Cordless Driver 3 Handpiece

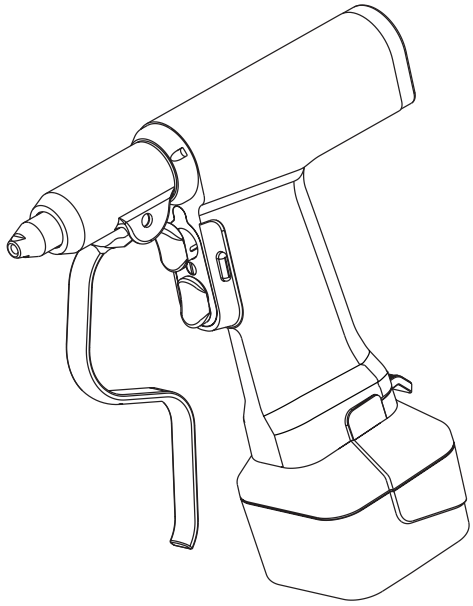
Ref 4300-000-000

stryker®

Instructions For Use

R_x ONLY

CE 0197



VETERINARY ORTHOPEDIC IMPLANTS

repairs@vetimplants.com

Important information

The words WARNING, CAUTION and NOTE have special meaning, which should be consulted.

WARNING: Ignore the warning information may endanger the safety of the patient or the health personnel and cause injury.

CAUTION: Ignore cautionary information can reduce the reliability of the product and cause damage.

NOTE: Information from the NOTES clarifies procedural information. A triangle with an exclamation point indicates the health professional should read and understand the accompanying instructions and in particular, information on operation, maintenance and safety.

Indications of use

The handpiece 3 with wireless motor (Cordless Driver 3 Handpiece) Stryker, used along with a number of attachments is designed for surgical interventions requiring drilling, reaming or cutting bone and hard tissue, and introduction of wire or pins.

Information about *

WARNING: Use only parts and accessories approved by Stryker, unless otherwise specified. The use of other accessories can increase electromagnetic emissions or decrease the electromagnetic immunity of the system. Do not modify any components or accessories. If the event is ignored this instruction may result in injury to the patient or medical personnel.

DESCRIPTION **REF**

Small battery pack (Small Battery Pack) .....
6212-000-000 Package large batteries

(Large Battery Pack) 6215-000-000 ..... Mineral oil light (light Mineral Oil) 1605-010-000 ..... battery Kit aseptically

(Aseptic Battery Kit) ..... 6126-000-000 Battery Kit aseptically small (small Aseptic Battery Kit) .....
6127-000-000

* Each cutting attachment has a specialized mechanism for retaining the blades, drill bits, burs, wires or pins. See the *Instructions for use of accessories of the drive unit Wireless (Cordless Driver) and universal power unit (Universal Driver)* for specific instructions for each accessory (link).

Safety of the user and the patient *

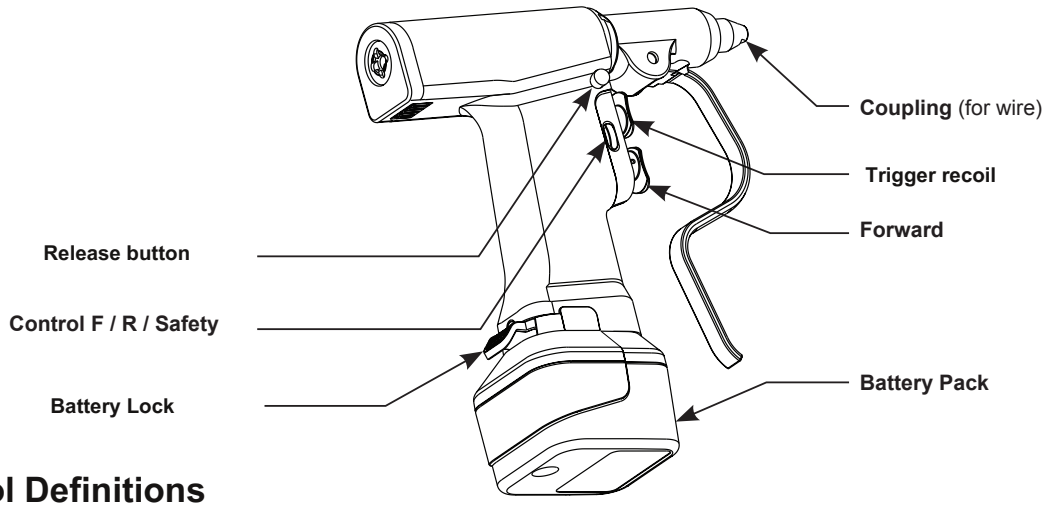
WARNINGS:

