

Number/Revision
9014-MAN-001-F

Page 1 of 4

Electromagnetic Issues and Concerns

As is the case with most medical electronic equipment, the correct operation of the family of CHECKPOINT® Surgical Nerve Stimulators/Locators (models 9092, 9094, 9095, and 9394) and limiting potential interactions with other nearby electronic monitoring, diagnostic, treatment, and communications equipment requires an awareness and management of the electromagnetic environment in which the equipment is used. This management of the electromagnetic environment is the responsibility of the user and his facilities management or clinical engineering support functions.

To aid the user in this EMC management process, the following information is provided to characterize the emissions and susceptibility of the family of CHECKPOINT® Surgical Nerve Stimulators/Locators. This information, in three tables, is provided in the format and content recommended by the IEC 60601-1-2:Ed4.1 standard for medical electrical equipment. This standard has been adopted by the medical industry in the United States and in Europe and is a recognized consensus standard of the US Food and Drug Administration.

MARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Electromagnetic disturbances may cause the Stimulator to stop functioning. Such loss of function is obvious to the surgeon.

Table 1: Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The family of CHECKPOINT® Surgical Nerve Stimulators/Locators is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is			
used in such an environment.			
Emission Test	Compliance	Electromagnetic Environment - Guidance	
RF emissions	Group 1	The family of Checkpoint Surgical Nerve	
CISPR 11		Stimulators/Locators 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	Class A	NOTE The EMISSIONS characteristics of the family	
CISPR 11		of CHECKPOINT® Surgical Nerve Stimulators	
Harmonic emissions	Not	/Locators make it suitable for use in professional	
IEC 61000-3-2	Applicable	healthcare facilities (CISPR 11 class A).	
Voltage	Not		
fluctuations/flicker	Applicable		
emissions			
IEC 61000-3-3			

	Document Name:	Number/Revision
CHECKPOINT	Guidance to Users in Electromagnetic Environment Management and the Family of CHECKPOINT® Surgical Nerve Stimulators/Locators	9014-MAN-001-F
	Business Confidential	Page 2 of 4

Table 2: Guidance and Manufacturer's Declaration – Electromagnetic Immunity¹

The Family of Checkpoint Surgical Nerve Stimulators / Locators are intended for use in a professional healthcare facility environment, with the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.

below. The customer or the user should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Electromagnetic Environment -	
		Guidance	
Electrostatic Discharge	± 8KV contact;	Floors should be wood, concrete or	
(ESD)	$\pm 2kV$, $\pm 4kV$, $\pm 8kV$, $\pm 15kV$	ceramic tile. If floors are covered with	
IEC 61000-4-2	air	synthetic material, the relative humidity	
		should be at least 30%.	
Radiated RF EM	3 V/m		
fields	80 MHz – 2.7 GHz		
IEC 61000-4-3	80 % AM at 1 kHz;		
	Six wireless RF frequency		
	bands as described in		
	60601-1-2 Table 9		
Power Frequency	30A/m	Power frequency magnetic fields should	
(50Hz/60Hz) magnetic		be at levels characteristic of a typical	
field		location in a typical commercial or hospital	
IEC 61000-4-8		environment.	
Proximity Magnetic	65A/m at 134.2kHz with		
Fields	2.1KHz pulse modulation		
IEC 61000-4-39	7.5A/m at 13.56MHz with		
	50kHz pulse modulation		

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¹ Power Mains Immunity Testing not applicable as battery powered device.

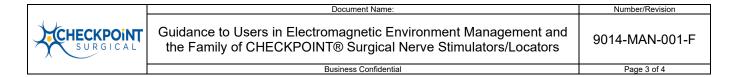


Table 3: Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Checkpoint Surgical Nerve Stimulator/Locator

Band (MHz)	Service	Separation Distance (meters)	Maximum Output Power of Transmitter (Watts)
380-390	TETRA 400	0.3	1.8
430-470	GMRS 460, FRS 460	0.3	2
704-787	LTE Band 13, 17	0.3	0.2
800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	0.3	2
1,700-1,990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	0.3	2
2,400-2,570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	0.3	2
5,100-5,800	WLAN 802.11 a/n	0.3	0.2



Document Name: Number/Revision

9014-MAN-001-F

Page 4 of 4

References

Document Number	Document Title
IEC 60601-1- 2:ED4.1	Medical Electrical Equipment – Collateral Standard for Electromagnetic Compatibility

Revision History

Rev.	Author	CO Number		Description of Changes
Α	Bob Strother	IQS 002492		Original document
В	S Galecki	IQS 7523		Modified to encompass the family of Checkpoint stimulators (Models 9094 & 9394)
Rev.	Author	CO Number	Approved Date	Description of Changes
С	S Galecki	IQS 13905	9/10/2018	Updated tables to agree with 60601-1- 2:2014
D	S Galecki	IQS 14391	12/13/2018	 Added two warnings Reclassified as Class A Removed conducted immunity requirements.
D1	Cottrill	IQS 0015567	27/OCT/2020	Include model 9095 stimulators
E	Cottrill	IQS 0015648	4/JAN/2021	Promote manual to "production" based on DVT evidence of 9495-VER-007.
F	S Galecki	IQS 0015996	22/MAR/2022	 Add model 9092 Gemini Stimulators Added information on Proximity Magnetic Fields Updated reference to 60601-1-2 revision