LABELING DEVELOPMENT AND APPROVAL

DDC Released

SECTION 1: GENERAL INFORMATION		
Date: 08/13/2019	Part Number: 18-0087	Revision: E
Document Title: G1 CLEANING AND STERILIZATION DFU		
Product Use: SC3001 SC3002 EG1A		

SECTION 2: LABELING TYPE	
☒	**Directions/Instructions for Use (DFU) / (IFU)** – Accompanying documentation in the BOM of the device as part of the Regulatory filing.
☐	**Product Literature**– Accompanying documentation in the BOM of the Product utilized in lieu or complementing the DFU or IFU.

SECTION 3: TECHNICAL CONTENT REVIEW (if applicable)	
Labeling Claims	**DRS and/or FDR Number**
☐ Sterilization	N/A
☐ Cleaning	N/A
☒ Performance	24-0113, 24-0114, 85-0004, 85-0029
☐ Shelf life and Storage	N/A
☒ Indications for Use	24-0113, 24-0114, 85-0004, 85-0029
☒Symbols	24-0113, 24-0114, 85-0004, 85-0029
☐ Other: _____	N/A

SECTION 4: LANGUAGES (Indicate by ISO 639-1 Language Code in rows below)					
English (EN)	German (DE)	Spanish (ES)	French (FR)	Italian (IT)	Portuguese (PT)
Dutch (NL)	Danish (DA)	Swedish (SV)	Finnish (FI)	Norwegian (NO)	Greek (EL)
Polish (PL)	Estonian (ET)	Lithuanian (LT)	Latvian (LV)	Hungarian (HU)	Czech (CS)
Croatian (HR)	Bulgarian (BG)	Romanian (RO)	Serbian (SR)	Other:	

List the associated article numbers, designate as an insert or outsert and where it will be packaged, and the languages by language code for each article.

Article Number	Insert/ Outsert	Ins/Ots Location	ISO 639-1 Language Codes
18-0087	Insert	PBG	EN, DE, ES, FR, IT, PT, NL
60240052	Outsert	Selzach	SV, FI, NO
60240053	Outsert	Selzach	PL, ET, LT, LV, CS, HR, EL

SECTION 5: PRINTER SPECIFICATIONS Enter "NA" if a field is not applicable

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Finished Dimensions	5" W X 7" H	127mm W x 178mm H
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Ink Type	N/A	N/A
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Finishing	Perfect Binding Full Bleed	Perfect Binding Full Bleed
Other Instructions	Anspach PN 18-0087 with revision and issue date (MM/YY), Manufacturer address/website/ email/phone & fax number, ECREP address, copyright disclaimer and Patent URL located on back cover.	Anspach PN 18-0087 with revision and issue date (MM/YY), Manufacturers address/website/email/phone & fax number, ECREP address, copyright disclaimer and Patent URL plus 2D barcode with Human Readable located on back cover.

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SECTION 6: REVIEW & APPROVAL			
Function	**Print Name**	**Approval Signature**	**Date**
PD Engineering	Jonathan Cadenhead	Jonathan Cadenhead	26-NOV-2019
Regulatory Affairs	Tamara West	Tamara J West	19 Nov. 2019
Marketing	Gwenael Gouery		21 Nov 2019
Design Quality Assurance	Denise Deluigi	Denise DeLuigi	19 Nov 2019
Sterility Assurance signature is required when sterilization claims & instructions are impacted by this revision. "N/A" otherwise.			
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ANSPACH 18-0087 Rev E 11/19 CE 2797

eG1® High Speed System

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General Information

Device Description

High Speed Drill Electric Drill System consisting of a console (SC3001, SC3002), handpiece (EG1A), foot control (E-FP, E-FP-DIR or E-FP-DIR/IRR), country or region specific medically rated A/C power cord, G1 Attachment (various options), G1 Dissection Tool (various options) and irrigation accessories.

Indications for Use

Cutting and shaping bone including spine and cranium.

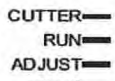
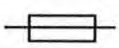
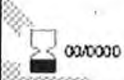
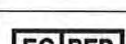
Cleaning and Sterilization

- Prior to first use the equipment must be processed as per the included G1 High Speed System Cleaning and Sterilization instructions.
- At the point of use the device must be cleaned as soon as possible after use to prevent drying of blood, tissue, other biological debris and contaminants on the device.
- Refer to the G1 High Speed System Cleaning and Sterilization instructions accompanying this device.

