do not operate the oscillating saw or reciprocator handpiece without a blade locked securely in place.
- 19. Always place the handpiece in the "safe" position when not in use and prior to repositioning the rotating head on the Oscillator Saw, rotating the collet on the Reciprocating Saw, or connecting or removing attachments and accessories.
- 20. When using the PowerPro Sagittal Saw attachment (PRO2043), 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.

1.5.2 Precautiwons



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.
- Use only associated CONMED Linvatec 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" and section "3.2 Sterilization Information").
- 9. Handpieces are factory sealed. Do not disassemble or lubricate, as this may void the warranty.



- 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.
- After each use, thoroughly clean the handpiece, attachments and accessories. (Refer to section "3. MAINTENANCE").
- 12. Do not stall handpieces, damage can occur.
- 13. When using a saw attachment (Reciprocating Saw PRO6045 or Sagittal Saw PRO2043) or reaming attachment, do not operate in the screw, tap or oscillate mode. Handpieces should only be operated in the drill/ream mode when used with these attachments.
- 14. Do not handle the handpiece by the cord. Do not pull on the cord to remove it from the surgical console. Damage can occur.
- 15. The PRO2045 Reciprocating Saw attachment should not be used on the PowerPro Electric II Modular handpiece (PRO6100). The PRO6045 Reciprocating Saw attachment is recommended for the PRO6100 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 Linvatec.

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

S	Indicates the "safe" or off position of the handpieces.	R)	Indicates the "reverse" position of the PRO6100 handpiece.
=@	Indicates the "forward" position of the PRO6100 handpiece.		Indicates the "run" positions of the PRO6125 and PRO6135 handpieces.

1.8.2 Warnings and Information Symbols

REF	Catalog Number	SN	Serial Number
	Manufacturer	M	Date of Manufacture
(i)	Consult Instructions for Use	(3)	Refer to Instruction Manual/Booklet (for critical safety instruction)
\triangle	Caution	PHT	DEHP Symbol
EC REP	Authorized Representative in the European Community	C E 2797	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 Linvatec service personnel
NON STERILE	Non Sterile	STERILE	Sterile
STERILE EO	Sterile - Sterilized Using EO	STERILE R	Sterile - Sterilized Using Irradiation
3	Do Not Steam Sterilize	(M)	Do Not Sterilize
STERINZE	Do Not Resterilize	2	Do Not Reuse (for Single Use Only)
8	Do Not Use Oil		Do Not Use for Plunge Cutting
	Eye Protection Required	6	Biohazard Risk
*	Do Not Immerse	QTY	Quantity

†	Type B Applied Part	፟	Type BF Applied Part	
C UL US MEDICAL EQUIPMENT	UL Classification Mark	<i>7</i> .1	UL Recognized Components	
	Rating Fuse		Fuse Location	
~	Alternating Current		Protective Earth Ground	
A	Equipotentiality (Equipment Potential)	(((((()))	Non-lonizing Electromagnetic Radiation (RF Symbol)	
	Temperature Limitation	(X)	Humidity Limitation	
€	Atmospheric Pressure Limitation	\square	Use by Date	
I	Fragile	<u>11</u>	This Side Up	
®	Do Not Use if Package is Damaged	Ť	Keep Dry	
	Warning: Corrosive Substance	1	Warning: Electrical Hazard/High Voltage	
X	Waste Electrical and Electronic Equipment (WEEE) Symbol. Regarding European Union end-of-life of product, indicating separate collection for electrical and electronic equipment			
	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 Linvatec representative for additional information on battery disposal or recycling.			

