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 conditions¹:

- 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.