Features & Compatibility

		Consoles		Foot Control Features	
		SC3001	SC3002	Active Direction Control Switch	Active Irrigation Control Switch
Foot Controls	E-FP	•	•		
	E-FP-DIR	•	•	•	
	E-FP-DIR/IRR	•	•	•	•
Handpiece	EG1A	•	•		
Console Features	Console Irrigation		•		

Symbols

	Anspach Product Icon	RPM	Revolution per Minute
	Indicates the attachment setting, refer to MA-D20-G1 section in this document for further details		Potential Equalization Terminal
	Located on the Foot Pedal switch this indicates a change state (on/off) for the Console Irrigation System		1. Console Control Touch pad:Indicates a change state (on/off) for the Console Irrigation System 2. Irrigation Pump: Indicates irrigation tube direction towards the irrigation source.
	Indicates position or location		Temperature Limits
	Direction of rotation		Found on the Console ON/OFF
	Located on the Foot Pedal switch this indicates a change of rotational direction for the handpiece		Reference Number (A.K.A. Item Number, Catalog Number, Part Number)
	Indicates position, alignment, or location. (Color: Black or Red)		Lot (A.K.A. Lot Number, Batch Number, Batch Code)
	FUSE		Serial Number
	Located on the Foot Pedal switch this indicates a change of rotational direction for the Handpiece		Use By Date (A.K.A. Expiration Date, Expiry)
	AC Power Source		Manufacturer
	Consult Operating Instructions		Authorized European Union Representative
	Located on the Console this indicates motor or handpiece connector		Sterilized Using Irradiation
	Located on the Console this indicates Foot Control connector		Single Use Only (A.K.A. Do Not Reuse)
	Located on the Console Touchpad; this feature is not active on these models.		Located on the Console Touchpad; Indicates foot Control Activation
	Located on the Console this indicates Forward (Clockwise rotation when looking at handpiece from proximal end)		Keep Dry (A.K.A. Protect from Moisture)
	Located on the Console this indicates Reverse (Counterclockwise rotation when looking at handpiece from proximal end)		Sterile unless damaged or open
	United States Federal law restricts this device to sale by or on the order of a physician or other licensed health-care provider		CE Mark (A.K.A. CE Mark [notified body number], Conformité Européenne) Meaning: Device complies with applicable EEC Directives

ETL CLASSIFIED Intertek	Certified/Accredited Test House		DO NOT DISPOSE OF IN HOUSEHOLD WASTE
	Run; System ready to operate.		Type B Electrical Equipment
	Load; Insert attachment and/or burr. System will not operate.	WARRANTY VOID IF SEAL BROKEN	Product warranty is void if seal is damaged or removed.
	Transmitter Interference may occur in the vicinity of equipment marked with this symbol.		CAUTION: Refer to accompanying documentation
	Located on the irrigation pump; Move in this direction to install irrigation tube.		Indicates position, alignment, or location. (Color: Black or Red)
	Located on the irrigation pump; Indicates the portion of the irrigation tube to be directed towards the handpiece.		Located on the irrigation pump; Indicates the amount of irrigation from minimum to maximum.
	Date of Manufacture	(01)	Global Trade Item Number (GTIN)
(10)	Batch or Lot Number	(17)	Expiration Date (YYMMDD)
(21)	Serial Number	QTY	Quantity
GTIN	Global Trade Item Number	50	Indicates Environmental Friendly Use Period of 50 years in China.
10	Indicates Environmental Friendly Use Period of 10 years in China.	4th EDITION	Compliant with IEC 60601-1-2 Ed. 4.0 (2014-02) Electromagnetic compatibility.

