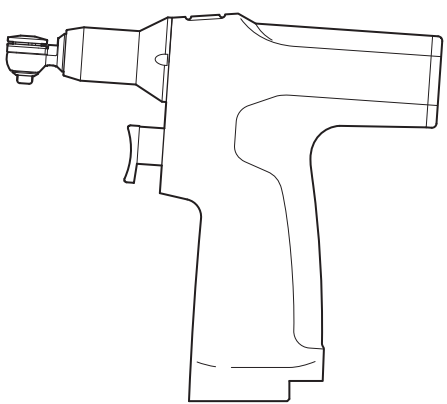
System 8
Sabo® Sagittal Saw

REF 4508-000-000

Instructions For Use

R_x ONLY

CE 0197



ENGLISH (EN)

Contents

Introduction

This instructions for use manual contains information intended to ensure the safe, effective, and compliant use of your product.

Keep and consult this reference manual during the life of the product.

NOTE: The user and/or patient should report any serious product-related incident to both the manufacturer and the Competent Authority of the European Member State where the user and/or patient is established.

Audience

This manual is intended for in-service trainers, physicians, nurses, surgical technologists, and biomedical equipment technicians.

Conventions

The following conventions are used in this manual:

- A **WARNING** highlights a safety-related issue. ALWAYS comply with this information to prevent patient and/or healthcare staff injury.
- A **CAUTION** highlights a product reliability issue. ALWAYS comply with this information to prevent product damage.
- A **NOTE** supplements and/or clarifies procedural information.

Contact Information

For additional information, including safety information, in-service training, or current literature, contact your Stryker sales representative or call Stryker customer service at 1-269-323-7700 or 1-800-253-3210. Outside the US, contact your nearest Stryker subsidiary.

Indications For Use

The Stryker System 8 Sabo system is a surgical battery-powered instrument intended for use during general surgical procedures to cut hard tissue and/or bone. This system is designed for general surgical use where hard tissue and/or bone must be cut, including but not limited to the hand, wrist, elbow, sternum, foot, ankle, knee, and hip.

Contraindications

None known.

Safety Directives

WARNINGS:

- Before using this equipment, or any component compatible with this equipment, read and understand the instructions for use. Pay particular attention to safety information. Become familiar with the equipment before use.
- Only healthcare professionals trained and experienced in the use of this medical device should operate this equipment.
- The healthcare professional performing any procedure is responsible for determining the appropriateness of this equipment and the specific technique used for each patient. Stryker, as a manufacturer, does not recommend surgical procedure or technique.
- Upon initial receipt and before each use, operate the equipment and inspect each component for damage. DO NOT use any equipment if damage is apparent or the inspection criteria are not met. See the care instructions manual supplied with the handpiece.
- Upon initial receipt and before each use, clean and sterilize the equipment as indicated. See the care instructions manual supplied with the handpiece.
- DO NOT use this equipment in areas in which flammable anesthetics or flammable agents are mixed with air, oxygen, or nitrous oxide.
- Take special precautions regarding electromagnetic compatibility (EMC) when using medical electrical equipment. Place this equipment into service according to the EMC information contained in this manual. Portable and mobile radio frequency (RF) communications equipment can affect the function of this equipment.
- ALWAYS lock the handpiece trigger before installing or removing attachments or accessories.

Accessories

WARNINGS:

- Use only Stryker-approved electronic components and accessories. Failure to comply may result in increased electromagnetic emissions or decreased electromagnetic immunity of the system.
- DO NOT modify any equipment without the authorization of the manufacturer.
- DO NOT reuse, reprocess, or repackage a device that is intended for single use only.
  - A single use device may not withstand chemical, chemical vapor, or high temperature sterilization reprocessing.
  - Design features may make cleaning difficult.
  - Reuse may create a contamination risk and compromise structural integrity resulting in operational failure.
  - Critical product information may be lost during repackaging.

  Failure to comply may lead to infection or cross infection and result in patient and/or healthcare staff injury.
- Upon initial receipt and before use, visually inspect the package for damage to confirm the integrity of the sterile barrier. Do not use the product if damage is apparent, the sterile barrier is compromised, or the package is unintentionally opened.

NOTES

- Sterile cutting accessories are sterilized by irradiation.
- For a complete list of accessories, contact your Stryker sales representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.

