Operations/Service Manual

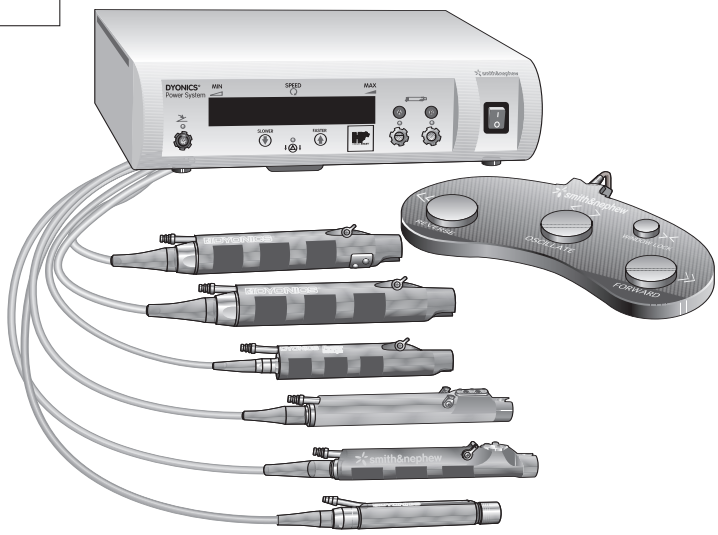
SHAR201

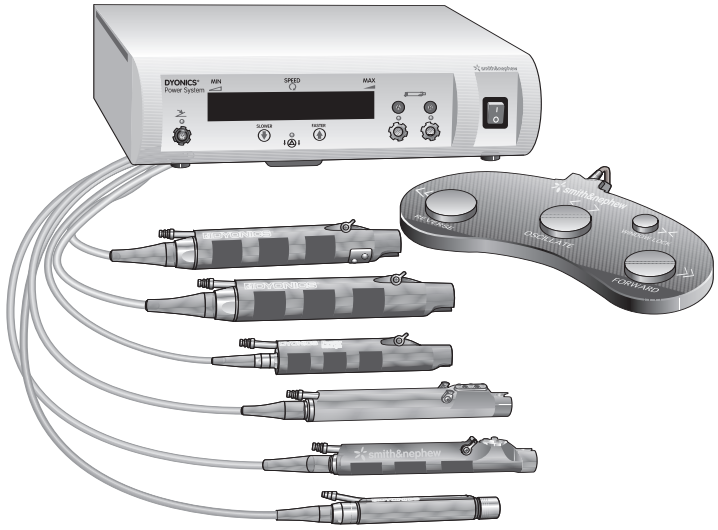
smith&nephew

Smith & Nephew DYONICS® POWER Shaver System

HERMES READY

Includes instructions for REF 7209912,
HERMES-Ready™ Shaver System





CE 0123

Glossary of Symbols

Rx ONLY	Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.
	Caution: See Instructions for Use
	Dangerous Voltage: Danger of electric shock
	Indicates explosion risk in the presence of flammable anesthetics.
	Power On Connection to the mains
	Power Off Disonnection from the mains
	Slower Decrease shaver speed
	Faster Increase shaver speed
	Handpiece Shaver motor drive unit
	Footswitch Foot pedal control
	Minimum Lowest shaver speed value
	Maximum Highest shaver speed value
	Speed Shaver rotation rate in revolutions per minute
	Bidirectional Port
	Equipment Classification— Type B Equipment
	Suction On Fluid flow through handpiece unrestricted
	Suction Off Fluid flow through handpiece blocked
	Diagnostic Display Button Displays diagnostic codes
>>	Forward Clockwise direction of shaver rotation (distal view)
<<	Reverse Counterclockwise direction of shaver rotation (distal view)
< >	Oscillate Alternating forward/reverse direction of shaver rotation
><	Blade Window Lock Adjustment of cutting window stop position
	Non-ionizing electromagnetic radiation
	Fuse
	Equipotentiality
IPX8	Watertight equipment per IEC 529
	Protective earth (ground)
	Alternating Current
NON-STERILE	Non-Sterile
REF	Catalog Number Part number or reorder number
	Date of Manufacture
SN	Serial Number
CLASSIFIED C UL US	UL Classification
CE 0123	CE mark
EC REP	European Representative
	This Way Up
	Fragile; handle with care
	Keep Dry
	Temperature Range
%	Humidity
	EU: Not for general waste

Preface

This manual provides the information you need to operate and maintain both the basic and HERMES-Ready™ Smith & Nephew DYONICS® POWER Shaver Systems. It is essential that you read and understand all the information in this manual before using or maintaining these systems.

Information that pertains **only** to the Smith & Nephew DYONICS POWER HERMES-Ready Shaver System (REF 7209912) is included where applicable.

Table of Contents

Introduction

The Smith & Nephew DYONICS® POWER Shaver System is a highly versatile surgical tool designed to meet the most demanding requirements of abrasion arthroplasty, synovectomy, and intra-articular cutting and shaving.

A variety of disposable straight and curved surgical blades and burrs can be inserted into the shaver handpiece for various surgical requirements. A footswitch is used to control blade action, selecting forward, reverse or oscillate. The control unit provides settings for the blade speed within minimum and maximum speeds, preprogrammed for each blade type. The optional Hand Control Shaver Handpiece allows the surgeon to control shaver operation without the need for a footswitch. The optional Mini-Shaver Handpiece accepts a special selection of blades designed for small-joint procedures, and for Functional Endoscopic Sinus Surgery (FESS).

Note: Blade types are not recognized by the POWERMAX OR POWERMAX ELITE Shaver Handpieces (REF 7210542, REF 72200616, and REF 72200617) when blades are inserted with the blade window aligned to the suction control lever.

Note: The Smith & Nephew Ultra Series curved blades and the Ultra Series TURBOWHISKER® blade may be used in all Smith & Nephew shaver handpieces. Standard curved blades and the standard TURBOWHISKER blade will not fit Smith & Nephew DYONICS UltraLight Handpieces.

The Smith & Nephew DYONICS POWER Shaver System features many performance and ease-of-use advantages, including:

- Intuitive front panel display and controls provide an immediate understanding and control of system performance.
- The system automatically detects the blade type in use and sets the operating parameters accordingly.
- When you change blades, Blade Family Recall automatically returns to the previous speed settings in Forward/Reverse and Oscillate modes (blade types are not recognized by the UltraLight Handpiece).
- Speed Shift offers the ability to alternate between user-defined, preset low and high speeds by simply depressing and holding the reverse or forward buttons on the handpiece, respectively (Hand Control Shaver Handpieces REF 7205354, REF 7209891, REF 72200616, and REF 7210542).
- The low profile footswitch enables more comfortable control of the system over a sustained period.
- Blade Window Lock, which can be set from the control unit, footswitch or hand control shaver handpieces, determines the stop position of the inner blade relative to the opening in the outer blade.
- Optional HERMES® Digital O.R. Control Center voice command and/or touch screen control.
- The optional Hand Control Shaver Handpieces (REF 7205354, REF 7209891, REF 72200616, and REF 7210542) feature push button controls that can be used instead of the footswitch controls.
- A latch button on the blade collar ejects the blade for faster, easier blade changes.
- A suction lever mounted on the handpiece, which operates from fully opened to fully closed, allows manual control over outflow.
- Front panel connectors for the footswitch and the handpiece are field replaceable.

HERMES-Ready™ System Information

The Smith & Nephew DYONICS® POWER HERMES-Ready Shaver System is configured to be connected to the HERMES® Digital O.R. Control Center via the bidirectional (HERMES-Ready) port, which uses an RS-232 serial communications protocol. When connected, the system functions may be accessed by direct voice commands or by manual use of a touch screen control.

It is recommended that the physician and support personnel are thoroughly familiar with the setup and operation of the HERMES Digital O.R. Control Center. Please refer to the HERMES Digital O.R. Control Center Operating and Maintenance Manual for the proper setup, use, and troubleshooting of the Voice Control Interface portion of that device.

When the HERMES Digital O.R. Control Center is connected and active, the function parameters of the Smith & Nephew DYONICS POWER HERMES-Ready Shaver System may alternatively be adjusted using the buttons on the front panel.

For troubleshooting or further information, please refer to your HERMES Digital O.R. Control Center Operating and Maintenance Manual.

Indications

The Smith & Nephew DYONICS POWER control unit is indicated for use, when used with appropriate procedure-specific blades, for resection of soft and osseous tissues including, but not limited to, use in large articular cavities, small articular cavities, and for Functional Endoscopic Sinus Surgery (FESS). The FESS application is limited to those small blades which are appropriate for the procedure.

Contraindications

Smith & Nephew DYONICS Shavers and Blades should not be used with patients exhibiting ankylosis, without adequate joint space or distention for arthroscopic inspection. Abrasion arthroplasty may not be effective in treating heavy patients or those with ankylosis, instability or expectations beyond the relief of pain.

Varus or valgus deformity is not of itself a contraindication in patients with a good range of motion and without gross instability or extreme malalignment (15° varus, 30° valgus).

Intracortical abrasion arthroplasty may be contraindicated in patients who do not qualify for high tibial osteotomy or total knee replacement.

Synovectomy is contraindicated when the disease has progressed beyond the phase of synovial proliferation, and advanced rheumatoid arthritis when erosion of the articular cartilage is present.

The 2.0 mm and 2.9 mm TURBOWHISKER® Blades and 2.9 mm Cutter are contraindicated for the FESS application.

Warnings

Please read this manual before using the Smith & Nephew DYONICS® POWER Shaver System. The brief operating instructions in this guide will make the system easier to use, while the recommended maintenance procedures will ensure optimal performance over years of reliable use. Of course, as with any surgical instrument, there are important health and safety considerations. These are listed below and highlighted within the text.

Upon turning the control unit to ON, and when no handpieces are plugged into channel A or B, the current software version is displayed on the front panel display window.

⚠ Warnings

- **Only Smith & Nephew DYONICS Disposable Arthroscopic Surgery Blades can be used with the Smith & Nephew DYONICS POWER Shaver System. The blades are intended for single use only. Do not resterilize. Do not lubricate blades. Discard the blades after use.**
- **Before using the shaver system for the first time, you should review all available product information. You should be experienced in arthroscopic surgery with powered instruments. Healthy articular soft tissue and cartilage can be injured by the blades. Use every available means to avoid such injury.**
- **DANGER: Risk of explosion if used in the presence of flammable anesthetics.**
- **DYONICS Disposable Arthroscopic Surgery Blades are packaged as a set. They must be used as supplied. Do not interchange blade components.**
- **Irreversible damage will result from any attempt to disassemble curved blades.**
- **Irreversible damage to burrs will result if they are run without the flow of irrigation (dry).**
- **Periodic irrigation of the tip of the burr or cutter is recommended to provide adequate cooling of the blade and to prevent accumulation of excised materials in the surgical site. Ensure that suction of 128 mmHg minimum is flowing while the instrument is running.**
- **HIGH VOLTAGE (1500 VAC) is present during dielectric strength testing. Exercise extreme caution while operating the Dielectric Strength Tester to prevent personal injury from electrical shock, or damage to the equipment. Ensure that only authorized personnel are in the test area during the tests, and that the cover is on the DYONICS POWER Control Unit before beginning the tests.**
- **Dangerous voltages are present during Leakage Current Testing. DO NOT TOUCH the control unit while power is applied.**
- **If this unit is configured as part of a system, the entire system should be tested for compliance with IEC 60601-1-1.**
- **If the leakage current of the configured system exceeds the limits of IEC 60601-1-1, install an appropriately rated UL 2601-1/ IEC 60601-1 approved isolation transformer and retest the system.**
- **The use of accessory equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:**
  - **– Use of the accessory in the patient vicinity.**
  - **– Evidence that the safety certification of the accessory has been performed in accordance with UL 2601-1/IEC 60601-1 and/or IEC 60601-1-1.**

Precautions

℞ ONLY U.S. Federal law restricts this device to sale by or on the order of a physician.

- Use of shaver blades, saw blades, burrs or accessories from a manufacturer or supplier other than Smith & Nephew or its authorized representatives may permanently damage, impede performance, or cause failure of your Smith & Nephew DYONICS® POWER Shaver System. Any such use will render any and all Smith & Nephew warranties null and void.
- Use of reprocessed, single-use shaver blades may permanently damage, impede performance, or cause failure of your DYONICS POWER Shaver System. Use of such products may render any warranties null and void.
- Do not allow the rotating portion of any blade or burr to touch any metallic object such as a cannula or arthroscope. Damage to both instruments is likely. Damage to the blade can range from a slight distortion or dulling of the blade edge to actual fracture of the tip in vivo. If such contact does occur, inspect the tip. If you find cracks, fractures or dulling, or if you have any other reason to suspect a blade is damaged, replace it immediately.
- Do not operate the handpiece in the open air for an extended period, as the lack of irrigation may cause the blade to overheat and seize.
- Excessive side-loading on the blade does not improve cutting performance and, in extreme cases, may result in wear and degradation of the inner assembly.
- Dried blood, saline, and other deposits inside the handpieces are a major cause of equipment malfunction.
- Do not sterilize or immerse the Smith & Nephew DYONICS POWER Control Unit in disinfectant.
- Do not cool the handpiece by immersing it in cold water.
- Do not connect any equipment to the serial port unless it was designed by Smith & Nephew to communicate with the shaver system control unit via this port.
- Electrical safety testing should be performed by a biomedical engineer or other qualified person.
- This equipment is designed and tested to minimize interference with other electrical equipment. However, if interference occurs with other equipment it may be corrected by one or more of the following measures:
  - Reorient or relocate this equipment, the other equipment, or both.
  - Increase the separation between the pieces of equipment.
  - Connect the pieces of equipment into different outlets or circuits.
  - Consult a biomedical engineer.
- This equipment contains electronic printed circuit assemblies. At the end of the useful life of the equipment it should be disposed of in accordance with any applicable national or institutional related policy relating to obsolete electronic equipment.
- The optional bidirectional port (HERMES-Ready™) is not a USB protocol-supported connection. Only connect the shaver system to a HERMES Digital O.R. Control Center.

The Smith & Nephew DYONICS® POWER Shaver System consists of a variety of components:

- The shaver system control unit provides for variable speed operation of the cutting tools, and displays user prompts and system diagnostic codes.
- The shaver footswitch allows you to select Forward or Reverse blade rotation, or Oscillate mode in which the blade alternates between Forward and Reverse rotation. The low profile footswitch can also be used to set Blade Window Lock.
- The shaver handpiece drives a variety of disposable surgical blades and provides manual control of suction flow. The optional Hand Control Shaver Handpiece features push-button controls for blade operation. The Mini Shaver Handpiece uses smaller blades for small-joint surgery and FESS applications.
- The optional HERMES® Digital O.R. Control Center allows alternative control of Speed up and Speed down, Blade Window Lock, and Port A or Port B selection.
- The shaver system control unit can also drive high powered arthroscopic instruments (i.e., drills, wire/pin drivers, sagittal saws), purchased separately.

