



ANSPACH™ EG1™ WIRELESS HAND CONTROL SYSTEM

General Information

Device Description

The eG1 Wireless Hand Control System consists of the non-sterile reusable Receiver for Wireless Hand Control, EG1A (RECEIVER-HC) and the disposable Wireless Hand Control, EG1A (WIRELESS-HC) which is provided in a sterile package configuration. The Wireless Hand Control, EG1A communicates wirelessly through the Receiver for Wireless Hand Control, EG1A to allow the user to regulate the speed of the eG1 High Speed System.

Intended Use

The eG1 High Speed System is intended for cutting and shaping bone including the cranium and spine.

Indications for Use

The eG1 High Speed System is indicated for cutting and shaping bone including the cranium and spine.

Contraindications

The eG1 High Speed System does not have any known product specific contraindications.

Potential Adverse Events

As with all major surgical procedures, risks, side effects and adverse events can occur. The following potential adverse events can occur:

- Infection
- Adverse Tissue Reaction
- Injury to Patient
- Injury to User

Intended User

This device is intended to be used by qualified health care professionals e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device.

Patient Target Group

The eG1 Wireless Hand Control System is for use with patients undergoing surgery where the cutting and shaping of bone, including bones of the cranium and spine, is desired.

Catalog number & Compatibility

Catalog Number	Consoles		Handpiece
	SC3001	SC3002	EG1A
RECEIVER-HC	•	•	
WIRELESS-HC			•

Note: DePuy Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

Cleaning and Sterilization

Receiver for Wireless Hand Control, EG1A (RECEIVER-HC)

Receivers are non-sterile capital equipment and shall always be maintained outside the Operating Room Sterile Field.

Warning: Do not immerse or sterilize the receiver.

1. Disconnect receiver from console.
2. Clean receiver by wiping with non-abrasive cloth and neutral pH detergent and deionized, distilled, or purified water after each case.
3. Dry thoroughly with non-abrasive cloth.

Wireless Hand Control, EG1A (WIRELESS-HC)

Warning: Do not reprocess the Hand Control. Hand Controls are disposable and SINGLE USE ONLY. Reprocessing hand controls may result in loss of function causing delay in surgery.

The Hand Control is provided sterile. Remove product from the package using established operating room procedures for sterile transfer.

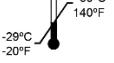
Store sterile devices in their original protective packaging, and do not remove them from the packaging until immediately before use.

Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use if the package is damaged.

Explanation of Symbols Used

General Symbols

	Direction of motion		Reference or Catalogue Number (Ref. 5.1.6 ISO 15223-1)
	Consult Instructions for Use (Ref. 5.4.3 ISO 15223-1)		Materials
	Caution: United States Federal law restricts this device to sale by or on the order of a physician or other licensed health-care provider (21 CFR 801.109)		Date of Manufacture Manufacturer (Ref. 5.1.1 and 5.1.3 ISO15223-1)
	Product is ETL listed to the requirements of US and Canada		Keep dry (Ref. 5.3.4 ISO 15223-1)
	Locked		Do not use if package is damaged. (Ref. 5.2.8 ISO 15223-1)
	Unlocked		

	Non-ionizing electromagnetic radiation. (IEC 60417-5140) Transmitter Interference may occur in the vicinity of equipment marked with this symbol.		CAUTION (Ref. 5.4.4 ISO 15223-1)
	Non-Sterile Ref. 5.2.7 ISO 15223-1		Made in
	Single sterile barrier system with protective packaging inside (Ref. 5.2.13 ISO 15223-1)		Packaging Unit - Indicates the number of pieces in the package (ISO 7000-2794)
	Sterilized using ethylene oxide (Ref. 5.2.3 ISO 15223-1)		Unique Device Identifier
	Use-by Date (Ref. 5.1.4 ISO 15223-1)		Lot or Batch Number (Ref. 5.1.5 ISO 15223-1)
	Temperature Limit ((Ref. 5.3.7 ISO 15223-1)		Humidity Limitation (Ref. 5.3.8 ISO 15223-1)
	Ingress protection rating according IEC 60529		Do not re-use (Ref. 5.4.2 ISO 15223-1)
	FCC Symbol		Follow instructions for use (ISO 7010-M002)

