Real-Time ECG Monitoring for Patients with Implantable Pacemaker – A Review of Current Status

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Introduction: Implantable pacemakers are widely used for managing patients with certain cardiac rhythm abnormalities to reduce mortality and morbidity while improving quality of life. However, for ECG devices that have to analyze these surface ECG signals, it has always been a major challenge to maintain a high level of performance. Several recent advances in pacemaker development have created even further challenges for the ECG devices.

Paced patients monitoring: In addition to detect the same arrhythmias as for the non-paced patients, several pacing related failures also need to be detected, including: failure to pace (over-sensing), failure to sense (under-sensing), and loss of capture. Monitoring systems are designed based on the observation and specification of the pace pulse characteristics and their interaction with patients' intrinsic rhythms. Deviation from these specific signal assumptions will likely cause the algorithms to perform poorly.

Issues: Earlier pacemaker developments such as single-chamber ventricular pacing, single-chamber atrial pacing, dual-chamber pacing, unipolar vs. bipolar pacing are well understood. However, more recent advances such as: biventricular pacing, multipoint pacing, leadless pacemakers, device-specific algorithms for reducing ventricular pacing frequency and managing pacing output to improve battery life are much more complex and thus are more difficult to evaluate whether the ECG devices can still function effectively.

Recommendations: To ensure safe and effective paced patients monitoring, the following development are proposed: 1) Development of high-fidelity paced databases with variety of pacing failure events for algorithm development and testing. 2) In addition to the directly acquired patient signals, simulated test signals that incorporate all aspect of the new signal characteristics are also required for ECG device validation. 3) Development of a mandatory protocol for pacemaker manufactures to disclose device specifications that may have monitoring impact with examples of surface ECGs. The disclosed information must be available publicly and easily accessible.