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Warnings

- Δ **Always use continuous irrigation to prevent heat build-up. Irrigation is necessary for proper performance**.
- 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.
- Visually inspect for damage before using; do not use if damage is evident.
- Do not use if the product sterilization barrier or its packaging is compromised.
- Do not use, or discontinue use of powered equipment exhibiting excessive temperatures that can cause patient injury (necrosis) and/or user discomfort.
- Use of damaged or improperly maintained power equipment and/or misused powered equipment can result in excessive temperatures.
- Use caution to avoid cutting or tearing gloves while handling dissection tools.
- Dissection tools must be adequately retained within attachment to prevent distal migration, which may cause injury. Confirm attachment is proper size for dissection tool and that it is secure.
- Gently pull on dissection tool shaft to ensure it is fully seated and properly installed.
- Only cut visible areas unless an image intensifier is utilized.
- Delicate structures in proximity to dissection must be thoroughly protected to prevent injury.
- Maintain firm control of instrument at all times.
- Do not bend or use as a lever.
- Use a gentle tapping motion or side-to-side motion and let instrument do cutting.
- Do not use excessive force.
- Forceful side loading of dissection tool may cause fracture of dissection tool, which may cause injury.
- Dissection tools are disposable and intended for single patient use only. Do not re-sterilize and/or re-use dissection tools.
- Use standard protocol for disposal of sharp instruments.
- Continuous extreme cutting at or near stalling conditions will quickly overheat handpiece.
- Use of accessories or cables other than those provided by DePuy Synthes Power Tools and specified for use with eG1 System may result in increased emissions or decreased immunity.
- The eG1 System should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the eG1 System should be observed to verify normal operation in the configuration in which it will be used. Do not stack equipment which is heavier than 13.6 kg (30 lbs).
- Medical Electrical Equipment needs special precautions regarding 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 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.
- 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 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.
- Power source should comply with applicable IEC, CEC, and NEC requirements. Grounding reliability can only be achieved when this equipment is connected to a receptacle marked "HOSPITAL GRADE."
- Do not use in oxygen rich environment.
- No modification of this equipment is allowed.
- Do not modify. Modifications could result in loss of electrical safety.
- 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.
- To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth. The use of Accessories, transducers, and cables other than those specified,

• Do not operate in an explosive flammable environment. • Do not modify ground or power cord. • Do not allow liquid into console.	with the exception of transducers and cables sold by the Manufacturer of this device as replacement parts for internal components, may result in increased Emissions or decreased Immunity of the eG1 System.

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Cautions

• 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 insure equipment operates as designed, read and follow manufacturer's instructions. • Do not operate handpiece without an attachment and the corresponding dissection tool.	• Only Anspach G1 Dissection Tools should be used with G1 Systems. • Use care to protect hose when handling, cleaning, and during system use. • Damage to hose can cause leaking, rupture, or other related failures. • Do not step on, set equipment on, pinch, kink, clamp, or otherwise occlude handpiece hose during use.

Latex Information

Not made with natural rubber latex.

Warranty & Return Policies

Warranty and return policy is available upon request.

Warning: All Instrument System components returned for servicing or repair should be properly cleaned and sterilized as applicable prior to shipping.

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 products used on a patient confirmed with a TSE/CJD diagnosis be incinerated. Anspach 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.

System Assembly

Warning

Prior to first use the equipment must be processed as per the included G1 High Speed System Cleaning and Sterilization instructions.

Note: When following these instructions hold handpiece and attachments with distal end pointing away from user.

Console, Handpiece and Foot Control Assembly

1. Place console on a flat sturdy surface.
   Warning: Console must be outside sterile field.
2. Plug hospital grade AC power cord into AC power inlet on back of console. Plug opposite end of power cord into standard, Hospital Grade grounded wall outlet.
   Caution: Connect to supply mains with protective earth only. Position equipment in such a manner that it provides access to the rear of the system in order to disconnect from mains
3. Insert foot control connector into foot control connector port on front of console with red dot on connector facing up.
   Warning: Foot control must be outside sterile field.
   Caution: Do not push foot control connector into console connector port when out of alignment.

4. Insert handpiece connector into handpiece connector port on front of console with red dot on connector facing up.
   Warning: Handpiece must remain inside sterile field with exception of handpiece connector which is connected to console.
   Caution: Do not push handpiece connector into console connector port when out of alignment.
5. Activate console by depressing power switch located on front of console. Display will illuminate.
6. Refer to Operating Instructions below.

Warning: Handpiece is fully functional at this time.

Caution: Do not use handpiece without an attachment and dissection tool properly locked in place. Damage to the burr lock mechanism could occur.