Warnings

<ul style="list-style-type: none"> Surgeon is responsible for learning proper techniques in use of equipment; improper use may cause serious injury to user or patient or damage to system. Instrument operator and all operating room personnel must wear eye protection. Do not use if product package has been damaged or opened. Do not use if the product sterilization barrier or its packaging is compromised. Visually inspect device/components for damage before using; do not use if damage or wear is evident (unrecognizable markings, missing or removed part numbers, corrosion, etc.). MR Unsafe—Not for use in Magnetic Resonance Imaging (MRI) environments. Do not use excessive force. Wireless Hand Control, EG1A is disposable and intended for single patient use only. Do not re-sterilize or reuse Wireless Hand Control, EG1A: reuse and/or re-sterilization 	<ul style="list-style-type: none"> Do not modify. Modifications could result in loss of electrical safety. Faulty devices must not be used. Refer to the section “Disposal of Waste”. Do not operate in an explosive flammable environment. Wireless Hand Control, EG1A is only compatible with eG1 Handpiece and Console (SC3001, SC3002). Using other than indicated high speed system may lead to injury. Receiver for Wireless Hand Control, EG1A and console must be maintained outside sterile field. Keep Wireless Hand Control, EG1A safety cover in locked position when not in use Medical Electrical Equipment needs special precautions regarding Electromagnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this accompanying documentation. The emissions characteristics of this equipment make it suitable for use in industrial areas and
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<p>of the hand control could result in reduced performance, material degradation, and/or patient contamination.</p> <ul style="list-style-type: none"> • Do not immerse or sterilize Receiver for Wireless Hand Control, EG1A. • Do not use in oxygen rich environment. • Dispose of items contaminated with body fluids with other biohazardous waste. • At end of life recycle or dispose of device in accordance with local and national regulations. • Verify that the Wireless Hand Control, EG1A is connected to the intended Receiver for Wireless Hand Control, EG1A. If the receiver controlling the console is paired to an unintended hand control, disconnect the receiver from the EG1 console to prevent unintended motion of the handpiece. 	<p>hospitals (CISPR 11 class A). This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications.</p> <ul style="list-style-type: none"> • Operation of this equipment in a residential area (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio frequency communication services. • In the event of interference, the user might need to take mitigation measures such as relocating or reorienting the equipment. • Portable and Mobile Radio Frequency (RF) communications equipment can affect Medical Electrical Equipment. • 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 eG1 system. Otherwise, degradation of the performance of this equipment could result, including intermittent loss of function or inability to pair the device.
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Precautions

<ul style="list-style-type: none"> • United States Federal law restricts this device to sale by or on order of a physician or other licensed healthcare provider. • Do not use accessories other than those provided by DePuy Synthes Power Tools and specified for use with Anspach Systems. • To ensure equipment operates as designed, read and follow manufacturer's instructions. 	<ul style="list-style-type: none"> • Use care to protect when handling, cleaning, and during system use. • Do not push receiver connector into console connector port when out of alignment.
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Latex Information

Not made with natural rubber latex.

Wireless Hand Control Set Up

Prior to first use the equipment (EG1A) must be processed as per the included EG1 High Speed System Cleaning and Sterilization instructions.

1. Inspect the equipment prior to use

Warning: Wireless Hand Control System is only compatible with eG1 Handpiece (EG1A) and Console (SC3001, SC3002). Use with other than the indicated high speed system may lead to injury or damage to product.

EG1A	<p>Visually inspect for damage to the silicone hose or to the electrical connector.</p> <p>Connect to console and operate.</p> <p>The handpiece should operate smoothly.</p> <p>There is no requirement to operate with attachment or dissection tool.</p>
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SC3001	Visually inspect for damage or cracks to the housing. Visually inspect for damage to the electrical power cord. Power the system and inspect for illumination of the LEDs. If there is an irrigation pump present, check for proper function.
SC3002	

2. Insert Receiver for Wireless Hand Control, EG1A into foot control connector port on front of console (SC3001 or SC3002) with red dot on connector facing up. See Figure 1.

Warning: Receiver and console must be outside sterile field.

Caution: Do not push receiver connector into console connector port when out of alignment.



