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.

⚠ WARNING: 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 CISPR 11	Group 1	The family of Checkpoint Surgical Nerve 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 CISPR 11	Class A	NOTE The EMISSIONS characteristics of the family of CHECKPOINT® Surgical Nerve Stimulators /Locators make it suitable for use in professional healthcare facilities (CISPR 11 class A).
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not Applicable	

Table 2: Guidance and Manufacturer's Declaration – Electromagnetic Immunity[1]

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

[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

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
A	Bob Strother	IQS 002492		• Original document
B	S Galecki	IQS 7523		• Modified to encompass the family of Checkpoint stimulators (Models 9094 & 9394)
Rev.	**Author**	**CO Number**	**Approved Date**	**Description of Changes**
C	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