2. SYSTEM INSTALLATION AND OPERATION

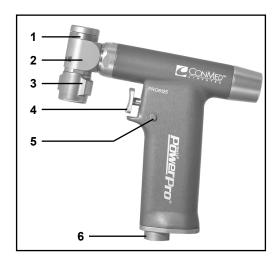
2.1 Product Description

2.1.1 PowerPro Electric II Modular Handpiece (PRO6100)



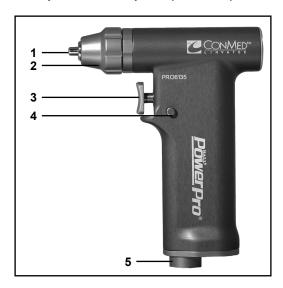
- 1. **Attachment Collet-Lock** Twist to release and remove attachments from the handpiece. It is not necessary to twist for insertion of attachment. Simply insert and push attachment to lock in place.
- 2. **Activation Trigger** Used to activate the handpiece. Depress when the safety/direction lever is in the "forward" or "reverse" position to operate.
- 3. **Safety/Direction Lever** To operate the handpiece, place in either the "forward" or "reverse" position. Place in the "safe" position prior to connecting or removing any attachment or accessory and during non-use of the handpiece.
- Handpiece Cord Receptacle The handpiece cord connects here to provide power to the handpiece. Uses the MC5057 Handpiece Cord.

2.1.2 PowerPro Electric II Oscillator Handpiece (PRO6125)



- 1. Blade Locking Collet Holds and locks the blade in place.
- 2. **Rotating Head** The rotating head gives the surgeon the ability to position the cutting blade for appropriate surgical access. The oscillator handpiece may contain one of two different rotating heads; either a 4 position, 90 ° indexing head, or an 8 position, 45° indexing head. The 4 position indexing head is no longer manufactured. To position the rotating head, grasp the rotating head, pull it out from the handpiece body, and turn it to the desired position.
- 3. **Blade Locking Knob** Rotate to open or lock the blade locking collet to insert and lock the blade securely in place.
- 4. **Activation Trigger** Depress when the safety/direction lever is in the "run" position to operate the handpiece.
- 5. **Safety/Direction Lever** To operate the handpiece, place in the "run" position. Place in the "safe" position prior to connecting or removing an accessory and during non-use of the handpiece.
- 6. **Handpiece Cord Receptacle** Connect the MC5057 Handpiece Cord here to provide power to the handpiece.

2.1.3 PowerPro Electric II Reciprocator Handpiece (PRO6135)



The PowerPro Battery Reciprocator Handpiece is designed to accept Hall 5052-058 through -061, -073, -179, -258 through -261, -273, -276 and -279 series blades. Refer to the Hall Catalog for specific blade information.

- Blade Collet Insert a blade here. Also used to rotate the blade to any of four (4) positions at 90° intervals for appropriate surgical access. Blade positioning must be done prior to locking the blade in the collet. To rotate, grasp the blade at the base of the collet and rotate to the desired position.
- 2. **Blade Locking Knob** Rotate counterclockwise to open the collet to insert a blade. Rotate clockwise to lock the blade securely in place.
- 3. **Activation Trigger** Used to activate the handpiece. Depress when the safety/direction lever is in the "run" position to operate the handpiece.
- 4. **Safety/Direction Lever** To operate the handpiece, place in the "run" position. Place in the "safe" position prior to connecting or removing an accessory and during non-use of the handpiece.
- Handpiece Cord Receptacle Connect the MC5057 Handpiece Cord here to provide power to the handpiece.

2.2 Assembly/Installation Instructions

NOTES:

- 1. The controller and connected attachment (drill or reaming) determine the speed and torque of the handpiece. (Refer to section "4.1 Product Technical Specifications").
- 2. A handpiece cord may be disconnected from one handpiece and connected to another without turning off the controller.
- 3. These handpieces will not operate by a footswitch.

2.2.1 Handpiece Cord Installation

To attach the handpiece cord:

1. Insert the handpiece cord into the cord receptacle of the handpiece. Push together until fully seated. Pull on the connector to ensure the cable is completely engaged.

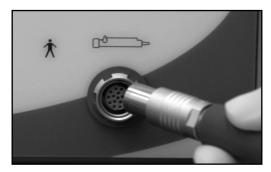


To remove the handpiece cord:

1. Press the latch on the cord and remove the cord from the handpiece.



2. With the red dot on the male end of the handpiece cord connector, insert it into the appropriate handpiece receptacle of the controller (PowerPro Controller shown).



