SUMMARY

Electromagnetic Interference (EMI) is the disruption of normal operation of an electronic device when it is in the vicinity of an electromagnetic field created by another electronic device.

VitalStim Therapy provides non-invasive in-clinic treatment for dysphagia, a condition that causes discomfort or difficulty in swallowing. This therapy applies low energy electrical current to the skin to stimulate muscles in the neck that are responsible for swallowing.

This article provides a brief overview of VitalStim therapy and describes the potential interaction between this device and Boston Scientific implantable pacemakers and defibrillators. It also provides suggestions to minimize potential interactions.

Products Referenced
All Boston Scientific ICDs, CRT-Ds, CRT-Ps and Pacing Systems

Products referenced herein may not be approved in all geographies. For comprehensive information on device operation and indications for use, reference the appropriate product labeling.

CRT-D: Cardiac Resynchronization Therapy Defibrillator
CRT-P: Cardiac Resynchronization Therapy Pacemaker
ICD: Implantable Cardioverter Defibrillator

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VitalStim® Therapy and Implanted Medical Devices

Description

VitalStim Therapy consists of an operating unit, lead wires, and surface electrodes that are placed on the front of the patient's neck. When operating, the VitalStim unit produces an AC current that is adjustable between 0-25 mA and pulsed at a fixed rate of 80 Hz at 300 µSec.[1]

Potential EMI interactions

Electromagnetic interference (EMI) may occur when electromagnetic waves from one electronic device interfere with the operation of another electronic device. Electromagnetic waves of sufficient amplitude and/or frequency, generated within the proximity of the implanted device system, may have the potential to mimic the electrical activity of the heart or be interpreted by the device as electrical noise. This could result in unnecessary shock therapy or inhibition of pacing therapy when needed.

VitalStim Therapy considerations

Boston Scientific CRM has not conducted EMI testing specific to pacemaker and defibrillator operation during VitalStim Therapy. Also, the VitalStim Therapy user manual includes the following cautions and a warning regarding the use of their product on patients with heart conditions[1]:

- This device should be used with caution on patients with cardiac demand pacemakers.
- Caution should be used for patients with suspected or diagnosed heart problems.
- Warning: Stimulation should not be applied transthoracically.

If the pacemaker or defibrillator patient receiving VitalStim Therapy experiences symptoms such as light-headedness, increased heart rate, a defibrillation shock, or hears beeping tones from their device, the clinician should promptly turn Off the VitalStim Unit because it may be acting as a potential source of EMI.

Adjusting the VitalStim Unit to the lowest clinically effective AC current setting may reduce potential EMI with an implanted pacemaker or defibrillator; however, it should not be assumed that minimizing VitalStim current will always prevent such interference.

[1]VitalStim Therapy Unit [User Manual]. Austin, TX: Encore Medical Corporation; 2003.