Attachment Assembly

1. Refer to the G1 Attachment instructions accompanying the specific device.

Dissection Tools

1. Refer to the G1 Dissection Tools instructions accompanying the specific device.

Optional Irrigation Tubing Set-Up (SC3002 only)

1. Remove sterile irrigation tube from sterile package.
2. Slide irrigation tubing onto proximal end of irrigation attachment clip.
3. Attach irrigation attachment clip to handpiece.
4. Attach irrigation attachment clip to attachment.
5. Route irrigation tube end into non-sterile area.
6. Open twist-lock for irrigation pump in direction of arrow shown.
7. Insert irrigation tube into pump in accordance with marking and close twist lock.
8. Insert IV pole into bracket on back of console.
9. Hang irrigation bag onto IV Pole (maximum 1 L bag).
10. Remove protective cap from cannula and connect cannula to irrigation bag. When doing so, make sure connection nipple of cannula is not touched by non-sterile persons while securing irrigation.
11. Secure tubing to handpiece hose using Irrigation Tube Hose Clips.
12. To activate, depress "Irrigation" button on front of console. Light on front of console will be on to indicate irrigation is active.
13. To control flow of irrigation, rotate knob located adjacent to irrigation pump.
14. Irrigation can also be activated from certain optional Foot Controls (see Step 4 of Foot Control Operation).

Caution: Tubing can disconnect from connectors without warning if occluded. Do not step on, set equipment on, pinch, kink, clamp, or otherwise occlude tubing during use.

Note: Nominal Maximum Flow Rate: 95 ml/min.

System Operation

Warning

- Do not use a dissection tool without an attachment, injury may occur.
- Only Use G1 Dissection Tools. Using other than indicated dissection tools may lead to injury.
- Use the correct dissection tool and attachment combination or injury may occur.

Caution

- Do not use handpiece without an attachment and dissection tool properly locked in place. Damage to the burr lock mechanism could occur.

Console Default Settings

Direction: Forward (clockwise with distal end pointing away from user)
Speed: 80,000 RPM (maximum)
User Interface: Foot Control
Irrigation: OFF

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Console Operation

1. To increase or decrease maximum operational speed of handpiece, depress blue arrows located on front of console. Maximum operational speed increases and decreases in 10,000 RPM increments. Lights on front of console will indicate the maximum Revolutions per Minute (RPM).
2. To change rotational direction of handpiece, depress "R" or "F" arrow located on front of console. Direction can only be changed when handpiece is not running. Lights next to "F" and "R" will indicate if console is set to forward or reverse. A series of three beeps indicates console is set to operate in reverse (counterclockwise) and the foot pedal is depressed.

Note: The following steps are to operate irrigation on SC3002 console only.

3. To activate irrigation, depress the Irrigation button on front of console. Light will be on to indicate irrigation is active. **Note:** Irrigation can also be activated from certain optional Foot Controls (see Step 4 of Foot Control Operation below).
4. To control flow of irrigation, rotate knob located adjacent to irrigation pump. Irrigation flow rate is controlled by position of knob on dial located adjacent to irrigation pump.

Note: Buttons with hand and foot symbols on front of console are non-operational. Light next to foot symbol is on indicating console is set to operate in foot control mode. There is no hand control mode for EG1A Handpiece, consoles will always be in foot control mode.

Foot Control Operation

Note: Certain optional foot controls have direction and irrigation control switches.

1. Set operational direction of handpiece (see Step 2 of Console Operation).

Warning: Handpiece is fully functional at this time.
Caution: Do not use handpiece without an attachment and dissection tool properly locked in place. Damage to the burr lock mechanism could occur.

2. Press foot control pedal to start handpiece. Increase pressure on pedal to increase speed of handpiece and release pressure on pedal to decrease speed of handpiece.
3. Optional (E-FP-DIR and E-FP-DIR/IRR only): To change direction of handpiece, depress Directional Control Switch located on top left of foot control for a minimum of one second. When direction changes, a single beep will sound and light on front of console will indicate direction of rotation once the pedal is depressed. Direction can only be changed when handpiece is not running.
4. Optional (E-FP-DIR/IRR only): To activate irrigation, depress Irrigation Control Switch on top right of foot control for a minimum of one second. Light on front of console will be on to indicate irrigation is active. Press on foot control pedal to start handpiece and irrigation.

Priming Irrigation System

1. Once irrigation tubing is set-up the line may be primed from console.
2. Press and hold irrigation button on front of console for a minimum of 3 seconds to start priming process.
3. Release irrigation button to stop priming process once irrigation fluid is visible at the handpiece.
4. Confirm light is on indicating irrigation system is operational.
5. If irrigation light is not on, depress irrigation button on front of console to activate irrigation.