2.2.2 Connecting and Removing Attachments to the Modular Handpiece

All attachments for the PowerPro Electric II Modular Handpiece connect/disconnect in the same manner. For more information, refer to the PowerPro Attachment Instruction Manual or the Information Insert supplied with the attachment.

To connect an attachment:

1. Place the safety/directional button/lever in the "safe" position.

NOTE: When placing the handpiece in the "safe" position, ensure the console displays the word "SAFE". If the console is in the graphical mode, ensure the "safe" symbol displays.

- 2. Orient the attachment shaft to the handpiece opening. Insert the shaft and press them until they snap together.
- 3. Pull on the attachment to ensure it is completely attached to the handpiece.

To disconnect an attachment:

- 1. Twist the attachment collet-lock.
- 2. Remove the attachment.

2.2.3 Connecting and Removing Blades to the Oscillator Handpiece

To attach a blade:

1. Place the safety/direction button in the "safe" position.

NOTE: When placing the handpiece in the "safe" position, ensure the console displays the word "SAFE". If the console is in the graphical mode, ensure the "safe" symbol displays.



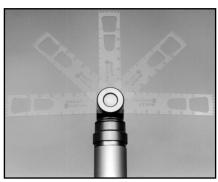
2. Rotate the blade locking knob in the direction of the arrow to the "OPEN" position. The blade locking collet will disengage.



3. Align the blade shank to the desired angle with the blade locking collet. Insert the blade.



4. Blades can be positioned 45° or 90° off the center line in either direction.



5. Rotate the blade locking knob in the opposite direction of the arrow to lock the blade into place.

WARNING: The blade locking knob must be completely closed to hold the blade firmly in place.



To remove the blade:

1. Ensure the safety/direction button is in the "safe" position.

NOTE: When placing the handpiece in the "safe" position, ensure the console displays the word "SAFE". If the console is in the graphical mode, ensure the "safe" symbol displays.



- 2. Rotate the blade locking knob to the "OPEN" position. The blade locking collet will disengage.
- 3. Remove the blade.

2.2.4 Connecting and Removing Blade to Reciprocator Handpiece

To attach a blade:

- 1. Place the safety/direction button in the "safe" position.
- 2. Rotate the blade locking knob counterclockwise to open the collet.



3. Completely insert the blade shank.





4. The rotating head may be set in any of 4 positions at 90° intervals for the appropriate surgical access. Position the blade to the desired position by grasping the blade at the base of the collet and rotating it to the desired position.



5. Rotate the blade locking knob clockwise to lock the blade into place.

WARNING: The blade locking knob must be completely closed to hold the blade firmly in place.

To remove the blade:

- 1. Ensure the safety/direction button is in the "safe" position.
- 2. Rotate the blade locking knob counterclockwise and remove the blade.

2.3 Operating Instructions

2.3.1 PowerPro Electric II Modular Handpiece (PRO6100) Operation

The PowerPro Electric II Modular handpiece operates in four individual modes:

Drill/Ream mode - used for drilling, and wire and pin driving, with a variable speed of 0-1500 rpm with all drilling, and wire and pin driving attachments, and a variable speed of 0-300 rpm with all 5:1 reaming attachments (identified with two of the same colored rings).



Oscillating Drill mode - used for drilling around soft tissue. This handpiece will operate at a variable speed of 0-750 rpm with 270° of rotation oscillation. Use only with the drilling attachments.



Tap mode - used in conjunction with a tap bit for making threads in holes for placement of screws.



Screw mode - used for driving and/or setting screws, with a variable speed of 0-250 rpm.

NOTE: Sawing and reaming attachments should not be used in the screw, tap or oscillating drill modes.

The individual operating modes are selected through the controller menu options using the handpiece cord button.

1. Place the handpiece safety/direction button in either the "forward" or "reverse" position.



2. Access the menu by pressing the handpiece cord button twice.



The controller display will indicate "**D/R**" "**Tap**" "**Scw**" "**OscDrill**" (D/R - Drill/Ream, Tape, Scw - Screw, OscDrill - Oscillating Drill). The active mode will be blinking.



