ADAPTIVE, PERFORMANCE-OPTIMIZING COMMUNICATION SYSTEM FOR COMMUNICATING WITH AN IMPLANTED MEDICAL DEVICE

FIELD OF THE INVENTION

This invention relates to the field of body-implantable medical devices, and more particularly relates to implantable medical devices which include a communication subsystem.

BACKGROUND OF THE INVENTION

Since the introduction of the first implantable pacemakers in the 1960's, there have been considerable advancements both in the field of electronics and the field of medicine, such that there is presently a wide assortment of commercially-available body-implantable electronic medical devices. The class of implantable medical devices now includes not only pacemakers, but also implantable cardioverters, defibrillators, neural stimulators, and drug administering devices, among others. Today's state-of-the-art implantable medical devices are vastly more sophisticated and complex than early ones, capable of performing significantly more complex tasks. The therapeutic benefits of such devices have been well-proven.

As the functional sophistication and complexity of implantable medical device systems have increased over the years, it has become increasingly more important for such systems to include a system for facilitating communication between one implanted device and another implanted device and/or an external device, for example, a programming console, monitoring system, or the like.

Shortly after the introduction of the earliest fixed-rate, non-inhibited pacemakers, it became apparent that it would be desirable for a physician to non-invasively obtain information regarding the operational status of the implanted device, and/or to exercise at least some amount of control over the device, e.g., to turn the device on or off or adjust the fixed pacing rate, after implant. Initially, communication between an implanted device and the external world was primarily indirect. For example, information about the operational status of an implanted device could be communicated via the electrocardiogram of the patient by modulating the rate of delivery of stimulating pulses in some manner. This was the case for the Medtronic Spectrax™, circa 1979, for which a 10% change in pacing rate was used to indicate battery status. This method could only provide a very low data rate transmission without interfering with the clinical application of the device. An early method for communicating information to an implanted device was through the provision of a magnetic reed switch in the implantable device. After implant, the reed switch would be actuated by placing a magnet over the implant site. Reed switch closure could then be used, for example, to alternately activate or deactivate the device. Alternatively, the fixed pacing rate of the device could be adjusted up or down by incremental amounts based upon the duration of reed switch closure.

Over time, many different schemes utilizing a reed switch to adjust parameters of implanted medical devices have been developed. See, for example, U.S. Pat. No. 3,311,111 to Bowers, U.S. Pat. No. 3,518,997 to Sessions, U.S. Pat. No. 3,623,486 to Berkovits, U.S. Pat. No. 3,631,860 to Lopin, U.S. Pat. No. 3,738,369 to Adams et al., U.S. Pat. No. 3,805,796 to Terry, Jr., and U.S. Pat. No. 4,066,086 to Alferness et al.

As new, more advanced features have been incorporated into implantable devices, it has been increasingly necessary to convey correspondingly more information to the device relating to the selection and control of those features. For example, if a pacemaker is selectively operable in various pacing modes (e.g., VVI, VDD, DDD, etc.), it is desirable that the physician or clinician be able to non-invasively select a mode of operation. Similarly, if the pacemaker is capable of pacing at various rates, or of delivering stimulating pulses of varying energy levels, it is desirable that the physician or clinician be able to select, on a patient-by-patient basis, appropriate values for such variable operational parameters.

Even greater demands are placed upon the communication system in implantable devices having such advanced features as rate adaptation based upon activity sensing, as disclosed, for example, in U.S. Pat. No. 5,052,388 to Sivula et al. entitled "Method and Apparatus for Implementing Activity Sensing in a Pulse Generator", or in U.S. Pat. No. 5,271,395 to Wahlstrand et al. entitled "Method and Apparatus for Rate-Responsive Cardiac Pacing." The Sivula et al. '388 and Wahlstrand et al. 395 patents are each hereby incorporated by reference herein in their respective entireties.

The information that is communicated to the implantable device in today's state-of-the-art pacemakers can include: pacing mode, multiple rate response settings, electrode polarity, maximum and minimum pacing rates, output energy (output pulse width and/or output current), sense amplifier sensitivity, refractory periods, calibration information, rate response attack (acceleration) and decay (deceleration), onset detection criteria, and perhaps many other parameter settings.

The need to be able to communicate more and more information to implanted devices (i.e., to establish "down/ink" communication channels) quickly rendered the simple reed-switch closure arrangement inadequate. Also, it has become apparent that it would also be desirable not only to allow information to be communicated to the implanted device, but also to enable the implanted device to communicate information to the outside world (i.e., to establish "uplink" communication channels). (As used herein, the terms "uplink" and "uplink communication" will be used to denote the communications channel for conveying information from the implanted device to an external unit of some sort. Conversely, the terms "downlink" and "downlink communication" will be used to denote the communications channel for conveying information from an external unit to the implanted device. Although this terminology assumes that communication is occurring between an implanted device and an external device, it is contemplated that the communication system described herein is equally useful and beneficial in situations where communication occurs between any two or more devices, whether some are implanted and others are implanted, or all are implanted, or all are external.)

For diagnostic purposes, it is deskable for the implanted device to be able to communicate information regarding the device's operational status and the patient's condition to the physician or clinician. State of the art implantable devices are available which can even transmit a digitized electrical signal reflecting electrical cardiac activity (e.g., an ECG, EGM, or the like) for display, storage, and/or analysis by an external device. In addition, known pacemaker systems have been provided with what is referred to as Marker Channel™ functionality, in which uplink information regarding the pacemaker's operation and the occurrence of physiological