

VitalStim Therapy and Implantable Device Systems

BACKGROUND INFORMATION

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.

ICD: Implantable Cardioverter
Defibrillator

CRT-D: Cardiac Resynchronization
Therapy Defibrillator

CRT-P: Cardiac Resynchronization
Therapy Pacemaker

CRM PRODUCTS REFERENCED*

All ICDs, CRT-Ds, CRT-Ps and Pacing
Systems

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

CRM CONTACT INFORMATION

Technical Services – U.S.
1.800.CARDIAC (227.3422)
Tech.Services@bsci.com

Technical Services – Europe
+32 2 416 7222
eurtechservice@bsci.com

LATITUDE Clinician Support
1.800.CARDIAC (227.3422)
latitude@bsci.com

Patient Services
1.866.484.3268 – U.S. and Canada
001.651.582.4000 – International

Description

VitalStim Therapy consists of an operating unit, lead wires, and surface electrodes that are commonly placed on the front of the patient's neck or occasionally along the jaw line. 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 with a duration of 300 μ Sec.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, pulse width, and/or frequency, generated within the proximity of an implanted pacemaker or defibrillator, 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

While Boston Scientific CRM has not conducted EMI testing specific to pacemaker and defibrillator operation during VitalStim Therapy, the VitalStim manufacturer recommends¹ that their system be used with caution on patients with cardiac demand pacemakers.

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.

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