Control Unit Front Panel

The control unit front panel includes system Speed Switches, Alphanumeric Display Window, Power Switch, Diagnostic Display Button, Diagnostic Indicator Light, Footswitch and Handpiece connection ports (Figures 1a and 1b).

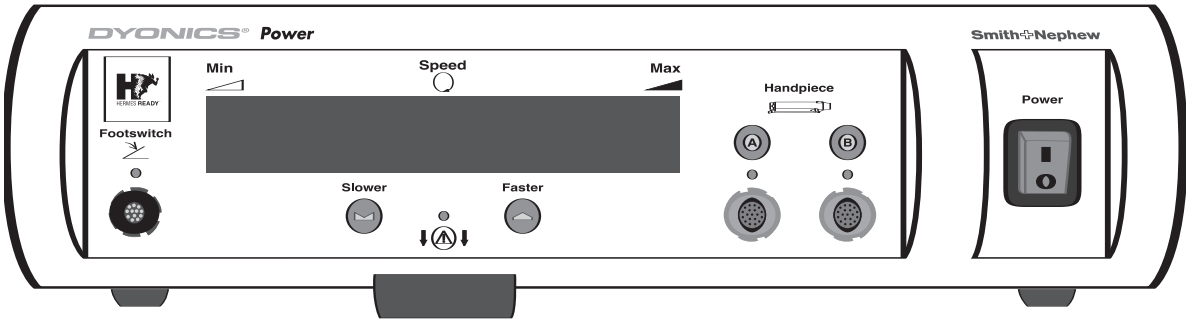


Figure 1a. Smith & Nephew DYONICS® POWER HERMES-Ready™ Control Unit Front Panel

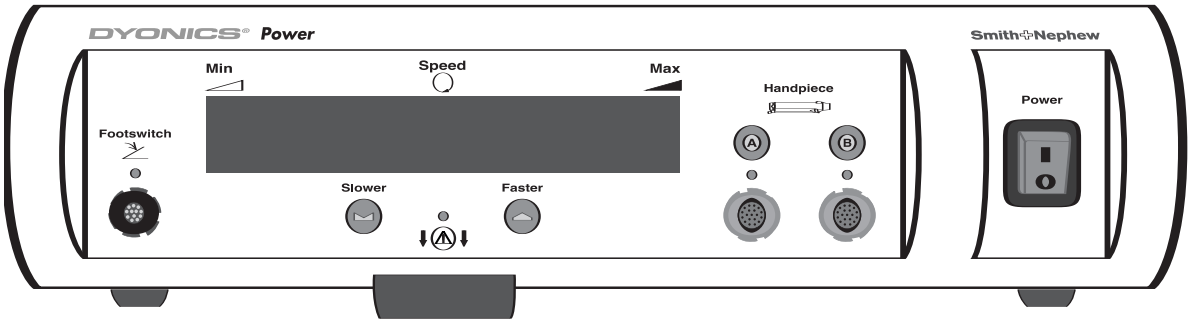


Figure 1b. Smith & Nephew DYONICS® POWER Control Unit Front Panel

Display and Control Switches

The control unit displays Minimum, Maximum and Set speeds, blade direction (Forward, Reverse, or Oscillate) and diagnostic codes. On the first line of the display, Forward (>>) and Reverse (<<) arrows indicate the blade direction. A horizontal bar graph in between the direction symbols indicates the speed of the blade relative to the range for the blade type. On the second line, from left to right, the shaver system displays minimum speed, the currently set speed, and the maximum speed. The shaver system senses the type of blade installed in the connected handpiece and sets the minimum and maximum speeds accordingly (blade types are not recognized by the UltraLight Handpiece). Set the actual blade speed using the Slower and Faster push buttons below the display.

Figures 2, 3, and 4 provide examples of how the screen displays speed and direction.

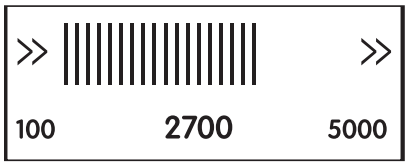


Figure 2. Forward Rotation

The (>>) symbols show the blade direction is Forward (rotating clockwise), while the bar graph indicates the blade is rotating at 2700 rpm. The minimum and maximum speeds for the blade in use are 100 rpm and 5000 rpm, respectively.

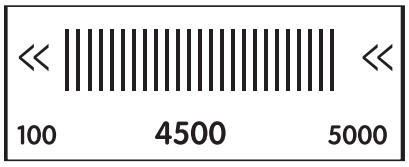


Figure 3. Reverse Rotation

The blade is rotating in Reverse (<<) at its set speed of 4500 rpm. The minimum and maximum speeds for the blade in use are 100 rpm and 5000 rpm, respectively.

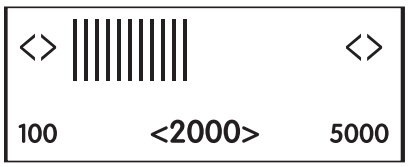


Figure 4. Oscillate Mode

The blade is oscillating (<>) between 2000 rpm Forward and 2000 rpm Reverse. The blade rotates in one direction until it reaches the set speed. It then stops, changes direction and accelerates to the set speed, at which point it will stop and reverse direction again.

System Components (continued)

Blade Family Recall

Note: Blade types are not recognized by the UltraLight Handpiece.

Blade Family Recall ensures that the last settings (Forward, Reverse, and Oscillate modes) for a blade "family" (i.e., straight, curved, and burrs) become the default the next time that family of blades is used, even after the unit is turned OFF.

- **Mode:** The last mode of operation (Forward, Reverse, and Oscillate) for each family is also remembered.
- **Reset:** The factory defaults may be reset by depressing and holding the Diagnostic Display Button (⚠) on the front panel while, at the same time, turning the power ON.

When the shaver system detects a condition that requires attention, an indicator light on the front panel is illuminated. When the Diagnostic

Display Button (⚠) located below the red indicator light is pressed, the system displays one or more diagnostic codes. A slide-out diagnostic tray below the control unit front panel provides detailed information about diagnostic codes. (See "Troubleshooting" for additional information.) Green indicator lights located above the footswitch and handpiece connectors flash to indicate a condition pertinent to the affected connector.

The speed selection buttons are directly below the display, Slower on the left and Faster on the right. Press these buttons to increase or decrease the most recently set speed within the minimum and maximum speeds for the blade type.

Power Switch

The rocker switch on the right side is the power ON/OFF switch for the entire system. The switch is illuminated when the system is ON.

Note: If system is turned off for any reason, wait at least 15 seconds before turning power back on.

Front Panel Connection Ports

There are three connection ports on the front panel: Footswitch on the left, and two Handpiece connection ports on the right. The buttons above each handpiece connection port (marked A and B) allow selection of the handpiece connected to that channel.

When a channel is selected the light above the connection port is on.

Control Unit Rear Panel

There are two connection ports and a ground terminal on the rear panel (Figures 5a and 5b):

- The 3-prong electrical connection port allows connection of the shaver system to any 100–120/200–240 VAC, 50/60 Hz, 350 VA source using the power cord supplied with the system.

  The shaver system power supply automatically detects the local power standard and adapts the shaver system to that standard.

- The 25-pin serial connection port links the shaver system to other Smith & Nephew equipment such as the Smith & Nephew INTELIJET• Fluid Management System and the On Screen Display Module. Information on making this connection is contained in the manual for the specific equipment.

- The Equipotential Compensator Terminal permits connection of the shaver system control unit to an external grounding system.

- The optional bidirectional port (HERMES-Ready™) allows connection to a HERMES Digital O.R. Control Center. When connected, the following shaver functions can be controlled by voice and/or Pendant commands.

  - Speed up and Speed down
  - Blade Window Lock
  - Port selection, A or B

CAUTION: *Do not connect any equipment to the serial port unless it was designed by Smith & Nephew to communicate with the shaver system control unit via this port.*

CAUTION: *The optional* bidirectional port (HERMES-Ready™) *is not a USB protocol-supported connection. Only connect the shaver system to a HERMES Digital O.R. Control Center.*

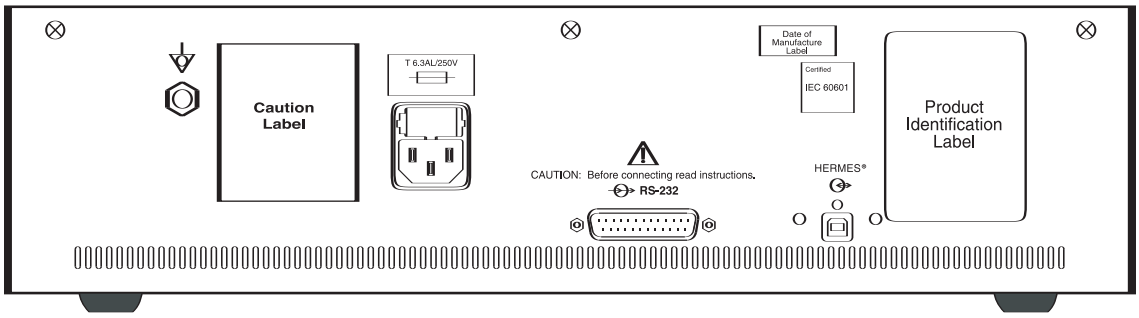


Figure 5a. Smith & Nephew DYONICS• POWER HERMES-Ready™ Control Unit Rear Panel

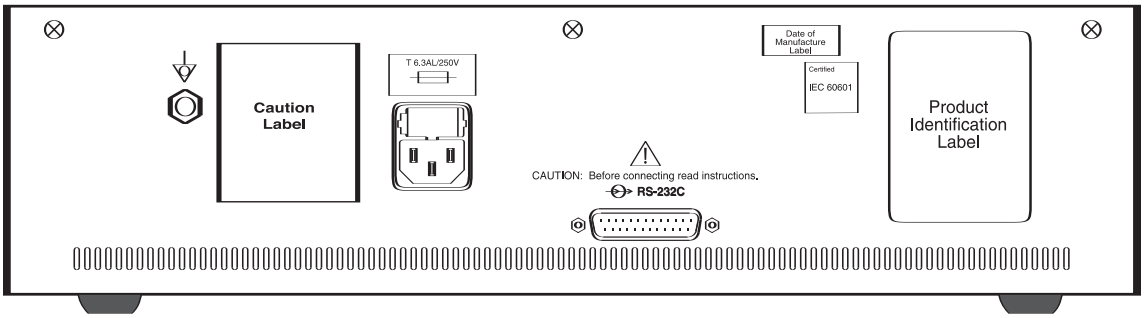


Figure 5b. Smith & Nephew DYONICS• POWER Control Unit Rear Panel

Handpieces

A variety of shaver handpieces can be used with the Smith & Nephew DYONICS® POWER Shaver System Control Unit.

The **Non-Hand Control Shaver Handpieces (REF 7205355 and REF 72200617)** are hand-held motor drives which are electrically connected to the control unit via a 10-foot (3-meter) cable and activated by a footswitch. These handpieces run a variety of DYONICS Disposable Surgical Blades. The handpieces are designed to sense the blade type installed and communicate that information to the control unit, which sets the operating parameters appropriate for the blade.

The **Hand Control Shaver Handpieces (REF 7205354, REF 7209891, REF 72200616, and REF 7210542)** features push-button controls for Forward, Reverse and Oscillate on the distal end of the handpiece. With these models you can control blade action with the handpiece as well as with the footswitch.

The **UltraLight Shaver Handpiece (REF 7205971)** is designed for optimum weight reduction and does not sense blade type. All blades will run to a maximum of 5000 rpm in Forward and Reverse mode and 3000 rpm in Oscillate mode. The Smith & Nephew Ultra Series Curved Blades and the Ultra Series TURBOWHISKER® Blade are required for curved blade applications using the UltraLight Handpiece. Standard curved blades and the standard TURBOWHISKER Blade will not operate in the UltraLight Handpiece. Footswitch operation when using the UltraLight Handpiece is the same as with the Standard Shaver Handpiece.

The **Mini Shaver Handpiece (REF 7205357)** activated by a footswitch, is designed for arthroscopic procedures on small joints and for FESS applications. This handpiece runs small blades between 100 rpm and 3500 rpm.

All handpieces can be connected to either the A channel or B channel connection port on the control unit front panel. The control unit automatically detects the type of handpiece connected. When a non-hand-control shaver is selected, the system prompts you to connect the footswitch by blinking the indicator light above the footswitch connection port.

Each handpiece model and its cable are autoclavable (see "Cleaning and Sterilization"). The handpiece cable is field replaceable on all handpieces with the exception of the Smith & Nephew DYONICS POWERMAX® Shaver Handpieces which must be returned to Smith & Nephew for replacement (see "Maintenance").

Set speeds are remembered for Forward/Reverse and Oscillate modes independently and in increments of 100 rpms.

Suction is connected to a portal on the proximal end of the handpiece and removes fluid and debris drawn through the blade window. In addition to removing fluids, the suction cools and lubricates the motor drive.

A lever on the distal end of the handpiece provides suction flow control. The lever can be adjusted from fully opened to fully closed to provide immediate manual control of the suction rate.

Cutting takes place when the blade edge rotates across the blade's outer window. The blade action alternately opens and closes the window to the suction flow. With the Blade Window Lock feature, you can set the handpiece to stop the blade in a specific position. The window can be fully opened or closed, or somewhere in between, depending on what is required for the technique.

CAUTION: *Do not operate the handpiece in the open air for an extended period, as the lack of irrigation may cause the blade to overheat and seize.*

Forward/Reverse Speed Shift

Depressing and holding the Forward or Reverse buttons on the handpiece for one second will alternately shift between two pre-set speeds (high and low) in the forward or reverse direction. High and low speeds are set by pushing the Slower or Faster buttons on the front panel of the Smith & Nephew DYONICS® POWER System Control Unit in either the slow or fast speed. If the slow and fast speeds are not set, then depressing and holding the handpiece buttons will not activate Speed Shift.

Note: Speed Shift is not applicable in Oscillate mode and does not work through any footswitch.

Footswitch

The footswitch is required when using the Standard Shaver handpiece, the UltraLight Shaver Handpiece, or the Mini Shaver Handpiece, and can be optionally used with the Hand Control Shaver Handpieces.

The shaver system uses a standard low profile footswitch (REF 7205399) to control blade action (Figure 6). The footswitch, which plugs into the connection port on the left side of the control unit front panel, has three circular buttons (REVERSE, OSCILLATE, and FORWARD) and a smaller button for blade WINDOW LOCK.

