



Radio Frequency Considerations for the Use of Wireless Telemetry

with the Medtronic CareLink[®] Programmer and Implanted Medical Devices

Radio frequency (RF) technology permits communication between programmers and implanted medical devices over distances of up to several meters, making an array of potential benefits available to clinicians and patients alike. Before using a wireless telemetry system in a clinic or hospital, it's important to understand the technical details of a vendor's system. This brief explains the capabilities and advantages of Conexus[™] Wireless Telemetry used by the Medtronic CareLink Programmer, Model 2090, including:

- Use of the Medical Implant Communications Service (MICS) frequency band, which Medtronic strategically chose for optimum operation in clinics and operating rooms
- Mechanisms used to avoid radio interference, when present
- Proven ability for multiple programmers to use Conexus Telemetry simultaneously in the same clinic or hospital
- The range (distance) over which reliable communications can occur
- Confidence that Medtronic's programmer will not interfere with other wireless communication systems in a clinic or hospital environment

FREQUENCY BAND

In the United States, the Federal Communications Commission (FCC) regulates use of the radio frequency spectrum, and regulatory rules make a number of frequency bands potential candidates for use by medical devices. However, one frequency band is designated specifically for implanted medical devices: the Medical Implant Communications Service (MICS). The FCC established MICS in 1999 to provide an "ultra-low power, mobile radio service for transmitting data in support of diagnostic or therapeutic functions associated with implanted medical devices."¹ The Medtronic CareLink Programmer, Model 2090, with Conexus Telemetry utilizes the MICS band.

The MICS band operates from 402 MHz to 405 MHz. The use of the 402-405 MHz band is compatible with international frequency allocations, and these frequencies are conducive to transmitting radio signals in the human body.²

MECHANISMS TO AVOID INTERFERENCE AND ENABLE SIMULTANEOUS PROGRAMMING SESSIONS

The FCC mandates that MICS users must cooperate in the selection and use of channels in order to avoid interference with other MICS transmissions. The MICS transmitter must incorporate a mechanism for monitoring the channel or channels that the MICS devices intend to occupy.³

Medtronic's programmer with Conexus Telemetry uses Smart Radio[™] Technology, a solution that selects one of ten channels within the MICS frequency band to establish a telemetry session based on the MICS standard "Listen Before Talk" (LBT) frequency-access protocol. This protocol allows multiple simultaneous programming sessions to be collocated without interference. The LBT protocol instructs the Conexus Telemetry RF receiver to scan all channels in the MICS band for other users, or noise, prior to establishing a telemetry session. Conexus Telemetry

will open a session on the least interfered channel. Automatic frequency coordination and interference avoidance is thus provided, allowing intelligent sharing of multiple interference-free Conexus Telemetry sessions within the MICS frequency band.

TELEMETRY RANGE

Conexus Telemetry has been designed to operate over a range of at least two meters, even in high-noise environments such as hospital operating rooms. The movement of people or other obstacles between the implant and the programmer should not degrade Conexus Telemetry performance significantly in this range.

Users can expect a typical operating range of two to five meters for highly reliable operation.

NO INTERFERENCE WITH OTHER INSTRUMENTS

Conexus Telemetry will not interfere with collocated medical instrumentation or other medical telemetry due to its low transmitter power (25 μ W EIRP [Effective Isotropic Radiated Power] for both the implant and the programmer).

FIELD TESTING

In addition to system verification testing in the product development process, Medtronic has demonstrated the performance of Conexus Telemetry through field testing. Several hundred individual RF tests were performed at a range of locations inside hospitals and clinics in the United States, Canada, and Europe.

REFERENCES

¹ See the FCC website at <http://wireless.fcc.gov/services/personal/medicalimplant/>

² <http://wireless.fcc.gov/services/personal/medicalimplant/data/bandplan.html>

³ <http://wireless.fcc.gov/services/personal/medicalimplant/operations/equipment.html>

BRIEF STATEMENT: 2090 PROGRAMMER

The **Medtronic/Vitatron CareLink® Programmer system** is comprised of prescription devices indicated for use in the interrogation and programming of implantable medical devices. Prior to use, refer to the Programmer Reference Guide as well as the appropriate programmer software and implantable device technical manuals for more information related to specific implantable device models. Programming should be attempted only by appropriately trained personnel after careful study of the technical manual for the implantable device and after careful determination of appropriate parameter values based on the patient's condition and pacing system used. The Medtronic/Vitatron CareLink Programmer must be used only for programming implantable devices manufactured by Medtronic or Vitatron.

See the device manual for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential adverse events. For further information, please call Medtronic at 1 (800) 328-2518 and/or consult Medtronic's website at www.medtronic.com.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

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