- This system should only be used by healthcare professionals with appropriate training and experience. Before using any component of the system or compatible with it, read and understand the instructions. Pay particular attention to information warnings. familiar with the components of the system before use.
- After receiving the product and before each use, operate the equipment and check all components for damage. DO NOT use an component that shows damage.
- Perform periodic maintenance as recommended in the instructions for use. maintaining this system should only be performed by health professionals with appropriate training and experience.
- Clean and sterilize handpieces, links and batteries before using them for the first time and before each use.
- NOT use this machine in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.
- In the medical electrical equipment used as the handpiece, take special precautions regarding electromagnetic compatibility (EMC). Install and commission the handpiece according to EMC information provided in this manual. Portable and mobile radio frequency communications equipment can affect the operation of the handpiece.
- Always place the F / R / Safety control in the SAFE position when the handpiece is inactive before installing or removing an accessory or handing the handpiece to another person.
- A loose attachment or incorrect wire/ pin placement can damage bone or tissue. If wobbling occurs, see *Guide for Troubleshooting*
- Do not reuse cutting accessories for single use.

The connector allows the power supply and connect future

characteristics

- **Battery pack -** The rechargeable battery pack (large or small) powering the handpiece. Press the catch to remove the battery pack from the handpiece.
- **Reverse trigger -** To turn the hand piece to the left and to vary the speed, press this sensitive trigger pressure.
- **Trigger forward -** To turn the hand piece to the right and to vary the speed, press this sensitive trigger pressure.
- **Control F / R / Security -** Depending on the position, the hand piece work mode forward, reverse or oscillation; Safety mode prevents operation of the handpiece.
- **Release button -** To release the coupling, press the release button.



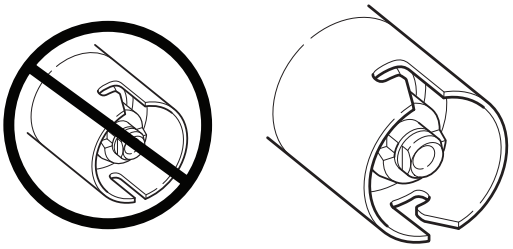
Symbol Definitions

F	**ADVANCE -** Press Control fully f / R / Safety lock the trigger return. forward the trigger is operational.	R	**REVERSE-** Squeeze the trigger to turn the handpiece to the left.
S	**SECURITY -** Center over f / R / Security block both triggers.		**OSCILLATE-** Press both triggers to use the handpiece in oscillation mode.
F/R	**FWD / REV -** fully extend over f / R / Security to unlock both triggers. Both triggers are operational.	F	**FORWARD-** Squeeze the trigger to turn the handpiece to the right.

Instructions

To install the coupling

WARNING: Always use approved Stryker attachments with two J-shaped slots. DO NOT USE attachments with a single J-shaped groove.



NOTE: Slide attachment firmly into the handpiece until it snaps into place, indicating that the attachment is securely fastened (see Figure 1.)