Figure 6. Smith & Nephew DYONICS® POWER System Footswitch

Depressing the FORWARD or REVERSE button causes the control unit to supply power to the handpiece to drive the blade in the direction indicated. The control unit accelerates the blade rotation until it reaches the set speed and maintains that speed until you release the button. The footswitch buttons are not throttles, but simply turn the motor drive ON or OFF in a specific direction.

Note: The footswitch does not control the Forward or Reverse Shift Speed settings.

The OSCILLATE button causes the control unit to send alternate forward and reverse commands to the handpiece. The control unit reverses direction when the blade rotation reaches the set speed. The control unit continues the alternating signals until you remove your foot from the pedal.

Blade Window Lock

Blade Window Lock sets the stop position of the inner blade relative to the opening at the top of the outer blade. Each time you press the WINDOW LOCK button, the blade rotates clockwise to a new stop position. Blade WINDOW LOCK can also be set by simultaneously pressing the Slower and Faster buttons on the shaver control unit, or by pressing and holding the Oscillate button on the Hand Control Shaver Handpieces.

Two optional footswitch models are available for use with the shaver system:

- The Accelerator Footswitch (REF 7205397) allows the Forward, Reverse and Oscillate buttons to control speed as well as blade direction.
- The Pedal Style Footswitch (REF 7205396) features two foot pedals to control blade action.

Smith & Nephew DYONICS Powered Instruments

The Smith & Nephew DYONICS POWER Shaver System provides the convenient capability to drive powered instrumentation (i.e., drill/wire drivers, sagittal saw, etc.) as well as a selection of associated blades and drill bits when purchased separately. If these items have been purchased, please read the Smith & Nephew DYONICS Powered Instruments Addendum. The addendum is located at the end of this manual.

Setting up the Shaver System for use in a Surgical Procedure

WARNING – Danger: Risk of explosion if used in the presence of flammable anesthetics.

1. Place the control unit on the instrument cart and plug the unit power cord into the rear panel connection port and a grounded AC power source.

   The control unit power supply automatically detects the local power standard and sets the unit to convert the supplied voltage.

2. Push the power switch to the ON (|) position.

   The control unit performs a status check and then displays a welcome message including the software version. The footswitch and handpiece connector lights blink, prompting connection of the system components.

3. Connect the shaver handpiece cable to the channel A or channel B front panel connection port.

   Push-on: The shaver handpiece cable connector has a locking sleeve which holds a protective cap. Pull the sleeve back to remove the cap. Orient the handpiece cable plug by aligning the red dots on the plug and the panel. Push the plug into the connection port and release the locking sleeve. The handpiece cable is fully engaged when the red dots are almost touching.

   Twist-on: Unscrew protective cap. Orient the handpiece cable plug by aligning the red dots on the plug and the panel. The handpiece cable is fully engaged when the red dots are almost touching.

   The system automatically selects channel A upon power up. If a handpiece is connected to channel B, you must press the channel B button to select it. If handpieces are connected to both channels, press the channel A or channel B button to select a handpiece.

   If the connected handpiece is the Hand Control Shaver Handpiece, the footswitch indicator light stops blinking. However, you can still connect the footswitch and control the shaver by foot.

4. Plug the footswitch cable into the connection port on the left side of the control unit front panel using the same insertion method as the handpiece connection.

5. Check the control unit display. When there is no blade in the connected handpiece, the control unit displays the speed range for a standard straight blade (100 rpm to 5000 rpm). The default set speed is 2000 rpm and the directional arrows indicate that the handpiece motor is stopped (><).

6. Press the Forward button on the footswitch to confirm shaver operation.

   The control unit bar graph will show the motor accelerating to 2000 rpm, while the directional arrows will indicate forward rotation (>>). The handpiece motor action can be observed by looking inside the distal end of the handpiece.

7. Verify Reverse and Oscillate modes.

8. Connect the suction by sliding the suction tubing onto the outflow portal on the proximal end of the handpiece.

WARNING: Before using the shaver system for the first time, review all available product information. You should be experienced in arthroscopic surgery with powered instruments. Healthy articular soft tissue and cartilage can be injured by the blades. Use every available means to avoid such injury.

WARNING: Only Smith & Nephew DYONICS• Disposable Arthroscopic Surgery Blades can be used with the Smith & Nephew DYONICS POWER Shaver System. The blades are intended for single use only. Do not resterilize. Do not lubricate blades. Discard the blades after use.

1. Verify that the handpiece and its cable are sterile.
2. Check to ensure that the blades and burrs required for the procedure are available.

Blade Motor Control

The button controls on the footswitch allow selection of three cutting actions: Forward (clockwise rotation), Reverse, and Oscillate.

With the standard Low Profile Footswitch (REF 7205399), the blade rotates in the direction specified, accelerates to the set speed and continues until you release the footswitch button.

With the Accelerator Footswitch (REF 7205397), the blade accelerates in the selected direction until it reaches set speed for the blade type. Speed can be decreased and then increased by varying foot pressure.

To activate the Hand Control Shaver Handpiece (REF 7205354, REF 7209891, REF 72200616, and REF 7210542), press and release the Forward, Reverse or Oscillate button. The blade will operate in the selected mode until any button is pressed, which will stop the motor. Press another button to restart or change direction.

Suction Control

The shaver handpiece has a suction flow control lever on the distal end of the handpiece which enables manual control outflow (Figure 7). The lever can be set anywhere between fully open and fully closed positions.

Standard Shaver Handpiece

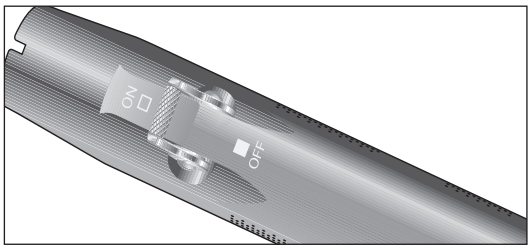


Figure 7. Suction Lever on the Standard Shaver Handpiece

1. Push lever toward blade to increase outflow.
2. Move lever away from blade to decrease outflow.

POWERMAX° Shaver Handpiece

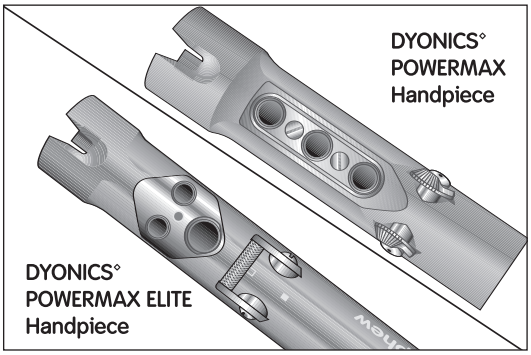


Figure 8. Suction levers on the POWERMAX• Handpieces

1. Push lever toward blade to increase outflow.
2. Move lever away from blade to decrease outflow.

Mini Shaver Handpiece

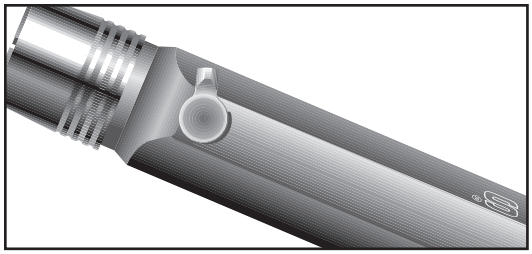


Figure 9. Suction Lever on the Mini Shaver Handpiece

The lever on the Mini Shaver Handpiece rotates to the left and the right (Figure 9).

1. For maximum flow, position the lever so that it is in line with the handpiece.
2. To reduce flow, rotate the lever away from the center position.

⚠ WARNINGS

- Smith & Nephew DYONICS• Disposable Arthroscopic Surgery Blades are packaged as a set. They must be used as supplied. Do not interchange blade components.
- Irreversible damage will result from any attempt to disassemble curved blades.
- Irreversible damage to burrs will result if they are run without the flow of irrigation (dry).

Blade Selection

All Smith & Nephew DYONICS Disposable Arthroscopic Surgery Blades have been extensively tested for safety and performance. Based on these tests, shaver blade speed ranges have been preset in the control unit (Table 1).

Tissue cutting performance has been determined at various speeds for each blade. This information indicates that Oscillate mode is more efficient for cutting soft tissue (Figure 10), while Forward mode is more efficient for cutting hard, osseous tissue (Figure 11).

Note: All blade speeds can be set in increments of 100 rpm in Forward/Reverse mode.

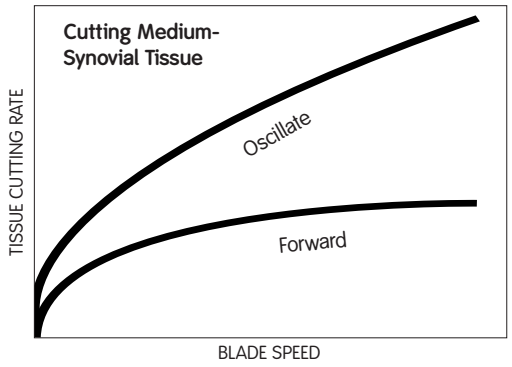


Figure 10. Cutting Efficiency with Soft Tissue

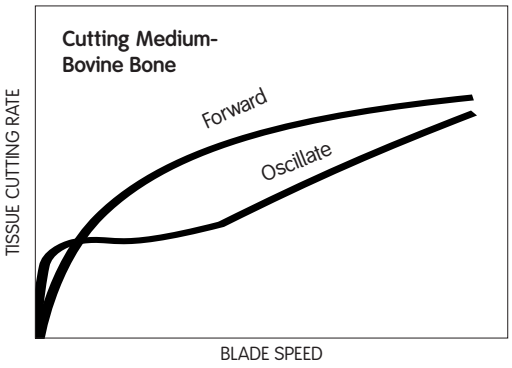


Figure 11. Cutting Efficiency with Osseous Tissue

Table 1. Programmed Blade Speeds

Blade Type	Default Set Speed	v3.0 Minimum	Maximum	Blade Direction
	2000	100	5000*	Forward/Reverse
Straight Blades	2000	500	3000	Oscillate
	2000	100	5000	Forward/Reverse
Curved Blades	2000	500	3000	Oscillate
Ultra Series Curved	2000	100	5000	Forward/Reverse
Blades	2000	500	3000	Oscillate
Burrs and	4000	500	8000†	Forward/Reverse
Series 3000 Blades	2000	500	3000	Oscillate
	2000	100	3500	Forward/Reverse
Mini Blades	1000	500	3000	Oscillate

* Excluding Smith & Nephew TURBOWHISKER• Blades (REF 7205316) which run to a maximum of 3000 rpm.
† Excluding Smith & Nephew HELICUT• Blades (REF 7205727), which run to a maximum of 5000 rpm.

When no blade is installed in the selected shaver handpiece, the control unit displays the default speed range and set speeds for straight blades.

Installing a Blade in the Shaver Handpiece

1. Remove the blade from the sterile package and insert the collar into the handpiece.

   Note: The Smith & Nephew POWERMAX◆ and POWERMAX ELITE Shaver Handpiece (REF 7210542, REF 72200616, and REF 72200617) allows for shaver blades to be inserted with the blade window aligned to the suction control lever or 180° opposite the lever.

   To insert a blade, orient the handpiece so that you can see the key slot (A) on the handpiece and the key (B) on the blade (Figure 12). Insert the blade into the handpiece so that the key goes into the slot. The key should be pushed in proximally as far as possible for a positive lock.

   Note that the cutting aperture is aligned 180° opposite the ridge on the handpiece. This feature allows for tactile orientation of the handpiece.

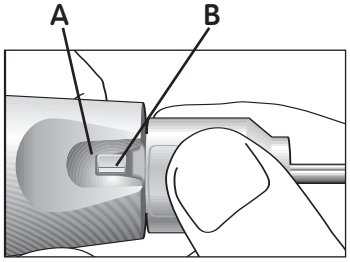


Figure 12. Key Slot (A) and Key (B)

   The Mini Shaver has a locking sleeve on the blade end of the handpiece. The Mini Motor Blades have four ridges that key the blade to one of four positions, that is, the blade window faces up, down, right or left relative to the handpiece.

   Pull the locking sleeve back, insert the blade and release the sleeve when the blade clicks into position.

   The system automatically detects the blade type (blade types are not recognized by the UltraLight Handpiece) and displays the appropriate speeds (Table 1). The blade is properly engaged when the control units displays the minimum and maximum speeds.

2. Press the Forward button and observe the blade action to verify that it is properly installed.

   The first time a blade type is installed in the handpiece during a procedure, the system sets the blade speed to a default value. Speed can then be increased or decreased when the blade types are changed during the procedure. The system recalls the speed last set for the blade type (this feature does not function when using the UltraLight Handpiece).

Blade Window Lock

Press the WINDOW LOCK button on the footswitch to rotate the blade until it is in the best stopping position for the procedure.

You can also rotate the blade to a new stop position by simultaneously pressing the Slower and Faster buttons on the control unit front panel. If you are using a Hand Control Shaver Handpiece, press and hold the Oscillate button down to advance the blade, and release the button when the blade is in the desired position.

If Blade Window Lock does not operate in a smooth, quiet manner, reset software by switching the handpiece channels or by turning the control unit power OFF and then ON.

⚠ **WARNING:** Periodic irrigation of the tip of the burr or cutter is recommended to provide adequate cooling of the blade and to prevent accumulation of excised materials in the surgical site. Ensure that suction of 128 mmHg minimum is provided while the instrument is running.

Blade Speed

When the Smith & Nephew DYONICS• POWER Shaver System is turned on, the system sets the default blade speeds for all blade types (blade types are not recognized by the UltraLight Handpiece). As blades and set speeds are changed, the system recalls the speed set for each blade type.

Blade Family Recall

Note: Blade types are not recognized by the UltraLight Handpiece.

To set Forward and Reverse Blade Speed:

1. On the handpiece, press the Forward or Reverse button.
2. On the control unit, press the Faster button once to increase the speed by one increment. Press the Slower button once to decrease the speed by one increment.
3. Press and hold a speed control button to quickly make large adjustments to set speed.

Note: To set blade speeds to factory settings, press and hold Diagnostic Display button (⏃) on the front panel of control unit while turning power to ON.

To set Oscillate Speed:

1. On the handpiece, press the Oscillate button.
2. Press the Slower or Faster buttons once to decrease or increase the speed by 100 rpm.

   There are 26 Oscillate speed settings in 100 rpm increments starting with the minimum speed.

CAUTION: *Do not allow the rotating portion of any blade or burr to touch any metallic object such as a cannula or arthroscope. Damage to both instruments is likely. Damage to the blade can range from a slight distortion or dulling of the blade edge to actual fracture of the tip in vivo. If such contact does occur, inspect the tip. If you find cracks, fractures or dulling, or if you have any other reason to suspect a blade is damaged, replace it immediately.*

CAUTION: *Do not operate the handpiece in the open air for an extended period, as the lack of irrigation may cause the blade to overheat and seize.*

CAUTION: *Excessive side-loading on the blade does not improve cutting performance and, in extreme cases, may result in wear and degradation of the inner assembly.*

IEC 60601-1-1 Compliant System Configuration for Smith & Nephew DYONICS◇ POWER Shaver System

Figure 13 indicates a system configuration that complies with IEC 60601-1-1 requirements.

