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Implantable electrocardiographic monitoring devices

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Recent advances in wireless communication, data storage, and implantable electronic technologies have ushered in a new era of real-time, remote electrocardiographic (ECG) monitoring using implantable devices. Existing continuous external ECG monitoring is limited by the patient's ability to tolerate adhesive electrodes applied to the skin for days at a time, and the need to have the device worn on the waist or around the neck at all times. These external ambulatory ECG monitoring devices are first line when limited monitoring are needed but are impractical for long term use. The incorporation of cellular communication technology to provide real-time, continuous external ECG monitoring is highlighted by Cardionet's monitoring services. In this model, ECG data is continuously transmitted to a central location via cell phone communication for analysis and reporting [1, 2].

Implantable ECG devices are indicated for patients requiring long-term monitoring to diagnose the cause of recurrent syncope or to aid in the active management of arrhythmias such as atrial fibrillation over prolonged periods of time (months to years). A key criterion for any implantable ECG monitor is that it be minimally invasive, reliable, wireless enabled, and programmable to meet the individual patient's diagnostic needs.

While these devices are clearly distinct from therapeutic devices such as pacemakers and implantable cardioverter-defibrillators, the technological advances of the latter group have facilitated the emergence of this technology.

In 1998 Medtronic received Food and Drug Administration approval for the "reveal" implantable loop recorder (ILR), ushering in the first generation of automatic implantable ECG recording technology [3]. The ILR provided physicians with a powerful tool for managing a specific group of patients: those with recurrent syncope of unknown etiology. The ILR platform allows for patient-activated storage of ECGs and automatic recording triggered by heart rate criteria programmed by the health provider. Until recently, access to the stored ECG data required an office visit to download the information. Within the past year remote transtelephonic transmission of data has been made possible, facilitating the exchange of information between patients and health care providers.

In 2007 Transoma introduced their "sleuth" implantable ECG monitoring system, which, in addition to standard automatic and patient-activated recording of ECG data, has the capability to automatically transmit the data to handheld "personal diagnostic manager" (PDM) [4]. The PDM then establishes a communication link with, and downloads data to, a base station in the patient's home. The base station then communicates with a monitoring centre that operates 24-hours a day, seven days a week to provide interpretation of the arrhythmia. The electrocardiographic data is reviewed by certified technicians and transmitted to the physician's office via fax, e-mail, or telephone. In addition, the active screening of all ECG data by the technicians reduces the physician's office time and the resources required to sort out artefacts and clinically irrelevant transmissions. In this situation, near real-time transmission of data to a central station is limited to those times that the patient is at home. Any arrhythmias occurring outside the home will not be available for analysis or notification until the patient returns home and a communication link is made between the patient's implanted device and the base station.

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Current clinical guidelines focus on using these devices in patients with unexplained syncope, near syncope, dizziness, or palpitations. However, implantable ECG monitors provide clinicians with a new set of tools that are not limited to diagnostics but allow long term arrhythmia management. The incorporation of a small handheld interface for patients provides an opportunity to develop patientspecific applications in the future that empower the patients to play an active role in their own health care. The potential utility of these technologies in clinical practice includes the monitoring of arrhythmias such as atrial fibrillation and its response to pharmacologic, radiofrequency or cryoablation techniques, or device-based therapeutics. In the future, implantable ECG monitoring devices will probably play a key role in clinical arrhythmia trials studying the efficacy of various therapeutic approaches such as pulmonary vein isolation in atrial fibrillation. The objective continuous control and

post-intervention monitoring of arrhythmias provided by this technology may facilitate and provide a much more accurate picture of treatment outcomes in the long term.

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