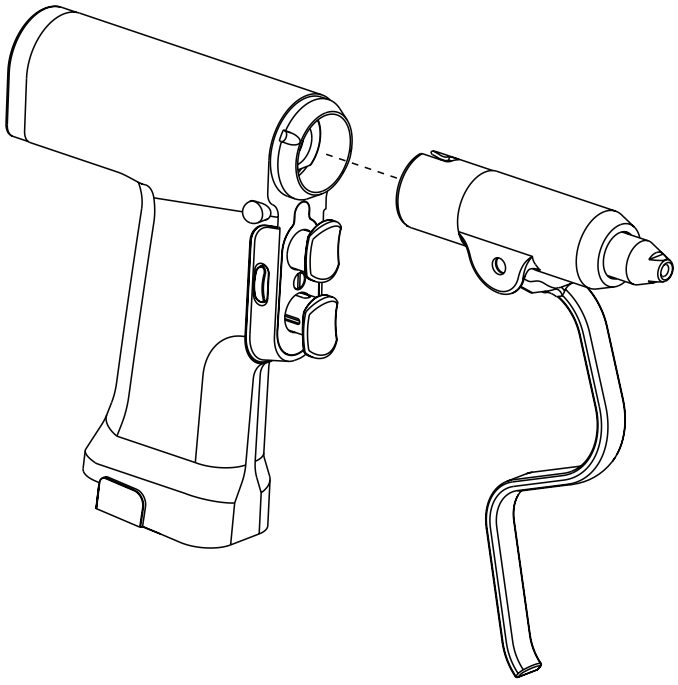


Figure 1 To install the coupling

Instructions (continued)

To install the battery pack NOTES:

- This handpiece is designed to accept a small battery pack, Ref 6212-000-000, or large, Ref 6215-000-000. these battery packs can be loaded into the battery charger 6 System (System 6 Battery Charger) Stryker, Ref 6110-120-000, configured with appropriate load modules.

- Consult charging details and specifications in the instructions supplied with the battery charger and the battery pack.

1. Firmly slilde the battery pack onto the handpiece until it clicks- which indicates battery pack is in place.

2. Ensure the handpiece functions by sliding trigger to each F / R / Safety position

3. Slide safety switch to SAFE position until ready for use.

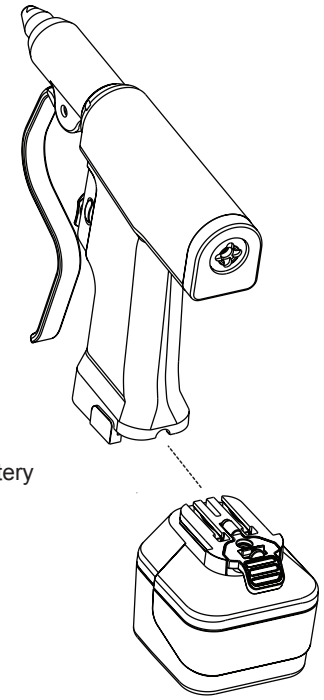


Figure 2 to install the battery pack

Instructions (continued)

To use the handpiece

WARNING: Always place the f Control / R / Safety at the safety position when the handpiece is idle before installing or removing an accessory, or handing the handpiece to another person.

PRECAUTIONS:

- Do not use force on the handpiece if it begins to slow down. It may damage the motor or battery pack. If the handpiece stalls, release the trigger immediately. Remove any obstructions before proceeding with surgery.

- If you experience loss of power to the handpiece, always replace battery pack for a fully charged battery pack. Otherwise, you could damage the battery pack or reduce battery life. Slide over F / R / Safety position.

1. Slide safety switch to appropriate function so handpiece goes in F / R oscillation.

2. Squeeze the trigger with the appropriate pressure to achieve variable speed. For oscillation mode, squeeze both triggers at the same time.

3. Make sure the safety is in the SAFE position when you finish using the handpiece

To remove the coupling

1. Slide safety into the SAFE position

2. Press the release button to remove the attachment

To remove the battery pack

Press the battery lock and pull the battery pack to remove it from the handpiece.