System Operational Assessment

1. Confirm attachment and dissection tools are properly locked in place.
2. Depress foot pedal to assure you have properly functioning device prior to proceeding.
3. Device functions as expected, if device does not function as expected refer to troubleshooting chart.

Prior to Use Inspection	
LONG-G1	Visually inspect for any damage to the tube.
LONG-HD-G1	
MEDIUM-G1	
MEDIUM-HD-G1	
MIA16-G1	
SHORT-G1	
SHORT-HD-G1	
MA-D20-G1	Visually inspect for bent or broken drive shaft and for any damage to the tube.
QD8-G1	
QD8-S-G1	
QD11-G1	
QD11-S-G1	
QD14-G1	
QD14-S-G1	
CRANI-A-G1	Visually inspect for bent or broken foot.
CRANI-L-G1	
CRANI-P-G1	
CSR60-G1	Visually inspect for overall damage or missing components.
E-FP	Visually inspect for damage to the electrical cord or connector. Visually inspect for damage or cracks to the housing or pedal.
E-FP-DIR	
E-FP-DIR/IRR	
EG1A	Visually inspect for damage to the silicone hose or to the electrical connector. Connect to console and operate. The handpiece should operate smoothly. There is no requirement to operate with attachment or dissection tool.
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	

System Shutdown

1. There are no special procedures for system shutdown. Depress power switch on front of console to shut down system for approximately 2-3 seconds.
2. To disconnect power cord from mains, grasp ridged portion of connector between thumb and forefinger of one hand. Gently pull connector away from console. Connector should remove easily. If not, ensure only ridged portion of connector is pulled. Do not pull on smooth part of connector, as connector will not disengage from console.

Additional Information

To isolate the device from the mains supply, remove the power cord. All specifications are subject to change.

The eG1 System operates continuously without a duty cycle under normal operating conditions. When a A-1 or H-1 alert is indicated on the Console display the following Duty Cycle must be employed:
1 minute ON / 1 minute OFF for unlimited number of cycles for ambient temperatures up to 29°C (85° F).

After completing the procedure perform the Inspection and Maintenance steps provided. If the alert does not clear, return the system for repair to DePuy Synthes Power Tools.

Potential Equalization Terminal

The purpose of additional potential equalization is to equalize potentials between different metal parts that can be touched simultaneously, or to reduce differences of potential which can occur during operation between the bodies of medical electrical devices and conductive parts of other objects. The eG1 System Console incorporates a dedicated potential equalization terminal that is identified by the symbol and is designed as a means of establishing potential equalization.

The potential equalization terminal is specially shaped so as to prevent the risk of accidental disconnection when used as intended and allows the lead to be removed without the need for tools. The terminal is located at the back of the eG1 System console and is accessible to the operator during normal use.

The potential equalization terminal on the eG1 System Console cannot be used as a protective earth connection. The eG1 System Console provides an IEC320 inlet with a dedicated protective earth blade. The power supply cord provided with the eG1 System Console does not provide a potential equalization conductor.

Prior to using the eG1 System, attach the potential equalization wire to the potential equalization terminal at the back of the eG1 System Console.

End of Life

Return all equipment for proper disposal.

Recommended Manufacturer Inspection Interval

It is recommended that the equipment be returned to DePuy Synthes Power Tools at a minimum every 12 months to perform a full product inspection.

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Console Alerts, Codes, and Displays

Result	Action	Display
Turn OFF Alert Sounds	Press speed increase, speed decrease, and forward buttons simultaneously	BEEP0
Turn On Alert Sounds	Press speed increase, speed decrease, and forward buttons simultaneously	BEEP1
Foot Pedal Connection	Foot Pedal is unplugged, or if the console is turned on without a foot pedal	FP 0
Foot Pedal Connection	Foot pedal is plugged in , or if the console is turned on with a foot pedal connected	FP 1
Handpiece Connection	Handpiece is connected, or if the console is turned on with a hand piece connected	E61A
Console Status	Console is ON, but not ready to run, because either the Handpiece or Foot Pedal, or both are not connected	⌐⌐⌐
Console Status	Console ready to run	0
Console Status	Console that has a connected Handpiece Running at full speed	80000
Software Version Revision	Forward and Reverse buttons are pressed simultaneously. NOTE: Example Only	10.00
Stall Condition	Handpiece does not start when the foot pedal is depressed. • Check Attachment Lock • Release Foot Pedal and restart	C-0
System Fault	Handpiece does not start when the foot pedal is depressed • Release Foot Pedal and restart	C-1
Handpiece Fault	The Handpiece must be detached from the console. If the alarm clears after the hand piece is removed, the hand piece is damaged.	C-2
Console Fault	The Console is damaged and must be returned for repair.	C-3
Temperature Alert	Handpiece temperature exceeded.	H-1
Airflow Alert	Handpiece cooling air flow is blocked. • Must use Duty Cycle.	A-1