The following Stryker-approved accessories are sold separately:

Blades

DESCRIPTION	REF (SERIES)
Blades	2296-003-XXX
	2296-023-XXX
	2296-033-XXX
	5400-003-XXX
	5400-134-XXX

Battery Packs

DESCRIPTION	REF
System 8 Battery Packs	8212-000-000 8215-000-000
SmartLife® Battery Packs	7212-000-000 7215-000-000
SmartLife Non-sterile Batteries	7126-110-000 7222-110-000
SmartLife Aseptic Housings	7126-120-000 7222-120-000
SmartLife Transfer Shields	7126-130-000 7222-130-000
System 6 Battery Packs	6212-000-000 6215-000-000
System 6 Aseptic Battery Kits	6126-000-000 6127-000-000

Insert Trays

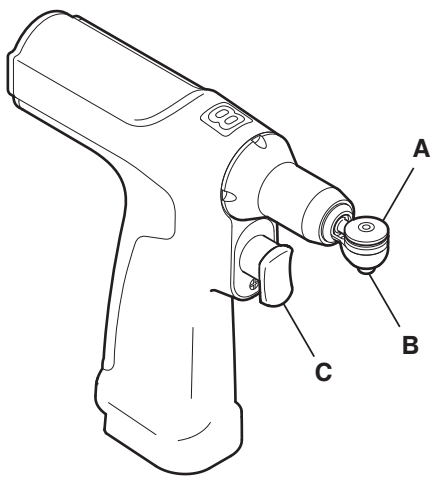
DESCRIPTION	REF
Insert Trays	4405-451-010 4405-452-010 4405-453-010 7102-453-010

Features

NOTE: The Stryker System 8 Sabo Sagittal Saw (handpiece) is a component of the Stryker System 8 Battery Powered Heavy Duty System.

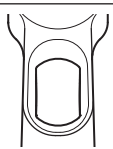
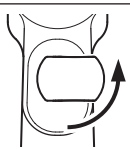
Handpiece

The System 8 Sabo Sagittal Saw is battery powered and has a trigger.



A	**Blade Mount** – Retains the blade in the handpiece. The blade mount may be indexed in 45-degree increments to achieve the desired cutting angle.
B	**Blade Lock Button** – Press the blade lock button to allow installation and removal of the blade.
C	**Trigger** – Depress the trigger to control the variable speed operation of the handpiece. Rotate the trigger 90 degrees to lock the trigger and prevent inadvertent operation of the handpiece. See the *Trigger* section.

Trigger

POSITION	DESCRIPTION
	**Run Mode** – The trigger is functional. Depress the trigger to control the variable speed operation of the handpiece.
	**Safe Mode** – The trigger is locked to prevent inadvertent operation of the handpiece.

Definitions

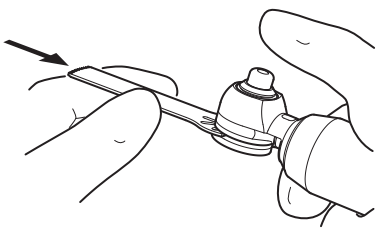
The symbols located on the equipment and/or labeling are defined in this section or in the *Symbol Definition Chart*. See the *Symbol Definition Chart* supplied with the equipment.

SYMBOL	DEFINITION
	General warning sign
	Run Mode
	Safe Mode
10 sec / 20 sec X 4	Duty Cycle – See the *Specifications* section.

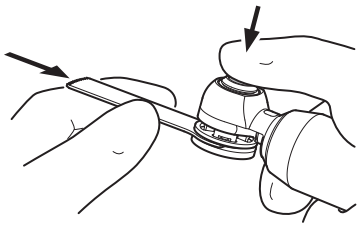
Instructions

To Install the Blade

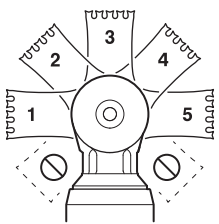
1. Lock the handpiece trigger.
2. Insert a blade into the gap in the blade mount.



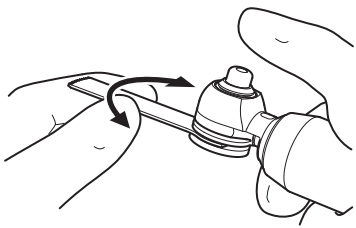
3. Fully depress the blade lock button and slide the blade to the center of the blade mount.



CAUTION: The blade can be safely installed in five possible cutting angle positions. ALWAYS install the blade in one of the five positions shown. Failure to comply may cause the blade to strike the handpiece during operation.

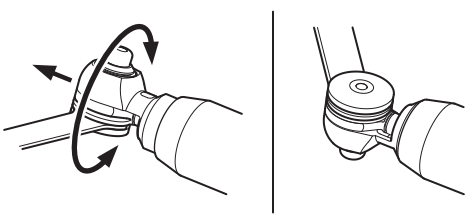


4. Release the button and rotate the blade until it snaps into the desired location. If necessary, depress the button again to reposition the blade.