WARNING: If this unit is configured as part of a system, the entire system should be tested for compliance with IEC 60601-1-1.

- **If the leakage current of the configured system exceeds the limits of IEC 60601-1-1, install an appropriately rated UL 2601-1/IEC 60601-1 approved isolation transformer and retest the system.**
- **The use of accessory equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:**
  – Use of the accessory in the patient vicinity.
  – Evidence that the safety certification of the accessory has been performed in accordance with UL 2601-1/IEC 60601-1 and/or IEC 60601-1-1.

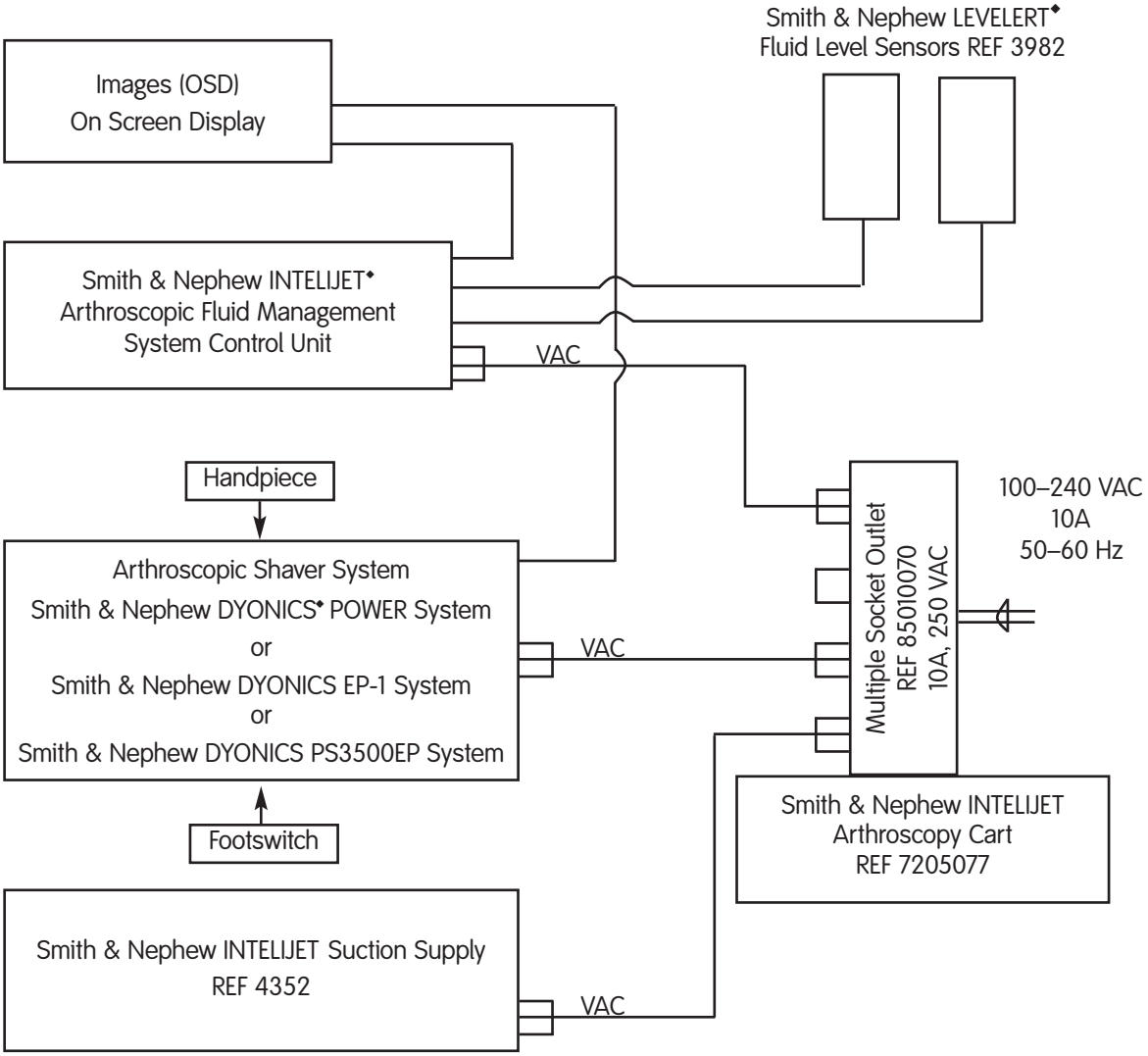


Figure 13. IEC 60601-1-1 System Configuration

IEC 60601-1-1 Compliant System Configuration for Smith & Nephew DYONICS◇ POWER HERMES-Ready™ Shaver System

Figure 14 indicates a system configuration that complies with IEC 60601-1-1 requirements.

WARNING: If this unit is configured as part of a system, the entire system should be tested for compliance with IEC 60601-1-1.

- **If the leakage current of the configured system exceeds the limits of IEC 60601-1-1, install an appropriately rated UL 2601-1/IEC 60601-1 approved isolation transformer and retest the system.**
- **The use of accessory equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:**
  – Use of the accessory in the patient vicinity.
  – Evidence that the safety certification of the accessory has been performed in accordance with UL 2601-1/IEC 60601-1 and/or IEC 60601-1-1.

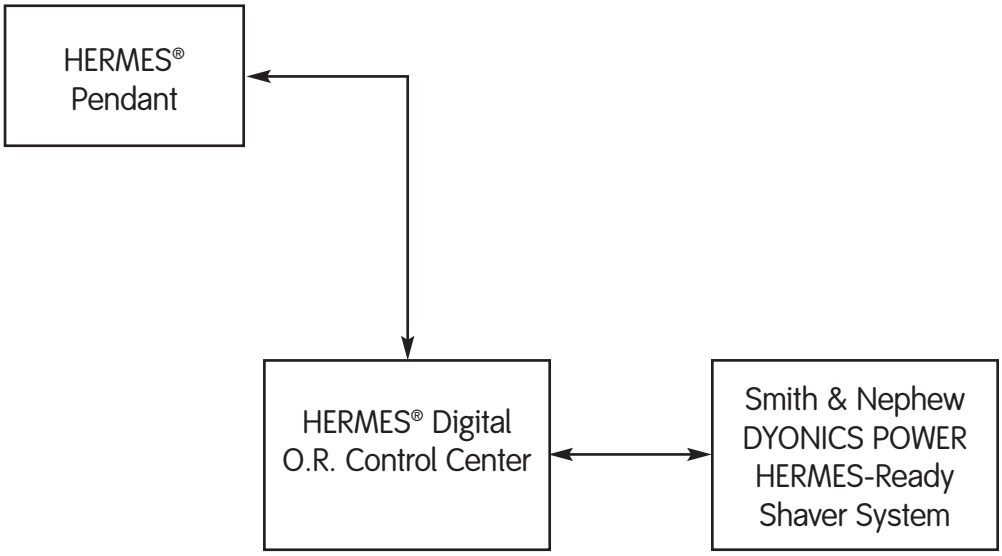


Figure 14. IEC 60601-1-1 System Configuration for HERMES-Ready™ Control Unit

Handpieces

Follow this procedure after each operation to sterilize the handpiece:

CAUTION: *Dried blood, saline, and other deposits inside the handpieces are a major cause of equipment malfunction.*

1. Dispose of the blade(s) and tube set(s) used during the operation following standard procedures for disposal of biohazardous waste.

WARNING: Only Smith & Nephew DYONICS® Disposable Arthroscopic Surgery Blades can be used with the Smith & Nephew DYONICS POWER Shaver System. The blades are intended for single use only. Do not resterilize. Do not lubricate blades. Discard the blades after use.

2. Disconnect the powered instrument cable from the front panel by pulling back the locking collar on the connector, then disengaging it from the control unit. Do not disconnect the cable from the handpiece.
3. Place the protective cap on the connector end of the cable, and set the suction control lever to fully open.
4. Clean the handpiece thoroughly with soapy water. The handpiece may be immersed.
5. Clean the drain tube with a brush. Rinse the unit thoroughly with water. Do not use saline or solvents such as alcohol or acetone.
6. Sterilize the handpiece using one of the following methods:

   First choice: Steam, pre-vacuum, wrapped at 270° F to 275° F (132° C to 134° C) for 4 minutes.

   Second choice: Steam, gravity method, wrapped at 270° F to 275° F (132° C to 134° C) for 10 minutes.

CAUTION: *DO NOT cool the handpiece by immersing it in cold water.*

Control Unit and Footswitch Cleaning

Follow this procedure after each operation to clean the control unit and the footswitch:

1. Disconnect the control unit from the electrical source.
2. Wipe the control unit with a clean damp cloth and mild germicide or isopropyl alcohol.

CAUTION: *DO NOT sterilize or immerse the Smith & Nephew DYONICS POWER Control Unit in disinfectant.*

3. Wipe the footswitch and footswitch cable with a clean damp cloth.

   The low profile, button-style footswitches (REF 7205397 and REF 7205399) and pedal footswitch (REF 7205396) are watertight per IPX8.

Maintenance

Electrical Interference

CAUTION: *This equipment is designed and tested to minimize interference with other electrical equipment. However, if interference occurs with other equipment it may be corrected by one or more of the following measures:*

- *Reorient or relocate this equipment, the other equipment, or both.*
- *Increase the separation between the pieces of equipment.*
- *Connect the pieces of equipment into different outlets or circuits.*
- *Consult a biomedical engineer.*

Environmental Protection

CAUTION: *This equipment contains electronic printed circuit assemblies. At the end of the useful life of the equipment it should be disposed of in accordance with any applicable national or institutional related policy relating to obsolete electronic equipment.*

Preventative Maintenance

Recommended Annual Performance Checks

Smith & Nephew recommends that Dielectric Strength, Earth Leakage Current, and Protective Earth Testing be performed annually to assure continued compliance with applicable safety requirements. These tests should be conducted in accordance with specifications UL 2601-1/ IEC 60601-1.

CAUTION: *Electrical safety testing should be performed by a biomedical engineer or other qualified person.*

Service

The following are replacement parts for Smith & Nephew DYONICS® POWER Shaver Systems:

REF	Description
7205393	Handpiece Connection port, Control Unit
7205394	Footswitch Connection port, Control Unit
7208207	Shaver Handpiece Cable
7209071	UltraLight Shaver Handpiece Cable
7208208	Mini Shaver Handpiece Cable
4428	Shaver Control Unit Power Cord
8100305	Rear Panel Fuse: Replace with 6.3 amp/250V Quick Acting

Note: There are no user-serviceable components, adjustments, or repairs other than those specifically described in this manual.

Note: Prior to installing replacement handpiece or footswitch connection ports, clean all mating surfaces with isopropyl alcohol.

Service Philosophy

There are no user serviceable components inside the Smith & Nephew DYONICS POWER Shaver System. Repairs and adjustments are to be performed only by Smith & Nephew authorized service centers.

If service becomes necessary, call your authorized Smith & Nephew Customer Service representative prior to returning the device and request a Return Authorization (RA) number. Your representative can also explain the available Service Replacement and Repair Programs.

Service items should be carefully repackaged and returned post-paid to Smith & Nephew. Your Smith & Nephew customer service representative can provide additional instructions.

Note: Product returned that is found to have been serviced by an unauthorized third party repair facility and/or sterilized with a sterilization method other than one approved by Smith & Nephew will incur additional costs, regardless of warranty status.

It is not necessary to include accessory items (i.e., power cords, etc.) when returning a device for service.

Handpiece Cables

The handpiece cable replacement is supplied in a kit with a set of installation instructions. An adjustable wrench and alcohol wipes will be required to clean the connector pins.

Note: The Smith & Nephew DYONICS® POWERMAX® and POWERMAX ELITE Shaver Handpieces (REF 7209891, REF 72200616, REF 72200617, and REF 7210542) do not have field-replaceable cables, and must be returned to Smith & Nephew for replacement.

To replace the handpiece cable

1. Using a standard adjustable wrench, loosen the stainless steel locking nut at the proximal end of the handpiece. Remove the nut from the old cable.
2. Ensure that the REF number on the replacement cord is identical to the REF number on the old cord.
3. Clean and dry the connector pins and baseplate of the handpiece.
4. Carefully align the pins to the sockets on the replacement cord and join the two pieces.
5. Tighten the locking nut securely to ensure a good electrical ground connection.
6. Connect the handpiece to the control unit and verify operation of the handpiece using the new power cable.

   Note: The Mini cable and the UltraLight cable are very similar. The threads on the locking nut are different for each type of cable. If you are having difficulty, recheck to see if the REF number is correct.

Control Unit Fuses

The control unit is protected by dual, 6.3 amp/250V fuses mounted on the rear panel below the three-pronged electrical connection port, and by a single, 6.3 amp/250V fuse on the power supply board.

If the control unit fails to power up when properly connected to a 100–120/200–240 VAC, 50/60 Hz, 350 VA, AC power source, check the fuses in the rear panel.

To change the rear panel fuses:

1. Disconnect the unit from the power source.
2. Locate the fuse tray just above the power cord socket and just below the fuse label (refer to the rear panel view of REF 7205841 or 7209912).
3. Use a slotted screwdriver to press the tabs on either side of the fuse holder in, toward the center of the tray.
4. Slide the fuse tray out.
5. Replace the fuses with 6.3 amp/250V Quick Acting fuses (REF 8100305).
6. Insert the tray into the holder until the tabs click into place.
7. Reapply power to the unit.

Note: Blown fuses usually indicate a short circuit or a failed component. Make sure components are properly interconnected. If the problem persists, contact Smith & Nephew Customer Service for troubleshooting assistance.

Do not open the cover of the unit. Smith & Nephew will not be liable for repair or replacement if damage occurs.

CAUTION: *Electrical safety testing should be performed by a biomedical engineer or other qualified person.*

Electrical Safety Checks

Three safety tests are conducted on each unit during factory acceptance testing:

- Dielectric Strength Test
- Ground Continuity Test
- Leakage Current Test

The following equipment is required for these tests:

- Dielectric Strength Tester (Refer to UL 2601 and IEC 60601-1)
- High-Current-Sourcing Ground Resistance Tester (Hypatia Model 307 or equivalent)
- Dale Safety Analyzer LT544D-20
  Dale Safety Analyzer LT544D-20E
  with IEC 60601 Load (or equivalent)
  See "Leakage Current Test".