Trouble Shooting

Trouble Shooting Chart		
Problem	**Possible Cause**	**Possible Solution**
Unit does not power ON when ON/OFF button at console is pressed.	1. Not enough time for console to detect signal.	1. Keep the ON/OFF button pressed for at least 1 second.
Unit does not power Off when ON/OFF button at console is pressed.	1. Not enough time for console to detect signal.	1. Keep the ON/OFF button pressed for at least 2 seconds.
Irrigation Pump does not rotate.	1. Irrigation pump is not enabled on display.	1. Keep the Irrigation button Pressed for at least 1 second.
Noise is heard from console even though there are no procedures being performed. **This noise was not heard when the console was first powered up.**	1. The air pump continues to functioning even when the handpiece is not being run.	1. This is a normal condition, the air pump will turn off automatically after approximately 15 minutes.
Excessive handpiece noise.	1. Faulty internal component.	1. Return attachment to DePuy Synthes Power Tools for service.
Lack of power to console.	1. Plug is not fully inserted/power switch not turned on. 2. Outlet is not functional.	1. Verify plugs to wall and back of console are pushed in completely. 2. Verify another piece of electrical equipment can receive power from outlet.
Handpiece vibration or extremely hot.	1. Faulty internal component. 2. Internal motor overheats due to continuous extreme cutting at near stalling conditions. 3. Hose may be kinked. 4. Handpiece out of balance. 5. Handpiece hose damaged.	1. Return to DePuy Synthes Power Tools for service. 2. Decrease cutting force, allow motor to cool. 3. Unkink hose (verify it is not being pinched or clamped to table). 4. Return to DePuy Synthes Power Tools for service. 5. Return to DePuy Synthes Power Tools for service.
Excessive vibration of dissection tool.	1. Dissection tool may be bent. 2. Dissection tool may not be fully seated. 3. Improper attachment and dissection tool combination. 4. Possible attachment bearing damage.	1. Replace with new dissection tool. 2. Reassemble dissection tool and attachment. 3. Only use correct dissection tool with appropriate attachment. 4. Return to DePuy Synthes Power Tools for service.
Unable to place or lock attachment.	1. The Indicator Bar in the handpiece in not aligned with the Unlock (Load) symbol. 2. Misalignment of the Angle Attachment shaft.	1. Manually rotate the Indicator Bar to the Unlock (Load) Symbol. 2. Manually rotate the unit shaft.
Unable to remove attachment.	1. Attachment has safety locking mechanism. 2. Attachment is captured by dissection tool.	1. Follow Instruction carefully to remove the attachment. 2. Manually rotate the Indicator Bar to the Unlock (Load) Symbol.
Attachment is hot.	1. Debris lodged inside attachment. 2. Possible bearing damage.	1. Clean attachment using Anspach Attachment Cleaning Instructions. 2. Return attachment to DePuy Synthes Power Tools for service.

Craniotome attachment is bent.	1. Excessive force used in operation.	1. Do not use, replace attachment.
Inoperative Foot Control.	1. Connector may not be fully inserted.	1. Verify plugs for handpiece and foot control are fully inserted. Plug will latch in place once fully inserted.

Technical Specifications for Devices Compliant with IEC-60601-1-2 3rd Edition

The device complies with the following standards:

IEC 60601-1:2005: + CORR. 1 (2006) + CORR. 2 (2007), EN 60601-1:2006 +A11:2011, ANSI/AAMI ES60601-1:2005, CAN/CSA-C22.2 No.60601-1:08, (3rd edition) Medical electrical part 1: General requirements for basic safety and essential performance;

UL 60601-1:2003 (Revised 2006), IEC 601-1:1988 +A1:1991 + A2:1995; EN60601-1:1990 with A1 and A12:1993, A2:1995 and A13:1996; and CAN/CSA C22.2 No. 601.1-M90, Standard for Medical Electrical Equipment – Part 1 General Requirements for Safety

With regard to electrical shock, fire, mechanical hazards, this ETL classified device conforms to AAMI STD ES60601-1, UL STD 60601-1, and is certified to CSA STD C22.2 No.60601-1 and 601.1

This device complies with applicable EEC directives. Medical Device Directive 93/42/EEC as amended by 2007/47/EC. Machinery Directive 2006/46/EC.