5. Gently tug the blade to make sure the blade is securely locked in the handpiece.
6. To index the blade mount, pull out and rotate the blade mount until it snaps into the desired location.

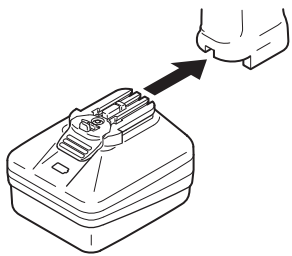
NOTE: The blade mount can be locked in eight possible cutting angle positions.



To Install the Battery Pack

NOTE: See the instructions for use supplied with the battery pack and/or battery charger for charging instructions and specifications.

1. Lock the handpiece trigger.
2. Slide a fully charged battery pack into the handpiece until the battery pack snaps into place.



3. Gently tug the battery pack to make sure the battery pack is securely locked in the handpiece.
4. Test the operation of the handpiece by unlocking and then depressing the trigger.

To Operate the Handpiece

WARNINGS:

- ALWAYS lock the handpiece trigger when the handpiece is idle or when passing the handpiece to another person.
- Before operating the handpiece, ALWAYS gently tug the cutting accessory to make sure the cutting accessory is securely locked in the handpiece.
- Before operating the handpiece, ALWAYS gently attempt to rotate the blade mount to make sure it is securely locked in position.
- ALWAYS operate the equipment within the specified environmental condition values. See the *Specifications* section.
- ALWAYS follow the recommended duty cycle to prevent the equipment from overheating. See the *Specifications* section.
- DO NOT apply excessive pressure, such as bending or prying, with the accessory. Excessive pressure may bend or fracture the accessory and result in tissue damage, loss of tactile control, and/or the ejection of accessory fragments at a high velocity.

CAUTIONS:

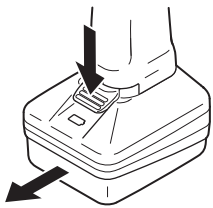
- When operating the handpiece, let the accessory do the cutting. DO NOT apply excessive pressure with the accessory. Excessive pressure may bend the blade and reduce the cutting quality.
- DO NOT stall the handpiece. Failure to comply may damage the electric motor and/or battery pack. If the handpiece jams, release the trigger immediately. Remove any obstructions before continuing to operate the handpiece.
- If any power loss is experienced while using the handpiece, ALWAYS replace the battery pack with a fully charged battery pack. Failure to comply may result in a drained or damaged battery pack with a shortened life.

NOTE: See the *Features* section for mode descriptions.

1. Rotate the trigger to the run mode position.
2. Depress the pressure-sensitive trigger to operate the handpiece.

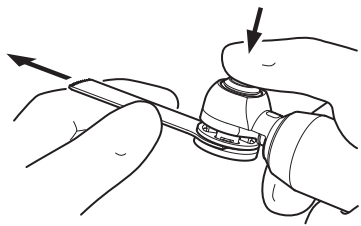
To Remove the Battery Pack

1. Lock the handpiece trigger.
2. Depress the battery latch and slide the battery pack out of the handpiece.



To Remove the Blade

1. Lock the handpiece trigger.
2. Fully depress the blade lock button and remove the blade from the handpiece.



Care Instructions

For processing instructions and disposal/recycle information, see the care instructions manual supplied with the equipment.

Troubleshooting

WARNING: DO NOT disassemble or service this equipment without the authorization of the manufacturer.

NOTE: For service, contact your Stryker sales representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.

PROBLEM	CAUSE	ACTION
The handpiece does not operate or operates at a reduced speed.	The battery pack is discharged.	Use a Stryker battery charger to recharge the battery pack.
	The battery pack is expended.	Replace the battery pack.
	The handpiece trigger is locked.	Unlock the handpiece trigger. See the *Features* section.
	The handpiece is damaged.	Return the equipment to Stryker for repair.
The handpiece operates but the cutting accessory does not move.	The attachment is not fully installed in the handpiece.	Remove and install the attachment. Make sure the attachment is securely locked in the handpiece.
	Excessive pressure is being applied to the cutting accessory.	Release the pressure and allow the cutting accessory to do the cutting.
	The handpiece is damaged.	Return the equipment to Stryker for repair.