⚠ **WARNING:** HIGH VOLTAGE (1500 VAC) is present during dielectric strength testing. Exercise extreme caution while operating the Dielectric Strength Tester to prevent personal injury from electrical shock, or damage to the equipment. Ensure that only authorized personnel are in the test area during the tests, and that the cover is on the Smith & Nephew DYONICS® POWER Control Unit before beginning the tests.

Dielectric Strength Test

To perform a Dielectric Strength Test:

1. Turn the Dielectric Strength Tester (DST) off and set the voltage knob to the minimum. Separate the DST test lead clips by at least one inch. DO NOT allow the clips to contact any personnel or conductive surface.
2. Connect the DST to its power source.
3. Turn the DST on.
4. Switch the test button ON, then gradually adjust the voltage up to 1500 VAC to verify that the tester is working properly.

   ⚠ **WARNING:** This step applies 1500 VAC to the DST leads.
5. Turn the DST's voltage adjustment down to its minimum setting. Turn the DST off.
6. Connect the output (or "high voltage") line from the DST to the control unit power cable's hot and neutral pins. Connect the DST input ("return" or "ground") line to the control unit cable's ground pin.
7. Make sure that the DST's voltage setting is adjusted to its minimum value. Turn the control unit power switch ON.
8. Turn the DST ON. Turn the TEST switch ON.
9. Increase the voltage adjustment on the DST until 1500 VAC is reached.
10. Allow the test to run for at least one second.

    The control unit passes if the Dielectric Strength alarm does not sound.
11. If the unit fails the 1500 VAC test, contact Smith & Nephew Customer Service.

Ground Test

To conduct the Ground Test:

1. Connect the power cord to the control unit receptacle. DO NOT connect the other end of the AC cord.
2. Connect the ground resistance tester to 115 VAC. Ensure that the power switch is OFF.
3. Connect the tester's leads to the control unit power cord ground pin (round) and the center cover mounting screw.
4. Turn the tester on. It should read less than 0.1 Ω (ohm).

Leakage Current Test 115 VAC with Power ON

Test Equipment: Dale Model LT544D-20 Safety Analyzer (115 VAC) or equivalent. See Table 2.

1. Connect safety analyzer to 115 VAC/60 Hz power line.
2. Connect the unit under test (UUT) to a safety analyzer receptacle.
3. Connect the chassis cable from the safety analyzer to the UUT chassis (ground stud).
4. Turn UUT power ON.
5. Connect MDU (REF 7205354) to CH-A on the control unit.
6. Set the safety analyzer switches to the position indicated in Table 2 and record the test measurement.

Note: Press any hand control button on the MDU to run the motor at its default speed during EACH NEUTRAL-CLOSED leakage test.

Note: Ensure to pause in the center OFF position, for approximately one second, before changing from NORMAL to REVERSE or REVERSE to NORMAL polarity.

Leakage Current Test 230 VAC with Power ON

Test Equipment: Dale Model LT544D-20E Safety Analyzer (230VAC) or equivalent; Stancor Autotransformer P-8689 or Equivalent. See Table 3.

1. Connect safety analyzer to 230 VAC 50/60 Hz power source.
2. Connect the unit under test to a safety analyzer receptacle.
3. Connect the chassis cable from the safety analyzer to the UUT chassis (ground stud).
4. Turn UUT power ON.
5. Connect MDU (REF 7205354) to CH-A on the control unit.
6. Set the safety analyzer switches to the position indicated in Table 3 and record test measurements.

Note: Press any hand control button on the MDU to run the motor at its default speed during EACH NEUTRAL-CLOSED leakage test.

WARNING: Dangerous voltages are present during Leakage Current Testing. **DO NOT TOUCH** the control unit while power is applied.

Table 2. 115 VAC 60 Hz Leakage Current Test

Neutral Switch	Polarity Switch	Leakage Switch	Function Switch	Measurement	Specification	Pass / Fail	
CLOSED	NORMAL	CENTER	LINE V	VAC	108 to 132 VAC	P	F
CLOSED	NORMAL	CENTER	LEAKAGE I	µA	≤ 85 µA	P	F
CLOSED	NORMAL	*CHASSIS*	LEAKAGE I	µA	≤ 425 µA	P	F
CLOSED	REVERSED	CENTER	LEAKAGE I	µA	≤ 85 µA	P	F
CLOSED	REVERSED	*CHASSIS*	LEAKAGE I	µA	≤ 425 µA	P	F
OPEN	REVERSED	CENTER	LEAKAGE I	µA	≤ 425 µA	P	F
OPEN	NORMAL	CENTER	LEAKAGE I	µA	≤ 425 µA	P	F

Table 3. 230 VAC 50/60 Hz Leakage Current Test

Neutral Switch	Polarity Switch	Leakage Switch	Function Switch	Measurement	Specification	Pass / Fail	
CLOSED	NORMAL	CENTER	LINE V	VAC	216 to 264 VAC	P	F
CLOSED	NORMAL	CENTER	LEAKAGE I	µA	≤ 85 µA	P	F
CLOSED	NORMAL	*CHASSIS*	LEAKAGE I	µA	≤ 425 µA	P	F
CLOSED	REVERSED	CENTER	LEAKAGE I	µA	≤ 85 µA	P	F
CLOSED	REVERSED	*CHASSIS*	LEAKAGE I	µA	≤ 425 µA	P	F
OPEN	REVERSED	CENTER	LEAKAGE I	µA	≤ 425 µA	P	F
OPEN	NORMAL	CENTER	LEAKAGE I	µA	≤ 425 µA	P	F

Indicate if measurement was made using 50 Hz or 60 Hz power input.
Circle response: 50 Hz 60 Hz

During system operation, the Smith & Nephew DYONICS® POWER Shaver System runs a concurrent diagnostic routine in the background, checking inputs from the attached components. When the system detects a condition that requires attention, a red indicator in the center of the front panel lights up. In many cases, the system will continue to operate normally, but occasionally allowable blade speed will be reduced.

To follow up on fault indicator:

1. Press the Diagnostic Display Button (⚠) below the red indicator light. The system displays one or more diagnostic codes (Figure 15).

Figure 15. Diagnostic Code in Display Window

2. Slide out the diagnostic tray under the control unit for detailed information about diagnostic codes.
3. Take the recommended remedial action. Do not attempt any repair when the remedy is **Call for Service**.
4. When the problem is resolved, return to system operation by activating the handpiece. Blade speeds will be returned to previous user-defined settings.

   The Diagnostic Codes and the recommended actions are listed in Table 2.

   Note: If system is turned off for any reason, wait at least 15 seconds before turning power back on.

Troubleshooting (continued)

Table 4. Smith & Nephew DYONICS® POWER Shaver System Diagnostic Codes

Error Code	Explanation	Remedial Action
E: 1	Handpiece Missing	Make sure the shaver handpiece is properly installed in Channel A or Channel B. Try another handpiece.
E: 2	Footswitch Missing	Check the footswitch plug for proper installation.
E: 3	Handpiece Not Identified	Check to make sure that the handpiece cable is properly connected to the front panel. Switch handpiece to the other channel. Try another handpiece.
E: 4	Hand Control Failure	Operate motor with footswitch. Try another handpiece.
E: 5	Bus Fault	Continue to operate at reduced default speeds. Try another handpiece.
E: 6	Motor Stalled	Check blade. Check for rotation of handpiece drive shaft. Try another handpiece.
E: 7	Serial Communication Errors	Check connection to RS-232 port on rear panel.
E: 9	Faulty Footswitch Connector	Check the footswitch plug for proper installation. Refer to manual for replacement instructions.
E: 10	Faulty Handpiece Connector	Check handpiece connection. Switch handpiece tothe other channel. Refer to manual for replacement instructions.
E: 11	ROM Failure	Do not use. Call for Service.
E: 12	RAM Failure	Do not use. Call for Service.
E: 13	SFR Failure	Do not use. Call for Service.
E: 14	ADC Failure	Do not use. Call for Service.

Smith & Nephew DYONICS◇ POWER Shaver System Control Units

REF 7205841 (v3.0)
REF 7209912 (HERMES-Ready™)

Dimensions

16.4" wide by 13.5" deep x 4.7" high
(41.6 x 34.3 x 11.9 cm)

Weight

11.25 lbs (5.1 kg)

Power

100–120/200–240 VAC, 50/60 Hz, 350 VA

Classification

CISPR 11, Group 1, Class B

Front Panel

Power ON/OFF

Illuminated rocker switch

System Display Window

20 character by two-line alphanumeric display which indicates minimum, maximum and set speeds for installed blade type; horizontal bar graph of blade speed relative to range; blade direction; diagnostic information.

Motor Speed Switches

Two momentary push switches for increasing and decreasing speed settings.

Channel Select Switch

Two momentary push switches for selecting handpiece channel.

Fault Indicator

Momentary push switch for displaying diagnostic codes.

Connection Ports

Separate Channel A and Channel B connection ports for the handpiece cable. Footswitch cable connection port for foot control.

Rear Panel

Cooling

None required

AC Power

Detachable cord with a three-pin hospital-grade connector. Power input circuit automatically detects AC power standard.

Access Ports

RS-232 DB-25 interface for the Smith & Nephew INTELJET◆ System and On Screen Display (OSD).

Ground Terminal

Equipotential Compensator Terminal

Fuses

Two 6.3 amp/250 V Quick Acting fuses
(REF 8100305).

Bidirectional Port (HERMES-Ready®) (Optional)

RS-232 communication port with USB Type B receptacle. (Not a USB protocol-supported connection. Connect to HERMES Digital O.R. Control Center only.)

Environmental Conditions:

Transport & Storage

Temperature : -20 to +60 degree C

Humidity: 20 to 90% (no condensation allowed)

Atmos. Pressure: 500 - 1060hPa

Use:

Temperature : 10 to 40 degree C

Humidity: 30 to 70% (no condensation allowed)

Atmos. Pressure: 700 - 1060hPa

Smith & Nephew DYONICS POWER Shaver System Handpieces

Standard Shaver Handpiece (REF 7205355)

Length

7.7" (19.4 cm)

Weight

16.2 oz (453 grams)

Equipped with 10-foot (3-meter) autoclavable, replaceable power cord.

Suction Control Lever

Hand Control Shaver Handpiece (REF 7205354)

Standard Shaver Handpiece with push-button motor controls: Forward, Reverse, Oscillate, and Blade Window Lock.

Suction Control Lever

Smith & Nephew DYONICS◇ POWERMAX◇ Shaver Handpiece (REF 7209891)

Length

7.1" (18.0 cm)

Weight

7.5 oz (223 grams)

Lightweight Handpiece with push-button motor controls: Forward, Reverse, Oscillate, and Blade Window Lock.

Equipped with 10 foot (3 meter) autoclavable power cord (**Not** field replaceable).

Suction Control Lever

Smith & Nephew DYONICS◇ POWERMAX◇ and POWERMAX ELITE Shaver Handpieces (REF 7210542, REF 72200616, REF 7220617)

Length

7.1" (18.0 cm)

Weight

7.5 oz (223 grams)

Lightweight Handpiece with push-button motor controls: Forward, Reverse, Oscillate, and Blade Window Lock.

Equipped with 10 foot (3 meter) autoclavable power cord (**Not** field replaceable).

Suction Control Lever

Allows for shaver blades to be inserted with the blade window aligned to the suction control lever or 180° opposite the lever.

UltraLight Handpiece (REF 7205971)

Length

7.5" (19 cm)

Weight

12.40 oz (319 grams)

Equipped with 10 foot (3 meter) autoclavable, replaceable power cord.

Suction Control Lever

Mini Shaver Handpiece (REF 7205357)

Length

5.25" (13.3 cm)

Weight

5.5 oz. (154 grams)

Equipped with 10 foot (3 meter) autoclavable, replaceable power cord.

Suction Control Lever

Handpiece date of manufacture: Date is on box label. Serial number is also traceable to the date of manufacture by Smith & Nephew.

Powered Instrumentation

Pistol Grip Drill (REF 7205785)

Length

3.7" (9.45 cm)

Weight

1 lb 5.6 oz (606.6 grams)

Pistol Grip Drill with variable-speed trigger, trigger "SAFE" position, Reverse and Forward direction selector, and accessory release button.

Inline Sagittal Saw (REF 7205786)

Length

7.3" (18.5 cm)

Weight

9.0 oz (255 grams)

Inline Sagittal Saw with variable speed throttle and Safe/Run switch.

Sagittal Saw Module (REF 7205791) used with Pistol Grip Drill REF (7205785)

Length

3.75" (9.53 cm)

Weight

5.6 oz (159 grams)

Saggital saw module with blade release button.

High Speed Drill (REF 7209391)

Length

7.0" (17.8 cm)

Weight

9.0 oz (255 grams)

Inline High Speed Drill with variable speed throttle and Safe/Run switch.

Reciprocating Saw (REF 7209392)

Length

7.6" (19.3 cm)

Weight

9.0 oz (255 grams)

Inline Reciprocating Saw with variable speed throttle and Safe/Run switch.

Oscillating Saw (REF 7209394)

Length

8.6" (21.8 cm)

Weight

9.0 oz (255 grams)

Inline Oscillating Saw with variable speed throttle and Safe/Run switch.

Heavy-Duty Oscillating Saw (REF 7209395)

Length

8.0" (20.3 cm)

Weight

10.4 oz (295 grams)

Inline Heavy-Duty Oscillating Saw with variable speed throttle and Safe/Run switch.

Footswitches

Low Profile Footswitch (REF 7205399)

Dimensions

18.0" wide by 5.0" deep by 1.0" high
(45.7 x 12.7 x 2.54 cm)

Weight

3.95 lbs (1.8 kg)

Directional Switches

Forward, Reverse, Oscillate and Blade Window Lock

Equipped with 12 foot (3.6 meter) cord.

Optional

Accelerator Footswitch (REF 7205397)

Low profile button control.