Figure 1: Receiver connects to the foot control connector port on console (SC3001 or SC3002)

3. Remove the Wireless Hand Control, EG1A from packaging and attach the hand control onto the eG1A handpiece. See Figure 2.

Warning: Keep hand control safety cover in locked position when not in use.



Figure 2: Attach hand control onto the eG1A handpiece

4. Pair Handpiece. Press and release the button on the receiver (See Figure 3) and the hand control (See Figure 4) within 30 seconds to complete the pairing. When pairing is complete you will see the blue light go from flashing to solid on the receiver.

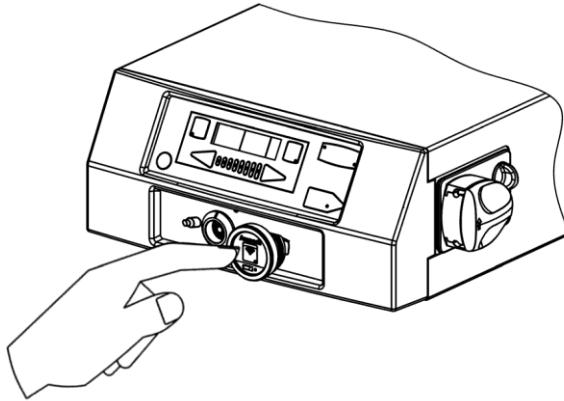


Figure 3: Push button on the receiver

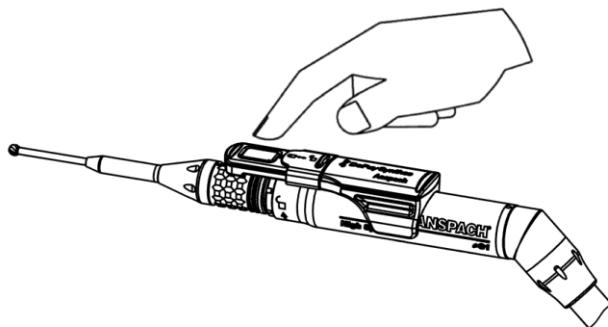


Figure 4: Push button on the hand control

5. Start operation: Unlock the hand control, grab the battery pull tab and remove it by pulling in the direction indicated by the arrow and press button on the hand control to start handpiece. Increase pressure on button to increase speed of handpiece and release pressure on button to decrease speed of handpiece.

Warning: Keep hand control safety cover in locked position when not in use.



Figure 5: Hand control cover shown in unlocked position

6. Stop Operation: Lock the wireless hand control and unpair the device. To unpair the device simply press receiver button or unplug receiver from console.

Warning: Do not re-sterilize or reuse hand control: reuse and/or re-sterilization of hand control could result in reduced performance, material degradation, and/or patient contamination.

End of Life

Wireless Hand Control, EG1A (WIRELESS-HC)

The hand control is a SINGLE USE only device. Product expiration date can be found on the device package label.

Receiver for Wireless Hand Control, EG1A (RECEIVER-HC)

The lifetime requirements of the receiver are event-related depending on the use and inspection of the device in clinical practice. The lifetime of the device may be compromised following normal conditions of use such as, but not limited to:

- Damage, including but not limited to corrosion (e.g. rust, pitting), discoloration, scratches, flaking, cracks and wear.
- Excessive temperature during operation.
- Improper function, including but not limited to inability to connect to console or failure to pair.
- Missing, faded, or removed device markings.
- Made obsolete or no longer in use.
- Damage impeding the ability to inspect or use the device.

Service Lifetime

These devices do not require periodic service.

Warranty & Return Policies

Warranty and return policy are available upon request.

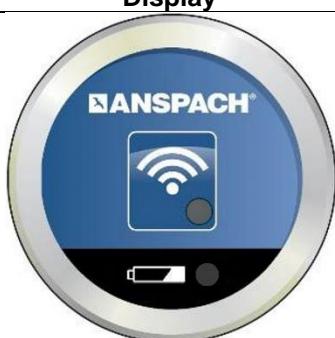
All Instrument System components returned should be properly cleaned as applicable prior to shipping to the manufacturer.