Periodic maintenance

INTERVAL	EXERCISE
Before each use.	Inspect, operate and test the handpiece to make sure it works properly. Make sure there are no loose components or no missing components. Check that all moving parts can move freely. Be alert to detect abnormal sounds or vibrations and note the operating speed.
Every three months.	Test coupling sagittal saw (Sagittal Saw) Ref 4100-400-000 with the handpiece for one minute to determine the operating temperature. If the distal tip and the body of the coupling are very hot to touch (approximately 43.3 ° C [110 ° F]), return the handpiece and coupling Stryker.
When necessary.	If the clutch or keyless attachment jams, light mineral oil applied Ref-1605-101-000 to the recess of the coupling. Wipe excess mineral oil.
When necessary.	If the release button of the handpiece gets stuck, apply light mineral oil (Ref 1605-010-000) to the trigger.

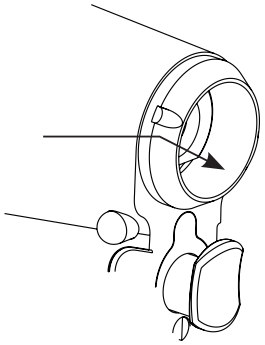


Figure 3 To lubricate the handpiece Place oil here

Storage and Handling

To ensure a long life, smooth operation and security to this computer, store it in the original packaging when storing or transporting.

Disposal and recycling

- For handling and disposing of cutting accessories for single use safely, follow local regulations concerning biohazardous waste.
- Follow local regulations on environmental protection when recycling or disposing the handpiece to the end of its useful life.

Recommendations for cleaning

WARNINGS:

- Clean and sterilize handpieces, attachments and batteries before using them for the first time and before each use.

- Before cleaning and sterilization, remove all attachments and handpiece accessories .

- DO NOT use solvents, lubricants and other chemicals unless expressly specified.

PRECAUTIONS:

- DO NOT immerse the handpiece, attachments or battery pack in any liquid. If moisture enters the device, it can cause corrosion and damage to the electrical and / or mechanical.

- DO NOT allow any liquid to make contact with the electrical connections. Moisture can cause corrosion.

To clean battery packs and accessories

See care instructions supplied with the battery packs, modules charge the battery and battery charger.

To clean the handpiece

1. Remove the battery packs and attachments from the handpiece.

2. Remove all visible dirt, such as blood, mucus or tissue, from the handpiece using a disposable cloth dampened with a cleaning solution with enzyme pH neutral or slightly alkaline, diluted according to recommendations of the manufacturer.

3. Be sure to wet all surfaces.

4. With a stiff brush and non-metallic hospital enzymatic cleaner, clean the debris from the handpiece. Pay particular attention to crevices and other hard to reach areas such as joints, seams and details about the retainer, the trigger and the areas of the connectors, which can be dirt even after brushing. Use a sterile syringe to wash hard to reach areas.

5. Rinse all external surfaces of the handpiece under filtered tap water. Hold the handpiece upward to prevent water from entering the contact area of the battery rinsing cannula with tap water.

Recommendations for cleaning (continued)

6. If water seeps inside the handpiece,
   tilt back so that the water runs through a small opening in the contact area of the battery pack (Figure 4).

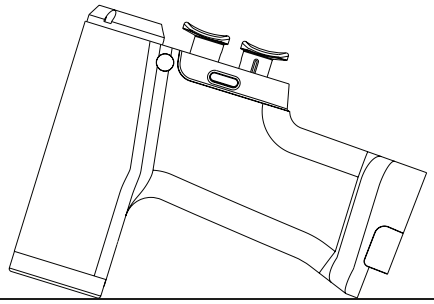


Figure 4 To remove water from the handpiece

7. Visually check the handpiece
   ensure that no residue; if they exist, repeat cleaning and rinsing with freshly prepared enzymatic cleaner hospital.