If the controller is set to graphical display mode, the following symbols will display with the active mode blinking.



- Press the handpiece cord button until the desired mode is selected. The selected mode will be blinking.
- Depress the handpiece trigger to operate the handpiece and activate the selected mode, or wait 2-3 seconds for the menu to time out. The handpiece is now ready for use in the selected operating mode.

Drill/Ream Selection Operation:

NOTE: The attachment connected (drill or reaming) determines the speed and torque.



With the safety/direction button in the "forward" position, depressing the trigger operates the plandpiece in the clockwise direction as viewed from the rear of the handpiece. The speed is variably controlled by the trigger.



With the safety/direction button in the "reverse" position, depressing the trigger operates the handpiece in the counterclockwise direction as viewed from the rear of the handpiece. The speed is variably controlled by the trigger.



Tap Selection Operation:

With the safety/direction button in the "forward" position, depressing the trigger operates
the handpiece 720° clockwise, then 360° counterclockwise (2 turns CW, 1 turn CCW).
The speed is variably controlled by the trigger between 0 and 250 rpm.



2. With the safety/direction button in the "reverse" position, depressing the trigger operates the handpiece in the counterclockwise direction. The speed is variably controlled by the trigger. A brief audible beeping tone indicates "reverse" direction when the handpiece is initially activated.

Screw Selection Operation:

 With the safety/direction button in the "forward" position, depressing the trigger operates the handpiece in the clockwise direction. The speed is variably controlled by the trigger between 0 and 250 rpm. Torque is limited to 18 in-lbs.



NOTE: When the torque limit is reached, the handpiece shuts off and the controller displays "Maximum Torque". To continue, release the trigger, then press again. If the controller is set to graphical display mode, the controller will display:



2. With the safety/direction button in the "reverse" position, depressing the trigger operates the handpiece in the counterclockwise direction. The speed is variably controlled by the trigger. Full torque is available. A brief audible beeping tone indicates "reverse" direction when the handpiece is initially activated.

Oscillating Drill Selection Operation:

1. With the safety/direction button in the "forward" position, depressing the trigger operates the handpiece in the oscillate mode within a range of 270° clockwise and 270° counterclockwise with a veriable and 120° counterclockwise, with a variable speed of 0 - 750 rpm.



2. With the safety/direction button in the "reverse" position, depressing the trigger operates the handpiece in the counterclockwise direction. The speed is variably controlled by the trigger. A brief audible beeping tone indicates "reverse" direction when the handpiece is initially activated.

Reaming and sawing attachments are not designed to be used in the screw, tap or oscillating drill modes.

2.3.2 PowerPro Electric II Oscillator Handpiece (PRO6125) Operation

- 1. Position the rotating head to the desired position for the appropriate surgical access. The oscillator handpiece may contain one of two different rotating heads; either a 4 position, 90° indexing head, or an 8 position, 45° indexing head. The 4 position indexing head is no longer manufactured.
- 2. Ensure the safety/direction button is in the "safe" position.

NOTE: When placing the handpiece in the "safe" position, ensure the console displays the word "SAFE". If the console is in the graphical mode, ensure the "safe" symbol displays.

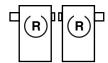
3. Pull the rotating head out and away from the handpiece body.



4. Twist the rotating head to the desired position and release the rotating head. Ensure it is locked into place and does not rotate.



- 5. Move the safety/direction button to the "run" position.
- 6. To activate the handpiece, depress the trigger.



PRECAUTION: When operating the PowerPro Electric II Oscillator Handpiece, let the saw blade do the cutting. Too much force will bind the blade which can damage the handpiece.



2.3.3 PowerPro Electric II Reciprocator Handpiece (PRO6135) Operation

- 1. Move the safety/direction button to the "run" position
- 2. To operate the handpiece, depress the trigger.

PRECAUTION: Do not operate the Reciprocator Handpiece with the collet in the open position or without a blade locked in the collet. Damage will occur.