Pedal Control Footswitch (REF 7205396)

Pedal Style.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The Smith & Nephew DYONICS® POWER and POWER HERMES-Ready™ Shaver Systems are intended for use in the electromagnetic environment specified below. The customer or the user of the Smith & Nephew DYONICS POWER or POWER HERMES-Ready Shaver System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	The Smith & Nephew DYONICS POWER and POWER HERMES-Ready Shaver Systems use RF energy only for their internal functions. Therefore, the RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Smith & Nephew DYONICS POWER and POWER HERMES-Ready Shaver Systems are suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

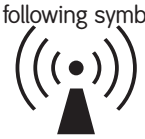
Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Smith & Nephew DYONICS® POWER and POWER HERMES-Ready™ Shaver Systems are intended for use in the electromagnetic environment specified below. The customer or the user of the Smith & Nephew DYONICS POWER or POWER HERMES-Ready Shaver Systems should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic (ESD) discharge IEC 61000-4-2	+/- 6kV contact +/- 8kV air	+/- 6kV contact +/- 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	+/- 2kV for power supply lines +/- 1kV for input /output lines	+/- 2kV for power supply lines +/- 1kV for input /output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1kV differential mode +/- 2kV common mode	+/- 1kV differential mode +/- 2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Smith & Nephew DYONICS POWER and POWER HERMES-Ready Shaver System requires continued operation during power mains interruptions, it is recommended that the Smith & Nephew DYONICS POWER and POWER HERMES-Ready Shaver System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	The power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity (continued)

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Smith & Nephew DYONICS® POWER and POWER HERMES-Ready™ Shaver Systems are intended for use in the electromagnetic environment specified below. The customer or the user of the Smith & Nephew DYONICS POWER or POWER HERMES-Ready Shaver System should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Smith & Nephew DYONICS POWER and POWER HERMES-Ready Shaver Systems, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 MHz	3 Vrms	**Recommended separation distance** $d = 1.2\sqrt{p}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{p}$ 80 MHz to 800 MHz $d = 2.3\sqrt{p}$ 800 MHz to 2.5 GHz Where p is the maximum output power rating of the transmitter in watts (w) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio, (cellular/cordless) telephones, land mobile radios, amateur radios, AM and FM radio broadcasts, and TV broadcasts cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Smith & Nephew DYONICS POWER and POWER HERMES-Ready Shaver Systems are used exceeds the applicable RF compliance level above, the Smith & Nephew DYONICS POWER and POWER HERMES-Ready Shaver Systems should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Smith & Nephew DYONICS POWER and POWER HERMES-Ready Shaver Systems.

[b] Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.

Guidance and Manufacturer's Declaration
Guidance for Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the Smith & Nephew DYONICS® POWER and POWER HERMES-Ready™ Shaver Systems.

The Smith & Nephew DYONICS POWER and POWER HERMES-Ready Shaver Systems are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of Smith & Nephew DYONICS POWER and POWER HERMES-Ready Shaver Systems can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Smith & Nephew DYONICS POWER and POWER HERMES-Ready Shaver Systems as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter W	**Separation distance according to frequency of transmitter M**		
	150 KHz to 80 MHz $d = 1.2\sqrt{p}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{p}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{p}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (w) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Smith & Nephew DYONICS◇ Powered Instruments Addendum

This addendum provides the information you need to operate and maintain the Smith & Nephew DYONICS Endoscopic Powered Instrumentation. It is essential that you read and understand all the information in this addendum before using or maintaining the equipment.

Table of Contents

Figures

Introduction

Prior to use, these instructions should be read and understood by all operating room staff handling the equipment. As with any surgical instrument, there are important health and safety considerations. These are listed below and highlighted within the text.

Note: All personnel should become familiar with the powered instruments before they are set up for use in any procedure. Personnel in-serviced should include, but not be limited to central processing personnel, members of the surgical team, and the biomedical engineering department.

The following powered instruments can be used with the Smith & Nephew DYONICS® POWER Control Unit (REF 7205841):

Powered Instruments

REF 7205785	Pistol Grip Drill
REF 7205791	Sagittal Saw Module
REF 7209391	High Speed Drill
REF 7205786	Inline Sagittal Saw
REF 7209392	Reciprocating Saw
REF 7209394	Oscillating Saw
REF 7209395	Heavy Duty Oscillating Saw
REF 7205789	Wire Driver
REF 7205790	Pin Driver

Note: All above powered instruments require the Smith & Nephew DYONICS Powered Instrument Cable, REF 7205788 (sold seperately).

Accessories

REF 7205792	Jacobs Chuck—5/32"
REF 7205794	Jacobs Chuck—1/4"
REF 7205793	Keyless Jacobs Chuck—1/8"
REF 7205795	Keyless Jacobs Chuck—1/4"
REF 7209393	Synthes Chuck
REF 7205788	Powered Instrument cable
REF 7205787	Sterilization Tray

Saw Blades—STERILE, with Markings:

REF	W (mm)	L (mm)	T (mm)	Depth Stop	Titanium Nitride Finish
7205806	4.5	25.5	0.4	NO	NO
7205803	5.8	25.4	0.4	NO	NO
7205805	9.4	25.5	0.4	NO	NO
7205804*	9.4	25.5	0.4	NO	NO
7205802	19.1	25.4	0.4	NO	NO
7205896	5.8	25.4	0.4	NO	YES
7205897*	9.4	25.5	0.4	NO	YES
7205895	19.1	25.4	0.4	NO	YES

* Fine Teeth

Saw Blades—STERILE, NO Markings:

REF	W (mm)	L (mm)	T (mm)	Depth Stop	Titanium Nitride Finish
7205807	9.4	10.0	0.4	10 mm	YES
7205808	9.4	12.0	0.4	12 mm	YES
7205809	9.4	15.0	0.4	15 mm	YES
7205898	9.4	10.0	0.4	10 mm	NO
7205899	9.4	12.0	0.4	12 mm	NO
7205900	9.4	15.0	0.4	15 mm	NO

Indications

The DYONICS Pistol Grip Drill, High Speed Drill, wire/pin drivers, Inline Sagittal Saw, Sagittal Saw Module, Reciprocating Saw, Oscillating Saw, Heavy Duty Oscillating Saw, and other accessories, when used in conjunction with the Smith & Nephew DYONICS POWER Control Unit (REF 7205841), are indicated for drilling and cutting bone.

⚠ Warnings

- **Smith & Nephew powered instruments are shipped non sterile. They must be sterilized before the first use. They must be cleaned and sterilized before every subsequent use.**
- **It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to the use of these devices.**
- **Read these instructions completely prior to use.**
- **After use, Smith & Nephew powered instruments may be a potential biohazard and should be handled in accordance with accepted medical practice and applicable local and national requirements.**
- **Prior to use, all system components should be inspected and operated to determine if there is product damage and/or malfunction. Do not use if product is damaged and/or malfunctioning. Contact Smith & Nephew Endoscopy Customer Service or your local representative.**
- **Ensure that sagittal saw blades, wires, pins, and drill bits, are not dull or bent, and that they lock correctly into the powered instrument.**
- **Inspect and test the powered instrument before the first and each subsequent use:**
  - **Inspect the powered instrument for damage, corrosion, or excessive wear.**
  - **Ensure that when the safety lock of a powered instrument is on "SAFE" it prevents activation of the motor. Ensure that the activation trigger and throttle lever do not stick in the full "RUN" position.**
- **Prior to installing or removing sagittal saw blades, drill bits, or any other attachments, ensure that the powered instrument is in "SAFE" mode.**
- **The safety lock should be in the "SAFE" position when either the powered instrument is not in use or when inserting or removing modules, blades, drill bits or any other attachments.**
- **The Sagittal Saw and the Pistol Grip Drill WILL BE ACTIVATED via the footswitch even when in the "SAFE" position.**
- **The trigger/throttle lever is active as the powered instrument cable is being plugged into either the powered instrument or the control unit. Keep the powered instruments in the "SAFE" mode to avoid inadvertent activation. Footswitches will activate the Pistol Grip Drill and Sagittal Saw even when they are in the "SAFE" position.**
- **Avoid using a sagittal saw blade as a lever. Excessive force may lead to fracture of the saw blade.**
- **If using a footswitch, ensure that the footswitch is not accidentally activated while inserting the blade.**
- **If burrs of insufficient diameter are used, they may slip under load resulting in rapid overheating, or they may eject at great velocity causing harm to patients or personnel.**
- **When operating the saw, be careful to retract and protect the patient's tissue near the locking collar. Pinching the tissue between the collar and the body of the instrument may cause a severe bruise or friction burn.**

Precautions

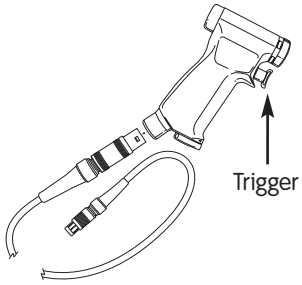
- ℞ ONLY U.S. Federal law restricts this device to sale by or on the order of a physician.
- Standard operating conditions eventually may cause overheating or total failure of the instrument. With the blade or drill bit attached, test run the powered instrument in the sterile field for three 10-second intervals, checking for any indication of irregular speed, noise, excessive heat, or vibration. Irregular grinding noises may indicate impending failure or overheating of the powered instrument.
- Periodically monitor the temperature of the nose section. The temperature should not rise above 115° F and should not become uncomfortable to touch with gloved fingers.
- Only Smith & Nephew Sagittal Saw Blades are compatible with the Sagittal Saw Module or the Inline Sagittal Saw.

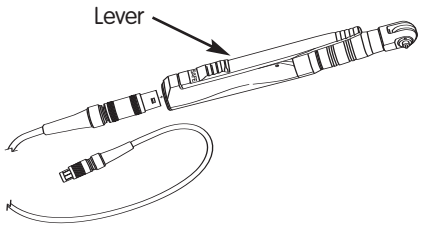
Precautions (continued)

- Dull saw blades are major contributors to problems with powered instruments. They require the surgeon to exert greater force, which increases stress, heat, and wear on gears, bearings, and other mechanisms. Use of excessive force also increases the risk of thermal necrosis and overheating of powered instruments.
- Dried blood, saline, and other deposits inside the handpieces are a major cause of equipment malfunction.
- It is difficult to determine when a drill bit is dull. Simply counting the number of uses is not adequate. While certain procedures cause relatively little wear on a drill bit, other procedures, especially where the drill bit scrapes against metal templates or retractors, produce immediate wear or damage to the drill bit.
- Collet must be in full "LOCK" position to prevent overheating of the powered instruments.
- DO NOT run a drill without a burr inserted or the drill will overheat.
- When using long or extra-long burrs, use a corresponding long or extra-long burr guard to prevent whipping or shattering of burrs.
- Make certain that all burrs used with the High Speed Drill are designed for use in orthopedic or oral surgery. The burr shaft diameter must be within the range of .0919" (2.3 mm) to .0928" (2.4 mm).
- Ensure that cable connector pins are dry at both ends prior to use.
- DO NOT use an ultrasonic cleaner or any other automated/sterilizing cleaning equipment. Ultrasonic cleaning can damage the bearings in the powered instruments, potentially resulting in overheating or seizure.
- DO NOT lubricate or oil the powered instruments. Lubrication will clog the motor and prevent it from starting. Also take special precautions to avoid the use of cleaners which contain lubricants.
- Soaking powered instrument cables may cause damage or corrosion to the connector pins inside, the control unit, and/or the powered instruments themselves.
- The powered instrument cable should be sterilized in the same manner and location as the Pistol Grip Drill and Sagittal Saw.
- DO NOT run powered instruments while warm. Cool by exposure to room temperature.
- DO NOT immerse powered instruments in saline, disinfectant, or any other liquid. DO NOT immerse powered instruments in liquid to cool.
- DO NOT process powered instruments in a washer/sterilizer. The washer cycle will damage the motor and other internal components.
- Electrical safety testing should be performed by a biomedical engineer or other qualified person.
- This equipment is designed and tested to minimize interference with other electrical equipment. However, if interference occurs with other equipment, it may be corrected by one or more of the following measures:
  - Reorient or relocate this equipment, the other equipment, or both.
  - Increase the separation between the pieces of equipment.
  - Connect the pieces of equipment into different outlets or circuits.
  - Consult a biomedical engineer.
- This equipment contains electronic printed circuit assemblies. At the end of the useful life of the equipment it should be disposed of in accordance with any applicable national or institutional related policy relating to obsolete electronic equipment.

Pistol Grip Drill (REF 7205785) or Inline Sagittal Saw (REF 7205786)

The Inline Sagittal Saw is activated by pressing a throttle lever and the Pistol Grip Drill is activated by pressing a trigger. These are variable speed devices and can also be activated via a footswitch. The throttle lever and trigger have two positions: "SAFE" and "RUN." When in the "SAFE" position, the throttle lever or trigger is inactive.



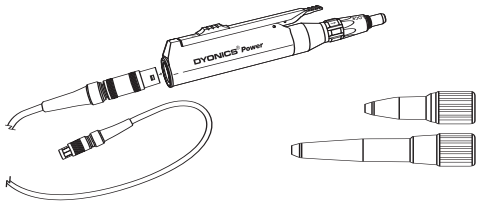


⚠ **WARNING:** The safety lock should be in the "SAFE" position when either instrument is not in use or when inserting or removing modules, blades, drill bits or any other attachments.

⚠ **WARNING:** The Inline Sagittal Saw and the Pistol Grip Drill WILL BE ACTIVATED via the footswitch even when in the "SAFE" position.

High Speed Drill (REF 7209391)

The High Speed Drill is supplied with a built-in, medium-length burr guard; a collet brush (REF 8106858); and a drill nose shield.



⚠ **WARNING:** If burrs of insufficient diameter are used, they may slip under load resulting in rapid overheating, or they may eject at great velocity causing harm to patients or personnel.

⚠ **WARNING:** When operating the high speed drill, be careful to retract and protect the patient's tissue near the locking collar. Pinching the tissue between the collar and the body of the drill may cause a severe bruise or friction burn.

CAUTION: *The blade hole must be seated over the indexing pin. If it is not, the head will be damaged when the locking lever is closed. DO NOT force the locking lever if excessive resistance is felt.*

CAUTION: *Collet must be in full "LOCK" position to prevent overheating of the instrument.*

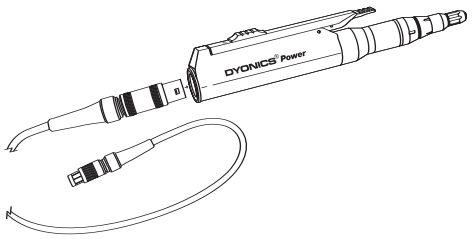
CAUTION: *DO NOT run drill without a burr or drill will overheat.*

CAUTION: *When using long or extra-long burrs, use a corresponding long or extra-long burr guard to prevent whipping or shattering of burrs.*

CAUTION: *Make certain that all burrs used with this drill are designed for use in orthopedic or oral surgery. The burr shaft diameter must be within the range of .0919" (2.3 mm) to .0928" (2.4 mm).*

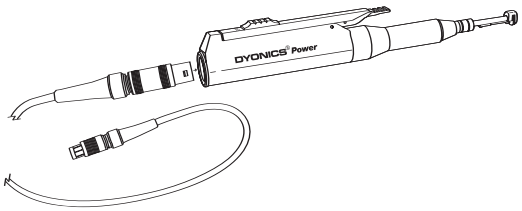
Reciprocating Saw (REF 7209392)

The Reciprocating Saw accepts a variety of specially-designed thin blades and rasps.