PROBLEM	CAUSE	ACTION
The handpiece continues to operate after the trigger is released.	The handpiece is damaged.	Depress the battery latch and slide the battery pack out of the handpiece. Return the equipment to Stryker for repair.
The equipment becomes unusually hot during use.	The duty cycle has been exceeded.	ALWAYS follow the recommended duty cycle to prevent the equipment from overheating. See the *Specifications* section.
	The handpiece is damaged.	Return the equipment to Stryker for repair.
	The battery pack is damaged.	Use a Stryker battery charger to check the integrity of the battery pack. See the instructions for use supplied with the battery charger for more information. Replace the battery pack if required.
The cutting accessory will not fit or cannot be secured in the handpiece.	The distal end of the handpiece contains debris.	See the care instructions manual supplied with the handpiece.
	The cutting accessory is damaged.	Replace the cutting accessory.
	The handpiece is damaged.	Return the equipment to Stryker for repair.

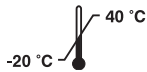
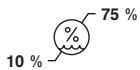
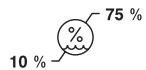
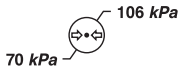
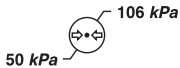
PROBLEM	CAUSE	ACTION
The handpiece is noisy and/or vibrates.	The cutting accessory is not properly installed in the handpiece.	Remove and properly install the cutting accessory. Make sure the cutting accessory is securely locked in the handpiece.
	The cutting accessory is not a Stryker product.	Use a Stryker cutting accessory.
	The cutting accessory is damaged.	Replace the cutting accessory.
	The blade mount is indexed but has not snapped into place.	Slightly rotate the blade mount until it snaps into the desired location.
	The handpiece is damaged.	Return the equipment to Stryker for repair.
The blade exhibits reduced cutting action under a light cutting load.	Normal wear of internal handpiece components.	Return the equipment to Stryker for repair.
The handpiece experiences sporadic electrical interference.	Electrical noise is present.	Turn off all electrical equipment not in use in the operating room.
		Relocate electrical equipment and/or increase spatial distance between electrical equipment.
		Plug operating room equipment into different operating room outlets.

Specifications

WARNING: ALWAYS consult any documentation that accompanies attachments and/or accessories for product-specific duty cycles and instructions for use.

CAUTION: ALWAYS store the equipment within the specified environmental condition values throughout its useful life.

Model:	System 8 Sabo Sagittal Saw (REF 4508-000-000)
Dimensions:	139 mm [5.5 inch] height, 34 mm [1.3 inch] width, 154 mm [6.1 inch] length
Mass:	0.64 kg [1.4 lb]
Maximum Speed:	25000 cpm
Excursion:	5 degree arc
Mode of Operation:	Non-continuous
Duty Cycle:	10 seconds on/20 seconds off, 4 times
Rest Between Cycles:	30 minutes
Applied Part(s):	The distal end of the handpiece as defined by the manufacturer
Maximum Temperature of Applied Part(s):	Less than 51 °C [124 °F] as tested to the *Product Safety Certification* standards
Power Supply:	Internally powered. Refer to battery housing for voltage rating.
Ingress Protection:	IPX9 during cleaning and sterilization
Equipment Type:	 Type BF Applied Part

Environmental Conditions:	Operation	Storage and Transportation
Temperature Limitation:		
Humidity Limitation:		
Atmospheric Pressure Limitation:		

Product Safety Certification

Canadian Standards Association (CSA) International

Canadian Standards Association (CSA)

CAN/CSA-C22.2 No. 60601-1:14, *Medical Electrical Equipment — Part 1: General Requirements for Basic Safety and Essential Performance;* (IEC 60601-1:2005+A1:2012, MOD)

American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI)

ANSI/AAMI ES60601-1:2005/(R) 2012, *Medical Electrical Equipment — Part 1: General Requirements for Basic Safety and Essential Performance;* Consolidated Reprint (2009/(R) 2012); Amendment 2 (2010/(R) 2012); Amendment 1 (2012)

Product Safety Compliance

International Electrotechnical Commission (IEC)

IEC 60601-1:2005, Ed: 3.1, *Medical Electrical Equipment — Part 1: General Requirements for Basic Safety and Essential Performance;* Corrigendum 1 (2006); Corrigendum 2 (2007); Amendment 1 (2012)

IEC 60601-1-2:2014 Ed: 4, *Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Electromagnetic Disturbances*

IEC 60601-1-2:2007 Ed: 3, *Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Electromagnetic Compatibility*

IEC 60601-1-6:2010+ A1:2013 Ed. 3.1, *Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Usability*

IEC 62366-1:2007+ A1:2014 Ed 1.1, *Medical Devices - Part 1: Application of Usability Engineering to Medical Devices*

European Committee for Electrotechnical Standardization (CENELEC)