2.4 Preoperative Functional Test

Prior to each use, perform the following preoperative functional test:

- 1. Attach power cord to handpiece.
- 2. Insert an attachment or blade into the handpiece. Gently pull on the attachment or cutting accessory to ensure it is properly seated.
- 3. Run the handpiece for less than 5 seconds to observe any abnormal noises, vibrations or heat rise.
- 4. If any operating difficulties occur, return the handpiece for service.

3. MAINTENANCE

3.1 Cleaning Information

3.1.1 Warnings, Precautions and Notes

- Follow universal precautions for protective apparel when handling and cleaning contaminated instruments.
- 2. Clean instruments within 30 minutes after use to minimize the potential of blood and debris drying.
- 3. Never clean equipment in an ultrasonic cleaner.
- 4. Always disconnect the handpiece cord prior to cleaning.
- 5. Always detach accessories from equipment prior to cleaning.
- 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. For aluminum surfaces, a neutral-pH agent should be used. To prevent corrosion, avoid contact with strong alkaline solutions (pH over 10.5) or agents containing iodine or chlorine.
- 8. Prior to using a washer/sanitizer, consult product labeling on all washer/sanitizer cleaning solutions for compatibility with aluminum. Use of a washer/sanitizer may decrease the life expectancy of the handpiece.
- 9. Refer also to section "1.5 Warnings and Precautions".

3.1.2 Manual Cleaning Instructions

- 1. Thoroughly scrub the handpiece, handpiece cord 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.
- 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.
- Manipulate all moving parts of the handpiece and attachments to ensure all debris is removed. If not, clean again until all debris is removed.
- Keeping the nose of the handpiece pointed downward, rinse under running water to remove all traces of soap. Rinse all attachments likewise.
- 5. Flush all surfaces free of tap water with distilled water to prevent metal discoloration.
- 6. Gently shake the equipment free of water and wipe the surfaces with a clean, lint-free towel.

Inspection Recommendations

- 1. Inspect Device Prior to Sterilization.
- 2. Generally, unmagnified visual inspection under good light conditions is sufficient. All parts of the devices 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. Remove and replace damaged instruments/containers.

3.1.3 Washer/Sanitizer Cleaning (Optional)

- 1. Prior to use, consult product labeling on all washer/sanitizer cleaning solutions for compatibility with aluminum.
- 2. Use of a washer/sanitizer may affect the life expectancy of the handpiece.
- 3. Load handpiece in washer/sanitizer and operate according to machine manufacturer's instructions. It is recommended to use a neutral pH cleaner.

3.2 Sterilization Information

3.2.1 Warnings, Precautions and Notes



- 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).
- Do not sterilize equipment or accessories using a STERIS system or by comparable sterilization methods.
- Do not sterilize equipment or accessories in cold sterilants like CIDEX.
- 5. Always detach accessories from equipment prior to sterilization.
- 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. The suction control valve, if one exists, must be in the fully open position during sterilization.
- 10. Attachments with collet mechanisms must be sterilized with the collet fully open.
- 11. An eight (8) minute minimum dry cycle 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.

Refer also to section "1.5 Warnings and Precautions".

3.2.2 Sterilization Instructions

Steam sterilization is safe and effective and has no contraindications for sterilizing this equipment.

- 1. Individually wrap handpiece and accessories.
- 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.

Handpieces and attachments may be processed in a pre-vacuum steam sterilizer (Steam Pre-vacuum) or in a gravity (downward) displacement sterilizer (Steam Gravity).

Minimum recommended sterilization exposure times are as follows:

Table 1: Sterilization Parameters

Sterilization Type	Minimum Temperature	Recommended Minimum Exposure Time	Minimum Dry Time
Steam Pre-vacuum	270°F (132°C)	4 minutes	8 minutes
Steam Gravity	270°F (132°C)	15 minutes	8 minutes
Steam Gravity	250°F (121°C)	40 minutes	8 minutes