8. Dry the handpiece and attachments with
   lint-free compressed air or medical grade air.

9. After cleaning, sterilize as directed.
   see *Recommendations for sterilization*.

Recommendations for sterilization

WARNINGS:

- Clean and sterilize handpieces, links and batteries before using them for the first time and before each use.

- Before cleaning and sterilization, remove the couplings and all accessories from the handpiece.

- DO NOT use sterilization box to perform sterilization with ethylene oxide of the handpiece. If you want to use a sterilization box, the health center should validate the sterilization technique to ensure efficient processing.

- Position the handpiece so that the flow of the steam is through the handpiece cannulation using a gravity displacement sterilizer.

NOTES:

- Steam sterilization (moist heat) is recommended. Stryker instruments validated several cycles of autoclaving for sterilization of this equipment. However, the design and performance of the autoclave can affect the efficiency of the process. Healthcare facilities should validate the process using the equipment that will be used.

- The ultimate responsibility for validation of sterilization techniques lies squarely in the hospital. To ensure the effectiveness of hospital processing must validate all cycles and with different methods of sterilization chambers, wrapping methods and / or load configurations.

Recommendations for sterilization (continued)

To sterilize battery packs

See care instructions supplied with the battery packs.

To sterilize handpieces

For optimum performance and avoid damage, do one of the procedures described below *:

Autoclave "Flash":

- Sterilizer gravity displacement
- 132-134 ° C (270-272 ° F)
- Unwrapped, in an instrument tray and upright, so that steam can flow through the cannula
- Minimum exposure time 10 minutes

Dynamic air removal: (I prevacuum or high vacuum)

- Dynamic sterilizer air removal
- 132-134 ° C (270-272 ° F)
- Wrapped or unwrapped, in an instrument tray or in a box fully perforated sterilization
- Minimum exposure time of 4 minutes
- Minimum drying time of 8 minutes

** Validation of sterilization is based on the protocol of the Association for the Advancement of Medical Instrumentation (AAMI)*

Parameters of ethylene oxide sterilization:

- Ethylene oxide to 100%
- Concentration: 880 mg / l
- Relative humidity 50 +/- 20%
- Double wrapping on an instrument tray
- Minimum exposure time 4 hours
- Shortest aeration 8 hours

Gravity at 121 ° C:

- Sterilizer gravity displacement
- 121-123 ° C (250-254 ° F)
- Wrapped in a tray or a box instrumental sterilization fully perforated
- Exposure time 50 minutes
- Minimum drying time of 8 minutes

Gravity at 132 ° C:

- Sterilizer gravity displacement
- 132-134 ° C (270-272 ° F)
- Wrapped in a tray or a box instrumental sterilization fully perforated
- Minimum exposure time 35 minutes
- Minimum drying time of 8 minutes

NOTE: After sterilization, let the equipment cool to room temperature to achieve a proper operating temperature.

Guide for troubleshooting *

PROBLEM	CAUSE	ACTION
The handpiece is not working or rotates at reduced speed.	The battery pack is discharged.	Recharge the battery pack in the battery charger Stryker.
	The battery pack is dead.	Replace the battery pack.
	F / R / Safety is in the safety position.	Slide over f / R / security to the forward position or forward / backward.
	The handpiece is not working properly.	Return the handpiece for service.
The motor works but the cutting does not move.	The handpiece is not working properly.	Return the handpiece for service.
	The coupling is not fully seated.	Remove and reinsert the link. Check that the coupling is full seated.
the battery pack becomes too hot during use.	The handpiece is not working properly.	Check the battery pack in the charger. If necessary, replace the battery pack. See the instructions supplied with the battery charger.
coupling does not fit into the handpiece.	There are remains in the attachment or inside the front of the handpiece.	Clean coupling and / or the handpiece with a small hard bristle brush but not metal.
	The coupling is damaged.	Return coupling for repair.
	The handpiece is damaged.	Return the handpiece for service.
Attachment wobbles in the handpiece	Attachment is bent, protrudes too far from the distal end of the coupling, is the wrong size or is not centered in the coupling.	Re-enter the cutting, wire or pin. If the wobble persists, return the handpiece and coupling for repair.