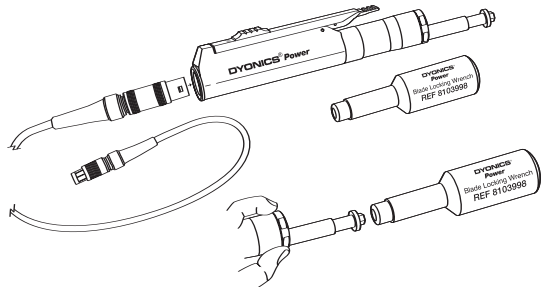
Oscillating Saw (REF 7209394)

The Oscillating Saw accepts extra-thin saw blades in either a straight or bent style.



Heavy Duty Oscillating Saw (REF 7209395)

The Heavy Duty Oscillating Saw accepts a wide selection of straight, bent, and arc cutting blades. This Heavy Duty Saw is supplied with a required Locking Wrench (REF 8103998).



Sagittal Saw Blades, Drill Bits, and K-wires

The Pistol Grip Drill will accept a Sagittal Saw Module, a variety of drill chucks, a Pin Driver, or a K-Wire Driver. The Inline Sagittal Saw will accept a variety of saw blades. All carbide or stainless steel saw blades and drill bits have sharp, precision ground teeth or flutes designed to provide optimum cutting performance.

Note: Use a new sagittal saw blade or drill bit for each procedure. Using disposable accessories reduces powered instrument wear, improves surgical cutting, and ensures quality patient care.

CAUTION: *Dull saw blades are major contributors to problems with powered instruments. They require the surgeon to exert greater force, which increases stress, heat, and wear on gears, bearings, and other mechanisms. Use of excessive force also increases the risk of thermal necrosis and overheating of powered instruments.*

CAUTION: *Sagittal saw blades are provided as sterile, single use products. Do not repackage or reuse sagittal saw blades.*

CAUTION: *Only Smith & Nephew sagittal saw blades are compatible with the Sagittal Saw Module or Inline Sagittal Saw.*

CAUTION: *It is difficult to determine when a drill bit is dull. Simply counting the number of uses is not adequate. While certain procedures cause relatively little wear on a drill bit, other procedures, especially where the drill bit scrapes against metal templates or retractors, produce immediate wear or damage to the drill bit.*

Foot Control

When the footswitch is plugged into the DYONICS® POWER Control Unit the green LED light (lower left corner of the control unit) is illuminated and active. All standard DYONICS footswitches will operate the DYONICS Powered Instruments. All powered instruments run in one direction when activated, except the Pistol Grip Drill, which runs in either the forward or reverse mode.

Note: If the trigger/throttle lever is active and then the footswitch is depressed, the footswitch will NOT activate. BOTH lever AND footswitch must be released for one second, and then only one depressed, to activate the powered instrument.

Note: The oscillate function from the footswitch is inoperable for the Pistol Grip Drill, High Speed Drill, Reciprocating Saw, and Inline Sagittal Saw.

⚠ **WARNING:** The trigger/throttle lever is active as the powered instrument cable is being plugged into either the powered instrument or the control unit. Keep powered instruments in the "SAFE" mode to avoid inadvertent activation. Footswitches will activate the powered instruments even when they are in the "SAFE" position.

Cutting Technique

⚠ **WARNING:** Avoid using a sagittal saw blade as a lever. Excessive force may lead to fracture of the saw blade.

CAUTION: *Avoid excessive pressure on the Inline Sagittal Saw or Sagittal Saw module when cutting. Use a light "pencil grip" and let the instrument do the work. Heavy force will rapidly wear components.*

CAUTION: *Avoid plunging and "burying" a sagittal saw blade straight into bone. This will lock the blade and prevent it from completing its stroke, damaging or possibly breaking the oscillating mechanism. Use a slight "back and forth" or "side to side" motion when cutting. This will keep the cut wide enough to permit the blade to complete its stroke and maintain speed. Continuous stalling of the motor will cause rapid heating of the powered instruments.*

CAUTION: *Take special care when making curved cuts to avoid locking the blade. Always keep the blade free to complete its stroke.*

CAUTION: *The sagittal saw blade may flex or whip at the tip when running at full speed in free air. This occurs due to the thinness of the blade which is also a key to its fast cutting ability. Always begin the cut with the throttle set for moderate speed. After establishing the cut in the bone, advance the throttle to full speed. The blade will not flex once in the bone.*

Setup and Operation

Setting-up the DYONICS® Powered Instruments for use in surgical procedures.

Note: The DYONICS Powered Instruments are designed for intermittent use. Instruments should be used for a maximum of 3 minutes of continuous operation followed by cool-down period of 40 minutes.

Normal environmental operating temperature for these devices is 10–30° C.

1. Place the DYONICS POWER Control Unit on a cart, turn power switch on front panel to the OFF position, plug the unit's power cord into the rear panel power connection port and the other end into a grounded AC power source (wall).

   Note: "OFF" position is designated by "O" and the "ON" position by "|."

2. Push the Power switch to the On "|" position.
3. Connect the powered instrument cable (REF 7205788) into either Handpiece A or B connection port on the Front Panel of the Control Unit. Select the A or B channel by pressing the A or B button on the front panel.

   CAUTION: *Ensure that cable connector pins are dry at both ends prior to use.*

   Note: Be sure to align the pins in the cable with the holes in the Control Unit connection port before inserting.

4. Firmly hold the powered instrument and insert the powered instrument cable into the cable receptacle on the instrument.

   Note: Avoid pressing the trigger, throttle lever, or footswitch while attaching the instrument cable. If this occurs, the instrument will not run until trigger or throttle lever is released for one second and then activated.

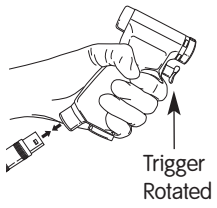
5. If using a footswitch, connect it to the footswitch connection port on the left side of the control unit front panel. Ensure that pins in cable are aligned with the holes in the connection port before inserting.

Pistol Grip Drill (REF 7205785)

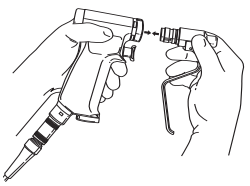
The Pistol Grip Drill is a modular device with attachments for a wire driver, pin driver, sagittal saw module, and a variety of drill chucks. The system includes a pistol grip, an automatic wire collet for K-wires up to .062" (1.6 mm), an automatic pin collect which accepts pins up to .125" (3.2 mm), and a selection of Jacobs chucks.

To insert a K-wire or Steinmann pin into the Pistol Grip Drill:

1. Attach powered instrument cable from control unit to drill receptacle and set safety lock to ON by rotating the trigger to either side.

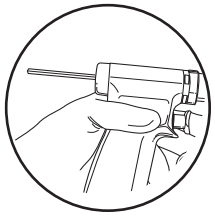


2. Snap wire or pin collet into the nose of the drill.

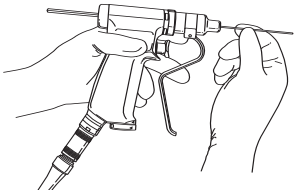


Setup and Operation (continued)

3. Screw the wire guard into the back of the drill to protect the operator from the point of the wire or pin.

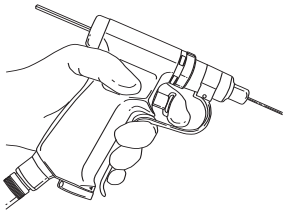


4. Insert wire or pin into the front or back of the drill.



5. Select Forward ("FWD") or Reverse ("REV") on the bottom of the pistol grip drill.

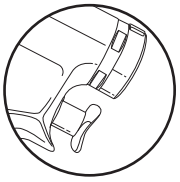
6. Move the trigger out of the "SAFE" position by rotating it straight up and down.
7. Squeeze the wire/pin advance lever and hold it down.



8. Depress the trigger to drive the wire/pin. The trigger is pressure sensitive, providing for variable speed operation.
9. To obtain additional wire or pin length, release the wire/pin advance lever and trigger, then pull back on the instrument. Squeeze the wire/pin advance lever and depress trigger to drive the wire.
10. To remove threaded wires or pins, put the drill in "Reverse," squeeze the wire/pin advance lever and then depress the trigger.
11. To release the wire or pin collet, put the trigger in the "SAFE" position.
12. Depress the release button on the top of the drill and pull the collet out.

To use the Jacobs or Synthes Chucks with the Pistol Grip Drill

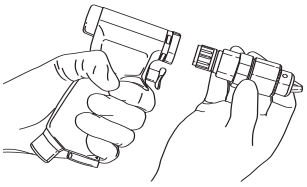
1. Set safety lock to "ON" position by rotating the trigger to either side.



⚠ **Warning:** If using a footswitch, ensure that the footswitch is not accidentally activated while inserting the blade.

2a. Jacobs Chucks:

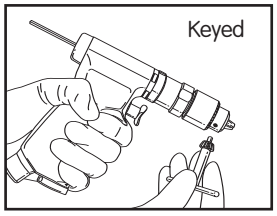
Snap Jacobs keyed or keyless chuck into nose of drill.

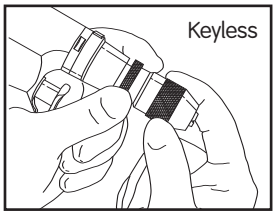


Open keyed chuck (via key)

or

keyless chuck (by rotating rings in opposite direction).

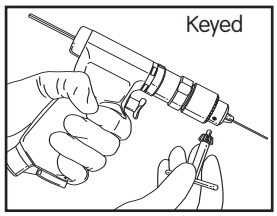


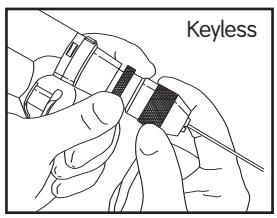


Insert drill bit, wire, or pin into nose of Jacobs chuck.

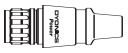
Use Jacobs chuck key to close drill bit, wire, or pin into place,

or if using keyless chuck, rotate rings in opposite direction.

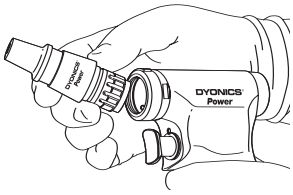




2b. Synthes Chuck:

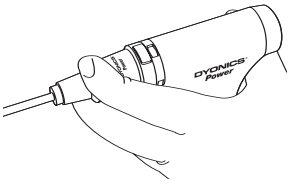


Snap the Synthes chuck into the nose of the drill.



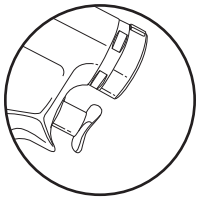
Pull back on the quick-release chuck collar and insert a drill bit, wire, or pin.

Release the collar and insure that the drill bit is fully seated.



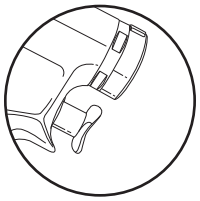
3. Select Forward ("FWD") or Reverse ("REV") on the bottom of the pistol grip drill.

4. Move the trigger out of the "SAFE" position by rotating it straight up and down.
5. Depress the trigger.

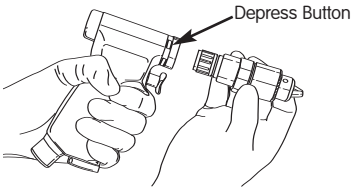


Removing the Jacobs Chucks

1. Place pistol grip drill trigger in the "SAFE" position.



2. Remove drill bit, wire, or pin.
3. Ensure trigger is in "SAFE" position, then depress release button on top of drill and pull out chuck.

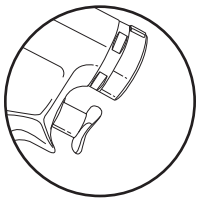


Removing the Synthes Chuck

1. To remove the Synthes chuck, put the trigger in the "SAFE" position.
2. Remove the drill bit, wire, or pin.
3. Depress the release button on top of the drill and pull the Synthes chuck out.

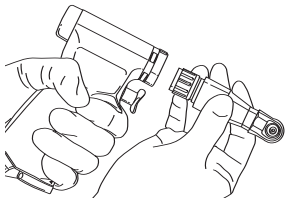
Using the Sagittal Saw Module (REF 7205791) with the Pistol Grip Drill

1. Set safety lock on the drill to "ON" by rotating the trigger to either side.

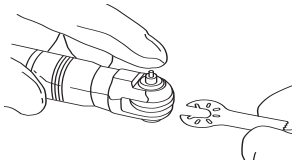


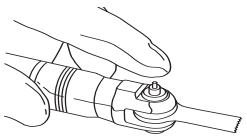
⚠ **WARNING:** If using a footswitch, ensure that the footswitch is not accidentally activated while inserting the blade.

2. Snap Sagittal Saw Module into nose of drill.

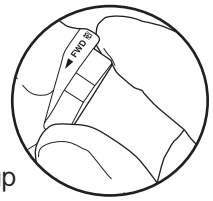


3. Press pin on the side of the module to open blade retention jaws, insert saw blade making sure that the blade is fully seated, then release pin to secure the blade.





4. Select Forward ("FWD") or Reverse ("REV") on the bottom of the pistol grip drill.
5. Move trigger from the "SAFE" position by rotating it straight up and down.



6. Depress the trigger to activate the saw.
7. To remove the blade, move trigger to the "Safe" position, then press pin to release jaws and remove blade.
8. To remove the Sagittal Saw Module from the drill, ensure trigger is in the "SAFE" position, then depress release button on top of the drill and remove the Sagittal Saw Module.

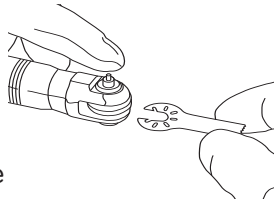
Inline Sagittal Saw (REF 7205786)

To insert a blade into the Pencil Grip Sagittal Saw:

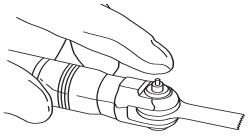
1. Move the safety lock on the throttle lever to "SAFE".

⚠ **WARNING:** If using a footswitch, ensure that the footswitch is not accidentally activated while inserting the blade.

2. Press pin on the side of the module to open blade retention jaws; insert saw blade making sure that the blade is fully seated, then release pin to secure the blade.



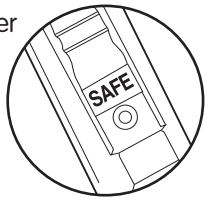
Note: The blade may be located in one of five positions.



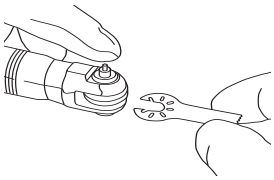
3. Move the safety lock out of the "SAFE" position.
4. Depress the throttle lever to activate the instrument.

