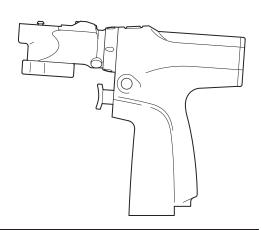
System 8 Stryker Precision® Saw

REF 8209-000-000

Instructions For Use

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ENGLISH (EN)

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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 Stryker Precision System is intended for use in the cutting and shaping of bone and other bone related tissue. The intended surgical applications are orthopedic surgeries involving the shoulder, hip, knee, and ankle.

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:

Cartridges

DESCRIPTION	REF (SERIES)
Precision Oscillating Tip	6425-XXX-XXX
Saw Cartridges	6525-XXX-XXX
Precision Falcon®	6625-XXX-XXX
Oscillating Tip Saw	6720-XXX-XXX
Cartridges	6725-XXX-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	7126-110-000
Batteries	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	6126-000-000
Kits	6127-000-000

Insert Trays

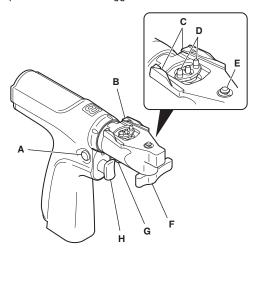
DESCRIPTION	REF
Insert Trays	4405-452-010
	7102-450-010
	7102-452-010
	7102-454-010
	7102-458-010

Features

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

Handpiece

The System 8 Stryker Precision Saw is battery powered and has a trigger and a function switch.



Α	Function Switch – Sets the speed or locks the trigger. See the Function Switch section.
В	Cartridge Mount – Retains the cartridge in the handpiece.
С	Tabs – Secure the proximal end of the cartridge to the cartridge mount.
D	Drive Pins – Interlock with the cartridge to allow oscillation of the blade.
E	Post – Secures the center of the cartridge to the cartridge mount.
F	Cartridge Mount Lever – Unlocks the cartridge mount to allow installation of the cartridge.
G	Index Button – Allows the cartridge mount to be indexed in 45-degree increments to achieve the desired cutting angle.
Н	Trigger – Controls the variable speed operation of the handpiece.

Function Switch



Fast Mode – The handpiece will operate at high speed when the trigger is depressed.



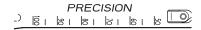
Standard Mode – The handpiece will operate at standard speed when the trigger is depressed.



Safe Mode – The trigger is locked to prevent inadvertent operation of the handpiece.

Cartridge

The cartridge is a single use, disposable cutting accessory with a stationary bar component and an oscillating cutting tip.



NOTE: The incremental marks on the length of the cartridge are for reference only.

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.

DEFINITION

SYMBOL	DEFINITION	
<u>^</u>	General warning sign	
	Fast Mode	
0	Standard Mode	
a	Cartridge mount locked	
3	Cartridge mount unlocked	
30 sec / 120 sec x 5	Duty Cycle – See the Specifications section.	
∼ FULL		
✓ INSERT	Full Insert	

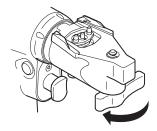
Instructions

To Install the Cartridge

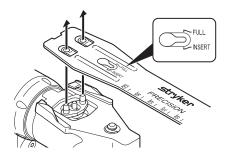


WARNINGS:

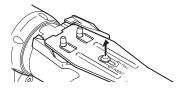
- ALWAYS install the cartridge with the FULL INSERT mark facing away from the handpiece.
- Make sure the post is aligned with the FULL INSERT mark on the cartridge after installation.
- 1. Lock the handpiece trigger.
- Rotate the cartridge mount lever to the unlock position.



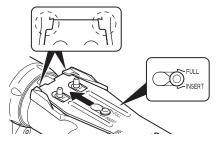
With the FULL INSERT mark on the cartridge facing away from the handpiece, install the cartridge onto the drive pins.



 With the drive pins engaged in the cartridge, pull the cartridge forward and allow the post to pass through the hole in the center of the cartridge.