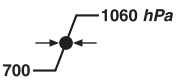
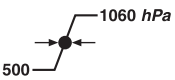
** DO NOT perform maintenance on this equipment. If you need service, please contact your VOI Repair representative at repairs@vetimplants.com or call 904-436-6540. Outside of the US, contact your nearest VOI Subsidiary.

Guide to Troubleshooting (continued)

PROBLEM	CAUSE	ACTION
Sliding on nail insert	Wrong introducer nails.	Use the introducer nails Ref 4100-126-000.
The installation of the coupling in the handpiece, or taken out of it, presents difficulties.	It is necessary to lubricate the release button.	Apply lubricant to the release button. See section *Periodic maintenance.*
The handpiece has become noisy and vibrates.	The handpiece is not working properly.	Return the handpiece for service.
Electrical interference occurs sporadically	There are electrical disturbances	Turn off all electrical equipment not being used in the operating room. Relocate electrical equipment; increase the separation distance.

Specs*

Model:	Handpiece 3 wireless power unit (Cordless Driver 3 Handpiece), Ref 4300-000-000	
Dimensions:	**Single handpiece**	**Handpiece with small battery pack and wire driver**
	Height 137 mm (5.40 inches)	187 mm (7.35 inches)
	Length 103 mm (4.04 inches)	170 mm (6.70 inches)
	Width 34 mm (1.33 inches)	57 mm (2.25 inches)
Weight:	0.58 kg (1.27 lb)	1.0 kg (2.20 lb)
Speed:	1600 rpm max	
Work cycle:	operation forward / reverse: 1 minute on and off 4 minutes, 5 times with a break of two hours oscillation mode operation 15 seconds on and 15 seconds off, 5 times with 90 minute rest	
approvals:	CSA International CAN / CSA-C22.2 No. 601.1-M90: 2003 BS EN 60601-1: 1997 UL 60601-1: 2003	
Kind of team:	Type BF Applied Part	
Power supply:	Internal supply 9.6 V ⎓	
Housing protection:	ordinary equipment IPX0	

Environmental conditions:	**Functioning**	**Storage and Transportation**
Temperature		
RH		
Atmospheric pressure		

*Specifications are approximate and may vary from one unit to another or due to fluctuations in the power supply.

Specifications (continued)

Guide and declaration of the manufacturer, electromagnetic emissions		
The handpiece 3 Ref wireless 4300-000-000 drive unit is suitable for use in the electromagnetic environment specified below. the client or user of the handpiece 3 wireless power unit Ref 4300-000-000 should make sure to use it in such an environment.		
Emissions Test	**Compliance**	**electromagnetic environment guide**
RF emissions CISPR 11	Group 1	The handpiece 3 wireless power unit Ref 4300-000-000 uses RF energy only for its internal function. Thus, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions	Class B	The handpiece 3 wireless power unit Ref 4300-000-000 is suitable for use in all establishments, including domestic and those directly connected to the public power supply low voltage that supplies buildings for domestic use .
harmonic emissions IEC 61000-3-2	n / d	
voltage fluctuations / emission flashes IEC 61000-3-3	n / d	

Specifications (continued)

