

PillCam™ Capsule Endoscopy and Implantable Device Systems

SUMMARY

This article describes the PillCam™ Capsule Endoscopy procedure, and provides information regarding its use in patients implanted with pacemakers and/or defibrillators.

- The PillCam manufacturer contraindicates its use in patients implanted with a pacemaker or defibrillator.
- Evaluation of the PillCam technical specifications and Boston Scientific CRM implantable device conformity to ANSI/AAMI PC-69 standards suggests that normal operation of the PillCam should not adversely impact pacemaker or defibrillator function.
- Patients should consult with their device following physician to discuss any concerns they might have concerning the potential for interference.

AAMI: Association for the Advancement of Medical Instrumentation

ANSI: American National Standards Institute

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

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PillCam™ Capsule Endoscopy¹

The PillCam Endoscopy procedure uses an ingestible imaging capsule (Figure 1) to help detect abnormalities of the esophagus and/or gastrointestinal tract. Once the PillCam capsule has been ingested, it passes naturally through the gastrointestinal tract.

Along the way, it captures and transmits video images to an array of electrodes affixed to the patient's thorax. The SensorArray™ electrodes detect the data signals and send them directly to an external recording device called the DataRecorder™, which collects and stores the video images to be downloaded to a computer workstation for review and diagnosis.



Figure 1. PillCam capsule.

Electromagnetic interference

Like most electronic devices, the PillCam generates electromagnetic waves, which can vary in amplitude and frequency. Electromagnetic interference (EMI) may occur when electromagnetic waves from one electronic device disrupt the functioning of another electronic device. If an electronic device interferes with the operation of an implanted pacemaker or defibrillator, the effects of the interference are typically temporary.

Evaluation for potential interference

Boston Scientific has not conducted testing for potential EMI between Boston Scientific CRM implantable pacemakers and defibrillators and the PillCam device. However, Boston Scientific did evaluate transmitter, frequency, and power specifications for the PillCam capsule and PC-69 standards testing for Boston Scientific implantable pacemakers and defibrillators.² This evaluation revealed that the radiated power/frequency of the PillCam is in a range where interference was not detected, suggesting that the PillCam is not likely to cause interference with the implanted pacemaker or defibrillator.

The PillCam manufacturer, Given Imaging, contraindicates the use of PillCam in patients implanted with a pacemaker or defibrillator.³

NOTE: Patients should consult with their device following physician to discuss any concerns they might have regarding the potential for interference. Boston Scientific cannot assure the safe and effective operation of its implantable CRM device or the PillCam when used in combination.

¹PillCam product page. Given Imaging Web site. Available at <http://www.given.co.il/Cultures/en-US/Given/English/Products/CapsuleEndoscopy/>. Accessed September 22, 2008.

²ANSI/AAMI PC69:2007. *Active implantable medical devices—Electromagnetic compatibility—EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators*. Boston Scientific CRM devices conform to these standards, which includes testing to withstand at least 40 mW of radiated interference between 450 MHz and 3 GHz, using a worst-case signal modulation of 20 ms. This reference level is the lowest expected-immunity level specified in AAMI PC-69 first edition. The PillCam operates at 434 MHz, slightly below the lower frequency bound (450 MHz) in the PC-69 radiated test, and with a very low radiated power of 1 µW (-30 dBm). Boston Scientific pacemakers and defibrillators incorporate high frequency protection filters, whose characteristics predict non-significant differences in filter performance between 434 MHz and 450 MHz. (Note: For comparison, the PC69 test level of 40 mW (16 dBm) is approximately 40,000 times (46 dB) greater than the specified power of the Pillcam. Evaluation conducted in April 2008.

³PillCam SB Package Insert. Given Imaging Ltd. Doc-0325-01.