 Guide the spring-loaded cartridge back toward the handpiece. Make sure the post is aligned with the FULL INSERT mark and the proximal end of the cartridge is fully seated under the tabs.



Rotate the cartridge mount lever to the lock position to lock the cartridge in the cartridge mount.



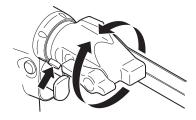
Gently tug the cartridge to make sure the cartridge is securely locked in the cartridge mount.

To Index the Cartridge Mount

CAUTION: ALWAYS securely lock the cartridge mount in position before operating the handpiece.

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

- 1. Lock the handpiece trigger.
- Depress the index button and rotate the cartridge mount to the desired cutting angle.

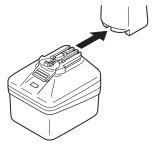


- Release the index button.
- Gently turn the cartridge mount to ensure the cartridge mount is securely locked in position.

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.
- Slide a fully charged battery pack into the handpiece until the battery pack snaps into place.



- 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.
- DO NOT change the position of the function switch while the handpiece is operating.
- DO NOT place a hand on the drive pins located on the cartridge mount of the handpiece. Friction between the drive pins and hand may cause excessive heat.
- If the function switch is set to the fast position for high speed operation, ALWAYS apply at least 5 mL of irrigation to the pivot points of the cartridge before operating the handpiece and before each cut.

- 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:

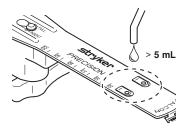
- DO NOT stall the handpiece. Failure to comply may damage the electric motor and/or battery pack. If the handpiece jams, release the trigger immediately. Remove any obstructions before continuing to operate the handpiece.
- If any power loss is experienced while using the handpiece, ALWAYS replace the battery pack with a fully charged battery pack.
 Failure to comply may result in a drained or damaged battery pack with a shortened life.

 Make sure the drive pins are free from all obstructions.



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

- Slide the function switch to the fast or standard position.
- If you set the function switch to the fast position, apply at least 5 mL of irrigation to the pivot points of the cartridge before operating the handpiece and before each cut.



4. Depress the pressure-sensitive trigger to operate the handpiece.

To Remove the Battery Pack

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



To Remove the Cartridge

- 1. Lock the handpiece trigger.
- Rotate the cartridge mount lever to the unlock position.
- 3. Pull the cartridge forward, and then lift to remove the cartridge 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 <i>Features</i> section.
	The function switch is in the standard position.	Set the function switch to the fast position.
	The cartridge is damaged.	Replace the cartridge.
	The handpiece is damaged.	Return the equipment to Stryker for repair.
The handpiece operates but the cutting accessory does not move.	The cartridge is damaged.	Replace the cartridge.
	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 damaged.	Replace the cutting accessory.
	The handpiece is damaged.	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.

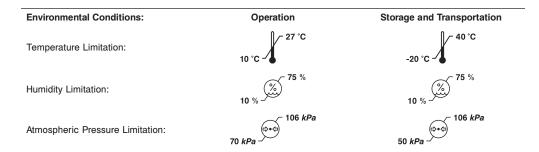
Specifications



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 Stryker Precision Saw (REF 8209-000-000)		
Dimensions:	150 mm [5.9 inch] height, 36 mm [1.4 inch] width, 178 mm [7.0 inch] length		
Mass:	1.09 kg [2.4 lb]		
Speed:	16000 cpm (fast mode), 12000 cpm (standard mode)		
Excursion:	12 degree arc		
Mode of Operation:	Non-continuous		
Duty Cycle:	30 seconds on/120 seconds off, 5 times		
Rest Between Cycles:	3 hours		
Applied Part(s):	The distal end of the handpiece and the cartridge as defined by the manufacturer		
Maximum Temperature of Applied Part(s):	Less than 51 °C [124 °F] as tested to the <i>Product Safety Certification</i> 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		