EN 60601-1:2006+A12:2014, Ed: 3.1, *Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance;* IEC Corrigendum 1 (2006); IEC Corrigendum 2 (2007); CENELEC Corrigendum (2010); CENELEC Amendment A11 (2011); IEC Amendment 1 (2013); IEC Corrigendum 3 (2014); CENELEC Amendment A12 (2014)

Electromagnetic Compatibility

Guidance and manufacturer's declaration - electromagnetic emissions		
The System 8 Sabo Sagittal Saw (REF 4508-000-000) is intended for use in the electromagnetic environment specified below. The customer or the user of the System 8 Sabo Sagittal Saw (REF 4508-000-000) should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The System 8 Sabo Sagittal Saw (REF 4508-000-000) uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The System 8 Sabo Sagittal Saw (REF 4508-000-000) is suitable for use in all establishments, including domestic establishments 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	N/A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration - electromagnetic immunity			
The System 8 Sabo Sagittal Saw (REF 4508-000-000) is intended for use in the electromagnetic environment specified below. The customer or the user of the System 8 Sabo Sagittal Saw (REF 4508-000-000) should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±2, ±4, ±6, ±8 kV Contact ±2, ±4, ±8, ±15 kV Air	±2, ±4, ±6, ±8 kV Contact ±2, ±4, ±8, ±15 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV at 100 kHz repetition frequency for power supply lines ±1 kV at 100 kHz repetition frequency for input/output lines	±2 kV at 100 kHz repetition frequency for power supply lines ±1 kV at 100 kHz repetition frequency for input/output lines	N/A
Surge IEC 61000-4-5	±0.5, ±1 kV line(s) to line(s) ±0.5, ±1, ±2 kV line(s) to earth	N/A N/A	N/A

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
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	N/A	N/A
	0% U_T (100% dip in U_T) for 0.5 cycle at 0˚, 45˚, 90˚, 135˚, 180˚, 225˚, 270˚, and 315˚	N/A	
	0% U_T (100% dip in U_T) for 1 cycle at 0˚	N/A	
	40% U_T (60% dip in U_T) for 5 cycles	N/A	
	70% U_T (30% dip in U_T) for 25 & 30 cycles at 0˚	N/A	
	<5% U_T (>95% dip in U_T) for 5 s	N/A	
	0% U_T (100% dip in U_T) for 5 s	N/A	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m, 30 A/m	3 A/m, 30 A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the alternating current mains voltage prior to application of the test level.

Guidance and manufacturer's declaration - electromagnetic immunity			
The System 8 Sabo Sagittal Saw (REF 4508-000-000) is intended for use in the electromagnetic environment specified below. The customer or the user of the System 8 Sabo Sagittal Saw (REF 4508-000-000) should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands 80% AM at 1 kHz 6 Vrms 150 kHz to 80 MHz in ISM bands 80% AM at 1 kHz	N/A	IEC 60601-1-2 3rd Edition: Portable and mobile RF communications equipment should be used no closer to any part of the System 8 Sabo Sagittal Saw (REF 4508-000-000), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d=1.2\sqrt{P}$ 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 strengths 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:  (Non-ionizing electromagnetic radiation) IEC 60601-1-2 4th Edition:  **WARNING:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the System 8 Sabo Sagittal Saw (REF 4508-000-000) including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz 3 V/m 80 MHz to 2.5 GHz 80% AM at 1 kHz	10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz 3 V/m 80 MHz to 2.5 GHz 80% AM at 1 kHz	

NOTE 1: At 80 MHz and 800 MHz 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 and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast 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 System 8 Sabo Sagittal Saw (REF 4508-000-000) is used exceeds the applicable RF compliance level above, the System 8 Sabo Sagittal Saw (REF 4508-000-000) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating System 8 Sabo Sagittal Saw (REF 4508-000-000).
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the System 8 Sabo Sagittal Saw (REF 4508-000-000)			
The System 8 Sabo Sagittal Saw (REF 4508-000-000) is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the System 8 Sabo Sagittal Saw (REF 4508-000-000) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System 8 Sabo Sagittal Saw (REF 4508-000-000) 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	**80 MHz to 800 MHz**	**800 MHz to 2.5 GHz**
	N/A	$d=1.2\sqrt{P}$	$d=2.3\sqrt{P}$
0.01	N/A	0.12	0.23
0.1	N/A	0.38	0.73
1	N/A	1.2	2.3
10	N/A	3.8	7.3
100	N/A	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.

ES/DE/FR/IT/NL	4508-001-710
JA/ZH/KO	4508-001-720
SV/DA/FI/PT/NO	4508-001-730
PL/EL	4508-001-750
TR	4508-001-760
RU	4508-001-770

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