Warning: Transmissible Spongiform Encephalopathies (TSE)

DePuy Synthes Power Tools will not authorize or accept the return of products that directly contact patients or are contaminated with a patient's body fluids who is suspected or confirmed with a Transmissible Spongiform Encephalopathies/ Creutzfeldt-Jakob Disease (TSE/CJD) diagnosis. DePuy Synthes Power Tools recommends that all ANSPACH High Speed System products used on a patient confirmed with a TSE/CJD diagnosis be incinerated. ANSPACH High Speed System Dissection Tools used on a patient suspected of TSE/CJD diagnosis must be incinerated.

Contact your Sales Representative for replacement of product incinerated under this policy or for temporary equipment while original equipment is quarantined. Contact the DePuy Synthes Power Tools Customer Service Department regarding TSE/CJD contamination for additional information.

Receiver for Wireless Hand Control, EG1A Displays

Display	Result	Description
	Not Paired	Press the pairing button on the receiver and wait until light flashes blue to <u>initiate pairing</u> .

	Pairing	The <u>blue</u> light indicator will “blink” with a slow flash during pairing.
	Paired	The <u>blue</u> light indicator will be solid <u>blue</u> .
	Out of Range	The <u>blue</u> light indicator will “blink” with a fast flash when device is out of range, or the signal is lost due to interference.
	Hand Control Battery is at FULL Capacity	The battery indicator will not be ON.
	Hand Control Battery is at <50% Capacity	The battery indicator will be solid <u>red</u> .

	Hand Control Battery is at <25% Capacity	The Battery indicator will start flashing <u>red</u> .
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Trouble Shooting

Wireless Hand Control, EG1A (WIRELESS-HC)
Receiver for Wireless Hand Control, EG1A (RECEIVER-HC)

Trouble Shooting Chart		
Problem	Possible Cause	Possible Solution(s)
Receiver LED does not turn on when plugged into Console.	<ul style="list-style-type: none"> • Receiver not fully inserted • Console not powered ON 	<ul style="list-style-type: none"> • Ensure receiver is fully inserted in foot pedal connector • Ensure Console is Power ON
Cannot pair the device	<ul style="list-style-type: none"> • Battery tab not removed from hand control • RF interference • Dead battery on hand control • Hand control was previously paired with another receiver 	<ul style="list-style-type: none"> • Ensure battery pull tab is removed on • Repeat "Pairing Instructions" found on set up section or ensure device maintain a minimum distance between portable and mobile RF communications equipment (transmitters) and the eG1 System as recommended in the " Recommended separation distances between portable and mobile RF communications equipment and the eG1 System " table • Discard and replace receiver • Discard and replace hand control (can only be paired with one receiver)
Paired, but does not actuate	<ul style="list-style-type: none"> • 1.EG1 Handpiece is unlocked (load) position • Interference 	<ul style="list-style-type: none"> • Ensure EG1 handpiece is in locked (run) position • Move equipment away from source of interference
Device becomes unpaired	<ul style="list-style-type: none"> • Lost connection due to possible RF interference • Battery failure 	<ul style="list-style-type: none"> • Ensure device maintain a minimum distance between portable and mobile RF communications equipment (transmitters) and the eG1 System as recommended in the " Recommended separation distances between portable and mobile RF communications equipment and the eG1 System " table • Discard and replace hand control

Loss of Power	<ul style="list-style-type: none"> Console power failure 	<ul style="list-style-type: none"> Ensure console is plugged in and repeat “pairing instructions” found on set up section.
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Technical Specifications

FCC ID:

WIRELESS-HC: 2AYUW-WHC1
RECEIVER-HC: 2AYUW-RHC1

IC:

WIRELESS-HC: 27015-WHC1
RECEIVER-HC: 27015-RHC1

The devices comply with the following standards:

FCC 47CFR PT 15.247 Issued:2004/10/01

Operation within the bands 902-928 MHz, 2400-2483.5 MHz, and 5725-5850 MHz.

All measurement performed in 10m chamber.