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 Certification

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 Stryker Precision Saw (REF 8209-000-000) is intended for use in the electromagnetic environment specified below. The customer or the user of the System 8 Stryker Precision Saw (REF 8209-000-000) should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions	Group 1	The System 8 Stryker Precision Saw (REF 8209-000-000) uses
CISPR 11		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	Class B	The System 8 Stryker Precision Saw (REF 8209-000-000) is suitable
CISPR 11		for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply
Harmonic emissions	N/A	network that supplies buildings used for domestic purposes.
IEC 61000-3-2		
Voltage fluctuations/flicker emissions	N/A	
IEC 61000-3-3		

Guidance and manufacturer's declaration - electromagnetic immunity

The System 8 Stryker Precision Saw (REF 8209-000-000) is intended for use in the electromagnetic environment specified below. The customer or the user of the System 8 Stryker Precision Saw (REF 8209-000-000) 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	$<5\% U_{\tau}$ (>95% dip in U_{τ}) for 0.5 cycle	N/A	
power supply input lines	0% <i>U_τ</i> (100% dip in <i>U_τ</i>)	N/A	
IEC 61000-4-11	for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°		
	$0\% U_{\tau}$ (100% dip in U_{τ}) for 1 cycle at 0°	N/A	
	$40\% \ U_{\tau} (60\% \ \text{dip in } U_{\tau})$ for 5 cycles	N/A	N/A
	70% U_{τ} (30% dip in U_{τ}) for 25 & 30 cycles at 0°	N/A	
	$<5\%~U_{\scriptscriptstyle T}$ (>95% dip in $U_{\scriptscriptstyle T}$) 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	3 A/m, 30 A/m	3 A/m, 30 A/m	Power frequency magnetic fields should be at levels
IEC 61000-4-8			characteristics of a typical location in a typical commercial or hospital environment.

NOTE: $U_{\scriptscriptstyle T}$ is the alternating current mains voltage prior to application of the test level.

Guidance and manufacturer's declaration - electromagnetic immunity

The System 8 Stryker Precision Saw (REF 8209-000-000) is intended for use in the electromagnetic environment specified below. The customer or the user of the System 8 Stryker Precision Saw (REF 8209-000-000) should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted	3 Vrms	N/A	IEC 60601-1-2 3rd Edition:
RF IEC 61000- 4-6	150 kHz to 80 MHz outside ISM bands 80% AM at 1 kHz		Portable and mobile RF communications equipment should be used no closer to any part of the System 8 Stryker Precision Saw (REF 8209-000-000), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
	6 Vrms 150 kHz to 80 MHz in ISM bands		Recommended separation distance: $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz
Radiated RF	80% AM at 1 kHz 10 V/m 80 MHz to	10 V/m 80 MHz to	Where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> 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. Interference may occur in the vicinity of equipment marked with the following symbol:
4-3	2.7 GHz 80 % AM at 1 kHz	2.7 GHz 80 % AM at 1 kHz	(((Non-ionizing electromagnetic radiation)
			IEC 60601-1-2 4th Edition:
	3 V/m 80 MHz to 2.5 GHz 80% AM at 1 kHz	3 V/m 80 MHz to 2.5 GHz 80% AM at 1 kHz	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 Stryker Precision Saw (REF 8209-000-000) including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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 Stryker Precision Saw (REF 8209-000-000) is used exceeds the applicable RF compliance level above, the System 8 Stryker Precision Saw (REF 8209-000-000) 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 Stryker Precision Saw (REF 8209-000-000).

^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 Stryker Precision Saw (REF 8209-000-000)

The System 8 Stryker Precision Saw (REF 8209-000-000) is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the System 8 Stryker Precision Saw (REF 8209-000-000) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System 8 Stryker Precision Saw (REF 8209-000-000) as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output	Separation distance according to frequency of transmitter m			
power of transmitter W	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz	
	N/A	<i>d</i> =1.2√ <i>P</i>	<i>d</i> =2.3√ <i>P</i>	
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 8209-001-710
JA/ZH/KO 8209-001-720
SV/DA/FI/PT/NO 8209-001-730
PL/EL 8209-001-750
TR 8209-001-760
RU 8209-001-770



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