3.3 Troubleshooting

Table 2: Troubleshooting Guide

Symptom	Possible Cause	Corrective Action
PowerPro handpiece does not operate.	Handpiece safety mechanism in non-operating position.	Move handpiece safety mechanism to an operating position.
	Handpiece cord not connected securely.	Securely connect handpiece cord to handpiece and controller.
	Handpiece cord/button faulty.	Replace handpiece cord.
	Handpiece faulty.	Return for service.
Error Messages		
MOTOR OVER SPEED	Handpiece, handpiece cord and/or System faulty.	Replace handpiece. If symptom is corrected, return handpiece for service.
\longrightarrow		Else, replace handpiece cord. If symptom is corrected, return faulty handpiece cord.
HP SERVICE REQUIRED		Else, return system for service.
CANNOT ID HANDPIECE		
messages display.		
CONNECT HANDPIECE	Handpiece or handpiece cord not connected securely.	Securely connect handpiece or handpiece cord.
message displays when	Handpiece, handpiece cord and/or System faulty.	Replace handpiece. If symptom is corrected, return handpiece for service.
the handpiece is already plugged into the console.		Else, replace handpiece cord. If symptom is corrected, return faulty handpiece cord.
		Else, return system for service.

3.4 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 Linvatec authorized service department is the most knowledgeable about this equipment and its accessories and will provide competent and efficient services. Service at CONMED Linvatec 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. CUSTOMER SERVICE".)

The PowerPro Electric II Handpieces shall be returned every 12 months for servicing.

4. 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 UL60601-1, CAN/CSA C22.2 No. 601.1-M90, IEC60601-1:1988 +A1:1991 +A2:1995, ES60601-1:2005 +A1: 2009 +A2: 2010, CAN/CSA C22.2 No.60601-1-1-08 and IEC60601-1:2005 +C1:2006 +C2:2009.

Tested to IEC60601-1-2:2007 and Part 15 of the FCC Rules as follows: 1) The system may not cause harmful interference: 2) The system will accept interference, including interference that might cause undesired operation. If interference occurs, separate the instruments. For more information, contact customer service.

4.1 Product Technical Specifications

4.1.1 Handpieces

Classification:	Class I (intended for connection to Class I surgical console). Type rating of applied part is dependent on surgical console.
Protection Ingress of Fluids:	IPX0 (ordinary)
Mode of Operation:	Intermittent Loading
Drill/Ream Mode:	Intermiter Edding
Drill Attachments:	
Speed Range:	0 - 1500 rpm
Torque (typical)*:	25 in-lbs.
5:1 Reaming/High Torque Attachments:	25 11 13 13 13 13 13 13 13 13 13 13 13 13
Speed Range:	0 - 300 rpm
Torque (typical)*:	125 in-lbs.
3:1 Reaming/High Torque Attachments:	
Speed Range:	0 - 500 rpm
Torque (typical)*:	75 in-lbs.
Tap Mode with Drill Attachments Only:	
Speed Range:	0 - 250 rpm
Screw Mode with Dill Attachments Only:	
Speed Range:	0 - 250 rpm
Torque forward (typical)*:	18 in-lbs.
Torque reverse (typical)*:	25 in-lbs.
Oscillating Drill Mode:	
Speed Range:	0 - 750 rpm
Oscillation Range:	0 - 270°
Height:	5.6 in. (14.2 cm)
Length:	3.8 in. (9.6 cm)
Weight:	1.3 lbs. (590 g)
Duty Cycle (once daily):	12 seconds ON, 12 seconds OFF (4x) 1 minute OFF 12 seconds ON, 12 seconds OFF (4x) 8 minute OFF 30 seconds ON, 1 minute OFF (4x) 1 minute ON

^{*}This is the torque specification using the PowerPro controller or the lower port on the Advantage controller. The torque generated using the E9000 controller or the top port on the Advantage controller will be approximately half this value shown.