Environmental Conditions	
Temperature	Operating: 18°-30°C (65°-85°F)
	Transportation and Storage: -29° – +50°C (-20° - +120°F)
Relative Humidity	Operating: 30% to 70%
	Transportation and Storage: 10% to 90%
Atmospheric Pressure	Operating: 0.7–1.06bar
	Transportation and Storage: Not applicable

Console (SC3001 and SC3002) Specifications
Primary: 100-240VAC, 50/60 Hz, 250 VA
Class I: Protective Earth
Fluid Ingress Protection: IPX0
Type B: Applied Part, Continuous Operation

Note: If a fuse replacement is necessary, use only a Time Lag, 5 x 20 mm, 5A, 250V fuse. Item to be replaced by DePuy Synthes Power Tools repair facility ONLY. Return all equipment to DePuy Synthes Power Tools for proper disposal.

Caution: For continued protection against risk of fire and electric shock, replace fuse only as marked.

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	±6 kV contact ±8 kV air	±6 kV contact ±8 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 power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) 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	<5 % *UT* (>95 % dip in *UT*) for 0,5 cycle 40 % *UT* (60 % dip in *UT*) for 5 cycles 70 % *UT* (30 % dip in *UT*) for 25 cycles <5 % *UT* (>95 % dip in *UT*) for 5 sec	<5 % *UT* (>95 % dip in *UT*) for 0,5 cycle 40 % *UT* (60 % dip in *UT*) for 5 cycles 70 % *UT* (30 % dip in *UT*) for 25 cycles <5 % *UT* (>95 % dip in *UT*) for 5 sec	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	3 A / m	3 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms 3 V/m	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. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 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:
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 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. [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 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 $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2.3\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (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.			

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 62366 Medical devices – Application of usability engineering to medical devices

IEC 62366: 2007 (First Edition) + A1: 2014 (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.

This device complies with applicable EEC directives. Medical Device Directive 93/42/EEC as amended by 2007/47/EC. Machinery Directive 2006/46/EC.

Environmental Conditions	
Temperature	Operating: 18°-30°C (65°-85°F)
	Transportation and Storage: -29° – +50°C (-20° - +120°F)
Relative Humidity	Operating: 30% to 70%
	Transportation and Storage: 10% to 90%
Atmospheric Pressure	Operating: 0.7–1.06bar
	Transportation and Storage: Not applicable

Console (SC3001 and SC3002) Specifications
Primary: 100-240VAC, 50/60 Hz, 250 VA
Class I: Protective Earth
Fluid Ingress Protection: IPX0
Type B: Applied Part, Continuous Operation

Note: If a fuse replacement is necessary, use only a Time Lag, 5 x 20 mm, 5A, 250V fuse. Item to be replaced by DePuy Synthes Power Tools repair facility ONLY. Return all equipment to DePuy Synthes Power Tools for proper disposal.

Caution: For continued protection against risk of fire and electric shock, replace fuse only as marked.

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 U_T) 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.			

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<table>
<tr><th colspan="4">Guidance and manufacturer's declaration –electromagnetic immunity</th></tr>
<tr><td colspan="4">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.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms
150 kHz to 80 MHz

6 Vrms in ISM bands
150 kHz to 80 MHz</td><td>3 Vrms
150 kHz to 80 MHz

6 Vrms in ISM bands
150 kHz to 80 MHz</td><td rowspan="2">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.

Recommended separation distance

$d = 1.2\sqrt{P}$
$d = 1.2\sqrt{P}$ 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:

 </td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to 2,7 GHz

80% at 1kHZ (AM modulation)</td><td>3 V/m
80 MHz to 2,7 GHz

80% at 1kHZ (AM modulation)</td></tr>
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[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

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 $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2.3\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (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.			

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For patent information go to http://www.depuysynthes.com/patentmarking.

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