Guide and declaration of the manufacturer, electromagnetic immunity			
The handpiece 3 Ref wireless 4300-000-000 drive unit is suitable for use in the electromagnetic environment specified below. the client or user of the handpiece 3 wireless power unit Ref 4300-000-000 should make sure to use it in such an environment.			
Immunity Test	**IEC 60601 test level**	**Level of compliance**	**electromagnetic environment guide**
Electrostatic discharge (ESD) IeC 61000-4-2	± 6 kV contact ± 8 kV Air	Contact ± 2 ± 4 and ± 6 kV Air ± 2, ± 4 and ± 8 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be to the less than 30%.
Electrical fast transient / burst IEC 61000-4-4	± 2 kV for power supply ± 1 kV for input and exit	n / d n / d	
Surge IEC 61000-4-5	± 1 kV line to line ± 2 kV line to ground	n / dn / d	
Dips, short interruptions and voltage variations on the input lines of the supply Electric IEC 61000-4-11	<5% OR_T (Lowering of> 95% in OR_T) for 0.5 cycles 40% OR_T (60% drop in OR_T) for 5 cycles 70% OR_T (30% drop in OR_T) for 25 cycles <5% OR_T (Lowering of> 95% in OR_T) for 5 s	n / d n / d n / d n / d	
Frequency magnetic field current (50/60 Hz) IeC 61000-4-8	3:00 a.m	3 A / m, 50Hz and 60Hz	The intensities of the magnetic fields of current frequency should be a normal commercial or hospital environment.
NOTE: OR_T is the voltage of the mains alternating current before application of the test level.			

Specifications (continued)

Guide and declaration of the manufacturer, electromagnetic immunity			
The handpiece 3 Ref wireless 4300-000-000 drive unit is suitable for use in the electromagnetic environment specified below. the client or user of the handpiece 3 wireless power unit Ref 4300-000-000 should ensure use in that environment.			
Immunity Test	**Test level IEC 60601**	**Level of compliance**	**electromagnetic environment guide**
radiofrequency led to IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	n / d	Portable and mobile RF communications equipment should be used no closer than the recommended separation distance any part of the handpiece 3 wireless power unit Ref 4300-000-000, including cables. The distance is calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,17\sqrt{P}$ 80 MHz to 800 MHz $d = 2,33\sqrt{P}$ 800 MHz to 2.5 GHz **Where *P* is the maximum rated output power of the transmitter in watts (W) according to the manufacturer of the transmitter and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, determined by an electromagnetic study site[to]. They must be** lower than the compatibility level set for each interval
radiofrequency IeC 61000-4-3 Radiated	3 V / m From 80 MHz to 2.5 GHz	3 V / m	frequency. in the vicinity of equipment marked with the following symbol can interferences occur: 
NOTE 1: At 80 and 800 MHz the higher frequency range is applied. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[to] **Field strengths from fixed transmitters, such as base stations for radio (cellular and wireless) and terrestrial radio transmitters, amateur radio, AM and FM broadcasters** radio and TV stations can not be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, you should consider an electromagnetic study of the site. If the measured field strength in the place where the handpiece 3 Ref wireless 4300-000-000 drive unit exceeds the level of compatibility is used Rf applicable indicated above, the handpiece 3 with drive wireless Ref 4300-000-000 should be observed to verify whether its operation is normal. If abnormal performance is observed,

Specifications (continued)

Recommended separation distances between portable and mobile communication equipment

Radiofrequency and handpiece 3 wireless power unit REF 4300-000-000

The handpiece 3 With drive unit Ref 4300-000-000 Wireless is designed for use in an electromagnetic environment with RF disturbances are radiated controlled. the client or user of the handpiece 3 wireless power unit Ref 4300-000-000 can help prevent electromagnetic interference by maintaining a minimum distance between portable computers and mobile RF communications (transmitters) and the workpiece handheld 3 with drive Ref wireless 4300-000-000 as recommended below, according to the maximum output power of the communications equipment. Maximum rated output power of the transmitter

W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz n / d	80 MHz to 800 MHz $d = 1,17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2,33\sqrt{P}$
0.01	n / d	0.12	0.23
0.1	n / d	0,37	0,74
one	n / d	1.2	2.3
10	n / d	3.7	7.4
100	n / d	12	2. 3

For maximum power transmitters with different output than those specified above, the separation distance *d* recommended in meters (m) can be calculated using the equation corresponding to the frequency of the transmitter, where *P* is the maximum rated output power of the transmitter in watts (W) according to the manufacturer of the transmitter.

NOTE 1: At 80 and 800 MHz the separation distance of the higher frequency range is applied. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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