PowerPro Electric II Oscillator Handpiece (PRO6125)			
Class I (intended for connection to Class I surgical console). Type rating of applied part is dependent on surgical console.			
Protection Ingress of Fluids:	IPX0 (ordinary)		
Mode of Operation: Intermittent Loading			
Speed Range:	0 - 11,000 cpm		
Oscillation Range:	4.5°		
Height:	6.5 in. (15.2 cm)		
Length: 6.1 in. (15.5 cm)			
Weight: 1.97 lbs. (894 g)			
Duty Cycle (once daily): 1 minute ON, 10 minutes OFF (3x)			

PowerPro Electric II Reciprocator Handpiece (PRO6135)			
Classification:	Class I (intended for connection to Class I surgical console). Type rating of applied part is dependent on surgical console.		
Protection Ingress of Fluids:	IPX0 (ordinary)		
Mode of Operation: Intermittent Loading			
Speed Range:	0 - 14,875 cpm		
Oscillation Range:	0.125" (3.2 mm)		
Height: 5.6 in. (14.2 cm)			
Length: 4.8 in. (12.2 cm)			
Weight: 1.4 lbs. (635 g)			
Duty Cycle (once daily):	15 seconds ON		

4.2 Product Environmental Requirements

4.2.1 Environmental Technical Specifications

Environmental Conditions	Operating	Storage and Transport
Temperature:	25°C 77°F	-20°C 158°F
Relative Humidity:	75% Non-Condensing	10% Non-Condensing
Atmospheric Pressure:	700 hPa	500 hPa

4.2.2 Electromagnetic Requirements

Refer to appropriate drive console instruction manual for electromagnetic requirements.

4.3 Handpieces, Attachments and Accessories

REF	<u>Description</u>
	A
07404	Accessories
C7104	AC Power Cord (115 VAC)
C7105	AC Power Cord (230 VAC)
MC5057	Handpiece Cord
	Attachments
PRO2029	Trinkle/AO Attachment
PRO2030	5/32" (4.0 mm) Chuck Attachment w/key
PRO2033	Hi Speed Drill Attachment
PRO2038	AO Small Attachment
PRO2039	Mini AO Attachment
PRO2040	AO Reamer Attachment
PRO2041	1/4" (6.5 mm) Chuck Attachment
PRO2042	1/4" (6.5 mm) High Torque Chuck Attachment
PRO2043	Sagittal Saw Attachment
PRO2046	Zimmer/Hudson Drill Attachment
PRO2047	Zimmer/Hudson Reamer Attachment
PRO2060	Aesculap Reamer Attachment
PRO2065	Hudson Reamer Attachment
PRO2070	AO Drill Attachment
PRO2075	Standard/Hudson Drill Attachment
PRO2080	DHS Reaming Attachment
PRO2250	1/4" (6.5 mm) Keyless Chuck Attachment
PRO2329	3:1 Trinkle Reamer Attachment
PRO2514	Radiolucent Drive Adaptor Attachment
PRO5095	PowerPro Sterilization Case
PRO6040	5:1 AO/ASIF Reamer Attachment
PRO6042	5:1 High Torque Chuck Attachment, 1/4" (6.5 mm)
PRO6045	Reciprocating Saw Attachment (Intended for use with the PowerPro PRO6100 Electric Single-trigger Handpiece)
PRO6047	5:1 Zimmer/Hudson Reamer Attachment
PRO6048	5:1 Hudson Reamer Attachment

REF	<u>Description</u>
	Attachments (Continued)
PRO6050	1/8" (3.175 mm) Keyless Chuck Attachment
PRO6060	5:1 Aesculap Reamer Attachment
PRO6128	Wire Driver Attachment
PRO6140	Pin Driver Attachment (1.8mm-4mm)
PRO7020	Multi-purpose High Speed Drill Attachment
	Handpieces
PRO6100	PowerPro Electric II Modular Handpiece
PRO6125	PowerPro Electric II Oscillator Handpiece
PRO6135	PowerPro Electric II Reciprocator Handpiece

5. 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 Linvatec Customer Service at

1-866-426-6633 or your CONMED Linvatec Sales Representative. Outside the U.S. contact your local CONMED Linvatec Representative.

Report any events involving injuries or malfunctions to the CONMED Linvatec 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 Linvatec Customer Service and provide the following information to obtain an S.R. number prior to returning any product for repair:

- · Product Number
- · Serial/Lot Number
- · Reason for Return
- · Original Invoice Number
- · Date of Purchase
- · Detailed description of the problem

CONMED Linvatec

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

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CONMED Linvatec Regulatory Product Support

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