FCC 47CFR: (Part 15 Subpart B)

Title 47 CFR Part 15 Subpart B: Unintentional Radiators

Concurrently with FCC Part 15.247

RSS-247

Issue: 2015/05/22 Issue 1 Digital Transmission Systems (DTSs),

Frequency Hopping Systems (FHSs) and License-Exempt Local Area Network (LE-LAN) Devices

Concurrently with FCC Part 15.247

RSS 102:2015 Ed.5

Radio Frequency (Rf) Exposure Compliance of Radiocommunication

Apparatus (All Frequency Bands)

Concurrently with FCC Part 15.247

IC ICES-003:2016Ed.6

Information Technology Equipment (Including Digital Apparatus) – Limits and Methods of Measurement

Concurrently with FCC Part 15.247

ETSI EN 300 328:2019 Ed.2.2.2

Wideband Transmission Systems; Data Transmission Equipment Operating in the 2,4 GHz band; Harmonized Standard for Access to Radio Spectrum

ETSI EN301489-1:2017Ed. V2.1.1

Electromagnetic Compatibility (EMC) Standard For Radio Equipment And Services; Part 1: Common Technical Requirements; Covering The Essential Requirements Of Article 3.1(B) Of Directive 2014/53/EU And The Requirements Of Article 6 Of Directive 2014/30/EU

Includes:

ETSI EN 301 489-17 V3.1.1 (2017-02)

ETSI EN 303 446-1 V1.2.1 (2019-07)

EN IEC 62311:2020 Testing and/or Evaluation

Receiver for Wireless Hand Control, EG1A and Wireless Hand Control, EG1A intentionally receive RF electromagnetic energy for the purpose of its operation:

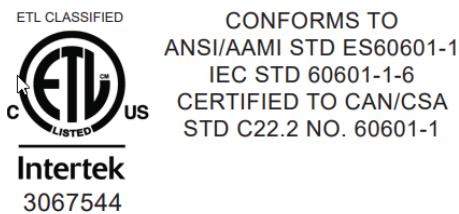
- Frequency band of reception: 2405MHz to 2475MHz
- Receiving bandwidth: 20dB bandwidth: 2.8MHz

Receiver for Wireless Hand Control, EG1A and Wireless Hand Control, EG1A include RF transmitters:

- Frequency band of transmission: 2405MHz to 2475MHz
- Type and frequency characteristics of the modulation: DSSS (direct sequence spread spectrum)/ QPSK (offset quadrature phase shift keying)
- Effective radiated power: 4dBm

FCC Compliance Statement:

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

ETL Authorization Mark:**Technical Specifications for Devices Compliant with IEC-60601-1-2 4th Edition**

The device complies with the following standards:

AAMI ES60601-1 Issued: 2006/03/09 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance, Amendment 1 – 2012

CSA C22.2#60601-1 Issued: 2014/03/01 Ed: 3 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

IEC 60601-1-6 Issued: 2013/10/29 Ed: 3 Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability; Amendment 1

IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint) EN 60601-1: 2005 + A1:2013, IEC 60601-1 / EN 60601-1, Medical electrical equipment Part 1: General requirements for basic safety and essential performance (CB Scheme)

IEC 60601-1-6:2010 (Third Edition) + A1:2013 for use in conjunction with IEC62366:2007 (First Edition) + A1:2014 and IEC 60601-1:2005 (Third Edition) + Corr.1 (2006) + Corr.2 (2007) + A1: 2012 or equivalent consolidated version IEC 60601-1:2012 (Ad.3.1), Medical electrical equipment Part 1-6 General requirements for safety - Collateral Standard: Usability

IEC 60601-1-2:2014 (Edition 4) Collateral Standard: Electromagnetic Compatibility- Medical Electrical Equipment.

Environmental Conditions		
	Wireless Hand Control, EG1A (WIRELESS-HC)	Receiver for Wireless Hand Control, EG1A (RECEIVER-HC)
Temperature	Operating: 18°-30°C (65°-85°F)	Operating: 18°-30°C (65°-85°F)
	Transportation and Storage: -29° – +60°C (-20° - +140°F)	Transportation and Storage: -29° – +60°C (-20° - +140°F)
Relative Humidity	Operating: 30% to 70%	Operating: 30% to 70%
	Transportation and Storage: 10% to 90%	Transportation and Storage: 50% to 90%