To remove a blade from the Inline Sagittal Saw:

1. To remove the blade, return lever to the "SAFE" position.



2. Press pin to release retention jaws and remove blade.



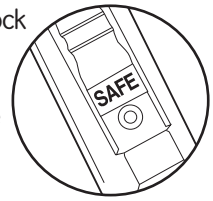
CAUTION: *Standard operating conditions eventually may cause overheating or total failure of the instrument. Periodically monitor the temperature of the nose section. The temperature should not rise above 115° F and should not become uncomfortable to touch with gloved fingers.*

High Speed Drill (REF 7209391)

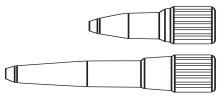
The High Speed Drill is supplied with a built-in, medium-length burr guard; a collet brush (REF 8106858); and a drill nose shield.

Inserting a burr into the High Speed Drill:

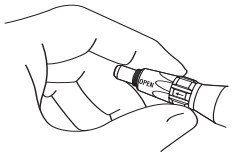
1. Move the throttle lever safety lock to "SAFE". If using a footswitch, ensure that the footswitch is not accidentally activated while inserting the burr.



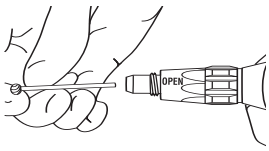
2. Remove the silicone cap.
3. If using long or extra-long burrs, use a long or extra-long burr guard.



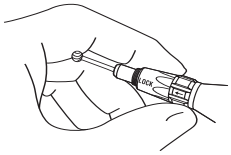
4. Twist the collet until it clicks into the "OPEN" position.



5. Insert the burr until fully seated.



6. Twist the collet until it clicks into the "LOCK" position.



⚠ **WARNING:** Collet must be in full "LOCK" position to prevent overheating of the drill.

7. Pull on the burr to make sure it does not slip loose.

⚠ **WARNING:** DO NOT run the drill without a burr or the drill will overheat.

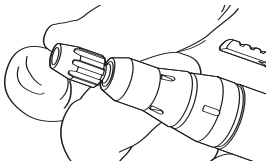
Reciprocating Saw (REF 7209392)

The Reciprocating Saw accepts a variety of specially-designed thin blades and rasps.

Inserting a blade or rasp into the Reciprocating Saw:

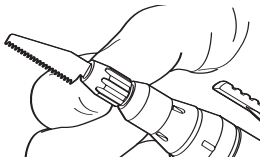
1. Move the throttle lever safety lock to "SAFE". If using a footswitch, ensure that the footswitch is not accidentally activated while inserting the blade/rasp.

2. Unscrew the locking collar two to four turns for a saw blade, four to six turns for a rasp.



Note: Do not completely unscrew the collar or it will become detached from the saw.

3. Insert the blade/rasp, making sure it is fully seated.



4. Lock the blade/rasp by screwing the collar down until it is tight.
5. Pull the blade/rasp to check for tightness.
6. Run the instrument for 10 seconds, then retighten collar.

Note: If a blade/rasp becomes loose while the saw is running it was not seated properly. Move the blade/rasp from side to side several times, and then retighten the locking collar.

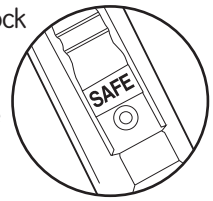
⚠ **WARNING:** When operating the saw, be careful to retract and protect the patient's tissue near the locking collar. Pinching the tissue between the collar and the body of the saw may cause a severe bruise or friction burn.

Oscillating Saw (REF 7209394)

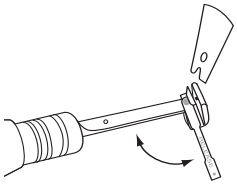
The Oscillating Saw accepts extra-thin saw blades in either a straight or bent style.

Inserting a blade into the Oscillating Saw:

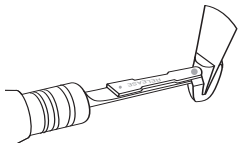
1. Move the throttle lever safety lock to "SAFE". If using a footswitch, ensure that the footswitch is not accidentally activated while inserting the blade.



2. Open the blade locking lever to release the floating jaw.
3. Insert the blade between the floating jaw and the indexing pin.



4. Fit the hole in the blade over the indexing pin.



CAUTION: *The blade hole must be seated over the indexing pin. If it is not, the head will be damaged when the locking lever is closed. DO NOT force the locking lever if excessive resistance is felt.*

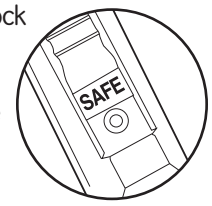
5. Close the locking lever.

Heavy Duty Oscillating Saw (REF 7209395)

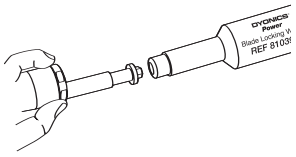
The Heavy Duty Oscillating Saw accepts a wide selection of straight, bent, and arc cutting blades. This heavy duty saw is supplied with a required Locking Wrench (REF 8103998).

Inserting a blade into the Heavy Duty Oscillating Saw:

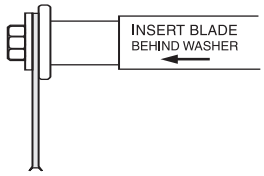
1. Move the throttle lever safety lock to "SAFE". If using a footswitch, ensure that the footswitch is not accidentally activated while inserting the blade.



2. Loosen the head nut with the supplied locking wrench.



3. Insert the blade behind the washer and head nut in any desired position.



Note: Blade must be placed behind washer or the saw will be damaged.

4. Tighten the nut, and then pull on the blade to check the tightness.
5. Run the saw for ten seconds, then retighten nut.

Cleaning

Precautions

CAUTION: *DO NOT immerse the powered instruments in saline, disinfectant, or any other liquid.*

CAUTION: *DO NOT use an ultrasonic cleaner or any other automated/sterilizing cleaning equipment. Ultrasonic cleaning can damage the bearings in the powered instruments, potentially resulting in overheating or seizure.*

CAUTION: *DO NOT lubricate or oil powered instruments. Lubrication will clog the motor and prevent it from starting. Also take special precautions to avoid the use of cleaners which contain lubricants.*

1. Disassemble and transport to the decontamination area.
2. If using the Inline Sagittal Saw, High Speed Drill, Reciprocating Saw, Oscillating Saw, or Heavy Duty Oscillating Saw slide the safety lock to the "SAFE" position. If using the Pistol Grip Drill, rotate the trigger to the "SAFE" position. Unplug the footswitch cable from the control unit.
3. Turn the power on the control unit to "OFF;" unplug the power cord from the wall outlet.
4. Disconnect all powered instrument cables from the control unit (not from the powered instrument).
5. Remove and discard used saw blades and drill bits after use, handling them as any contaminated sharp instrument.

⚠ **WARNING:** Sagittal Saw blades are single-use, disposable devices. DO NOT REUSE.

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

   CAUTION: *Soaking the powered instrument cable may cause damage or corrosion to the connector pins inside, the control unit, and/or the powered instrument itself.*

7. Ensure that the saw or drill is connected to the powered instrument cable to keep detergent solution and water out of the motor.
8. Clean the powered instrument thoroughly with warm water, mild detergent, and a soft brush. Pay careful attention to crevices.
9. Use a cannulation brush on cannulated components (i.e., drills, wire and pin drivers).
10. Clean the cannulated shaft with a small cannulation brush.
11. Clean inside drill and wire collets.
12. Flush under pressure the noses of drills and wire drivers to remove blood, debris, and saline deposits.
13. Keep the powered instrument cable connected and rinse components under running water to remove all traces of detergent solution. If possible, use distilled water for the final rinse.
14. Dry and disconnect the powered instrument cable from the handpiece, grasping it firmly on the grooved or knurled area of the plug. Be sure to pull straight back and DO NOT pull on the strain relief immediately behind it.

    Note: The powered instrument cable has a mechanical snap-lock mechanism. To disconnect, pull on the grooved or knurled area of the plug (not on the strain relief immediately behind it).

CAUTION: *The powered instrument cable should be sterilized in the same manner and location as the drill and saws.*

Sterilization parameters

Smith & Nephew's powered surgical instruments (including drills, saws, powered instrument cable, and reusable accessories), are sterilized by steam, using either a gravity displacement or pre-vacuum sterilization only.

First choice:

Pre-vacuum steam sterilization for
4 minutes at 270° F (132° C), 8 minutes drying time.

Second choice:

Gravity displacement steam sterilization for
35 minutes at 270° F (132° C), 8 minutes drying time.

Note: These parameters have been validated to ensure sterility. Sterilizer functioning should be monitored at regular intervals with biological indicators to ensure products have been subjected to sterilization conditions.

Precautions

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

CAUTION: DO NOT immerse powered instruments in liquid to cool.

CAUTION: DO NOT process powered instruments in a washer/sterilizer. The washer cycle will damage the motor and other internal components.

Accidental immersion

If a powered instrument is accidentally immersed in saline, disinfectant, cleaning fluid, or any other corrosive substance, take the following steps:

1 Totally immerse the drill or saw in distilled water for one minute to dilute the corrosive fluid. DO NOT allow the water to dry in the drill or saw.

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

Maintenance

CAUTION: *Electrical safety testing should be performed by a biomedical engineer or other qualified person.*

Electrical Interference

CAUTION: *This equipment is designed and tested to minimize interference with other electrical equipment. However, if interference occurs with other equipment, it may be corrected by one or more of the following measures:*

- *Reorient or relocate this equipment, the other equipment, or both.*
- *Increase the separation between the pieces of equipment.*
- *Connect the pieces of equipment into different outlets or circuits.*
- *Consult a biomedical engineer.*

Environmental Protection

CAUTION: *This equipment contains electronic printed circuit assemblies. At the end of the useful life of the equipment it should be disposed of in accordance with any applicable national or institutional related policy relating to obsolete electronic equipment.*

Service

Service Philosophy

Repairs and adjustments are to be performed only by Smith & Nephew authorized service centers.

If service becomes necessary, call your authorized Smith & Nephew Customer Service Representative prior to returning the device and request a Return Authorization (RA) number. Your representative can also explain the available Service Replacement and Repair Programs.

Service items should be carefully packaged and returned post-paid to Smith & Nephew. Your Smith & Nephew Customer Service Representative can provide additional instructions.

Note: Product returned that has been serviced by an unauthorized third party repair shop and/or sterilized with a sterilization method other than one approved by Smith & Nephew and/or damaged by contact with other mechanical devices (such as shavers) may incur additional costs, regardless of warranty status.

Troubleshooting

SYMPTOM	REMEDY
Powered instrument cable (REF 7205788) is difficult to insert into drill, saw, or control unit.	Ensure that the pins on the powered instrument cable are aligned with the matching holes or red dots on the control unit and/or drill/saw receptacle. This connection is a tight fit to keep particles from entering the drill or saw. Ensure that each end of the plug is fully engaged via the "snap lock." **Note:** The termination connectors should retract into the plug while pulling back on the notched portion of the plug sleeve. If the connector sleeves do not retract, send the powered instrument cable to the factory for inspection, and use an alternate powered instrument cable.
Drill or saw will not start.	a. Ensure that the Control Unit is "ON" (the main power switch is in the "|" position) and the display panel and power switch are illuminated. b. Ensure that either the throttle lever or trigger is in the "RUN" not "SAFE" position. c. If using the footswitch, ensure that the connector is fully inserted into the connection port. d. Test the drill or saw in the other handpiece connection port (A or B). e. Test the drill or saw with another powered instrument cable. If new powered instrument cable starts the drill or saw, return first powered instrument cable for repair. f. Test a different drill or saw in both handpiece connection ports (A and B). If the new drill or saw runs properly, return the faulty drill or saw for repair. g. If using a footswitch, disconnect it and plug drill or saw into the Control Unit. If the drill or saw runs properly, return the footswitch for repair. h. If the above steps do not cause the drill or saw to run properly, return the DYONICS® POWER Control Unit for repair. **Note:** Pressing either the trigger or throttle lever too slowly may prevent the drill or saw from starting.
Drill or saw runs slowly.	Ensure that the safety lock is in the "RUN" position. Repeat steps "b–h" above under "Drill or saw will not start." Pressing the throttle lever or trigger too slowly may prevent drill or saw from achieving the maximum set speed. Release trigger or lever and press again after one second.
Motor overheats.	Turn the drill or saw off and let it cool down. When the drill or saw has cooled, check to see that the blade is properly seated and locked. If the drill or saw overheats again, send it to Smith & Nephew for repair.
Trigger or throttle lever sticks.	Repeat cleaning and sterilization procedures. If problem persists, return product to Smith & Nephew.

Warranty

Smith & Nephew products are guaranteed to be free from defects in material and workmanship for the warranty period for a particular product, beginning from date of invoice. Refer to the current Smith & Nephew Product Catalog or contact Smith & Nephew Customer Service for specific warranty information.

This limited warranty is restricted to repair or replacement by Smith & Nephew, at its option, of any product found to be defective during the warranty period. Damage inflicted to a product by the user that causes it to be unsuitable for refurbishment may result in additional charges, regardless of warranty status. All warranties apply to the original buyer only. In no event shall Smith & Nephew be liable for any anticipated profits, consequential damages, or loss of time incurred by the buyer with the purchase or use of any product.

NO OTHER WARRANTY, EXPRESSED OR IMPLIED, IS GIVEN.

EC REP

Smith & Nephew
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United Kingdom

Service Replacement Units Warranty

The Smith & Nephew DYONICS• POWER and POWER HERMES-Ready™ Shaver Systems replacement units are warranted to be free from defects in material and workmanship for 90 days from the date of original invoice unless otherwise provided by local law.

Service Replacement Program

Smith & Nephew offers a 24-hour Service Replacement Program for its products to minimize downtime in your operating room. Our goal is to ship you a service replacement unit within 24 hours** of your call (during normal business hours). For a Return Authorization (RA) number or for additional information on this program, call Customer Service at 1-800-343-5717 in the U.S., or contact your authorized representative.

***24-hour shipment is not offered in all countries.*

Repair Service Program

For devices no longer under warranty, repairs can be made by Smith & Nephew or by an authorized agent. Non-warranty repairs will be made at the list price of replacement parts, plus labor. If requested, we will provide an estimate of repair cost and time required for the repair before any work is done. Repair items should be carefully repackaged, marked with the Return Authorization (RA) number, and returned postpaid to the appropriate Smith & Nephew Service Center. Smith & Nephew Customer Service or your local authorized representative can provide shipping information.

Covered by one or more of the following U.S. Patent Numbers: Re. 34,556; 4,203,444; 4,274,414; 4,834,729; 4,842,578; 4,983,179; 5,077,506; 5,133,729; 5,152,744; 5,270,622; 5,322,505; 5,510,070; 5,563,481; 5,602,449; 5,620,447; 5,630,826; 5,672,945; 5,707,350; 5,712,543; 5,745,647; 5,749,885; 5,804,936; 5,833,692; 5,871,493; 5,913,867; 6,090,122; 6,328,752; Des. 381,425; Des. 388,170; Des. 390,955; Des. 390,956; other patents pending.

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