Atmospheric Pressure	Operating: 0.7–1.06bar Transportation and Storage: Not applicable	Operating: 0.7–1.06bar Transportation and Storage: Not applicable
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Receiver for Wireless Hand Control, EG1A powered through Console (SC3001/SC3002) Specifications
Primary: 100-240VAC, 50/60 Hz, 250 VA
Class I: Protective Earth
Wireless Hand Control, EG1A Specifications
Powered through: CR1620 lithium coin battery, nonreusable – disposable
Fluid Ingress Protection: IPX2

Guidance and manufacturer's declaration –electromagnetic emissions		
The eG1 System is intended for use in the electromagnetic environment specified below. The customer or the user of the eG1 System should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The eG1 System 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 A	The eG1 System is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration –electromagnetic immunity			
The eG1 System is intended for use in the electromagnetic environment specified below. The customer or the user of the eG1 System 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	±8 kV contact ±15 kV air	±8 kV contact ±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 for AC lines ±1 kV for I/O lines 100kHz Pulse Repetition Frequency	±2 kV for AC lines ±1 kV for I/O lines 100kHz Pulse Repetition Frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5, 1kV line to line ±0.5, 1, 2 kV line to earth	±0.5, 1kV line to line ±0.5, 1, 2 kV line to earth	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	0% UT (100% dip in UT) for 0.5 periods) at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% UT (100% dip in UT) for 1 period) 70% UT (30% dip in UT) for 25 periods (50Hz) 30 periods (60Hz) Interruptions 0% UT (100% dip in UT) for 250 periods (50Hz) 320 periods (60Hz)	0% UT (100% dip in UT) for 0.5 periods) at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% UT (100% dip in UT) for 1 period) 70% UT (30% dip in UT) for 25 periods (50Hz) 30 periods (60Hz) Interruptions 0% UT (100% dip in UT) for 250 periods (50Hz) 320 periods (60Hz) *	Mains power quality should be that of a typical commercial or hospital environment. (*) If the user of the eG1 System requires continued operation during power mains interruptions, it is recommended that the eG1 System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A / m	30 A / m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration –electromagnetic immunity			
The eG1 System is intended for use in the electromagnetic environment specified below. The customer or the user of the eG1 System 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 6 Vrms in ISM bands 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands 150 kHz to 80 MHz	<p>Portable and mobile RF communications equipment should be used no closer to any part of the eG1 System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3\sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,7 GHz 80% at 1kHz (AM modulation)	3 V/m 80 MHz to 2,7 GHz 80% at 1kHz (AM modulation)	<p>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).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^ashould be less than the compliance level in each frequency range. ^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>^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 eG1 System is used exceeds the applicable RF compliance level above, the eG1 System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the eG1 System.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

eG1 System Enclosure Port Immunity to RF Wireless Communications Equipment (IEC 61000-4-3)												
Test Frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)						
385	380 –390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27						
450	430 – 470	GMRS 460, FRS460	FM c) ± 5 kHz deviation 1 kHz sine	2	0,3	28						
710	704 – 787	LTE Band 13,17	Pulse modulation b) 217HZ	0,2	0,3	9						
745												
780												
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18Hz	2	0,3	28						
870												
930												
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28						
1 845												
1 970												
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation b) 217 Hz	2	0,3	28						
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9						
5 500												
5 785												
NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the eG1 System may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.												
a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50 % duty cycle square wave signal. c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.												

**Recommended separation distances
between portable and mobile RF communications equipment and the eG1 System**

The eG1 System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the eG1 System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the eG1 System 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
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
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.

Customer Service

Contact your local Depuy Synthes representative for Troubleshooting assistance.
To request a paper copy of the IFU call 800-255-2500.

Disposal of Waste

Dispose of items contaminated with body fluids or with other biohazardous waste. Please send devices that are no longer used to your local DePuy Synthes representative. Devices must be disposed of as a healthcare medical device in accordance with hospital procedures. The device contains electronics/battery and should be disposed off in accordance to local and/or national regulations.



www.e-IFU.com
US / 800-255-2500



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Not all products are currently available in all markets. Data available on request.

Please contact your DePuy Synthes Representative for more information.

All DePuy Synthes Implant Instructions for Use as well as general Instructions for Use are available as PDF files at

www.e-ifu.com

www.depuySynthes.com

Pat. www.jnjmedicaldevices.com/en-US/patentmarking

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