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October 11, 2011

Patrick Conway, MD  
Chief Medical Officer and Director  
Office of Clinical Standards and Quality  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

RE: November 9<sup>th</sup> Medicare Evidence Development & Coverage Advisory  
Committee (MEDCAC) Meeting

Dear Dr. Conway:

The American College of Cardiology (ACC) is pleased to submit comments on the use of electrocardiogram based signal analysis technologies (SAECG) to detect myocardial ischemia or coronary artery disease (CAD). The College is a 39,000-member nonprofit medical society composed of physicians, nurses, nurse practitioners, physician assistants, pharmacists, and practice administrators, and bestows credentials upon cardiovascular specialists who meet its stringent qualifications. The ACC is a leader in the formulation of health policy, standards and guidelines, and is a staunch supporter of cardiovascular research.

First, we want to specify the technology to which we refer in our comments. We understand MEDCAC uses the term SAECG to describe devices that assess electrical activity of the heart and that transform and/or interpret the signal through spatial imaging or advanced mathematical modeling to produce new indices. The MEDCAC is not evaluating 12-lead ECG or other technologies used only to diagnose arrhythmias. During our review, we found that confusion exists about exactly which technologies fit into the SAECG definition. We attempted to limit comments to those technologies we felt best align with the above definition.

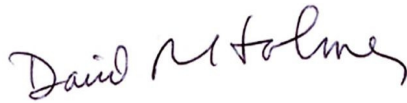
Several ACC documents address computer analysis of ECG, although none focus exclusively on SAECG. A 2001 clinical competence statement discussed computer interpretation of ECGs. This document noted, "...although computer interpretations of ECGs may have useful adjunctive value, they cannot substitute for interpretations by experienced electrocardiographers and should not be used in making clinical decisions."<sup>i</sup> More recently, a scientific statement on standardization and interpretation of ECGs emphasized that computer-based interpretation of ECG is an adjunct to

the electrocardiographer that requires physician overreading.<sup>ii</sup> The algorithms should be based on well-constructed databases and should be validated with data that have not been used for development.

ACC reviewers stressed that a number of developing devices utilize this general technique. A lack of literature currently exists to support widespread use. We believe the technique to be experimental/investigational at this time.

We hope you find these references helpful in your review of SAECG technologies used to manage myocardial ischemia. Please contact James Vavricek, Senior Specialist for Regulatory Affairs, at 202-375-6421 or [jvavricek@acc.org](mailto:jvavricek@acc.org) if you have any questions or need additional information.

Sincerely,

A handwritten signature in dark ink, appearing to read "David R. Holmes, Jr.", with a stylized, cursive script.

David R. Holmes, Jr., MD, FACC  
President

<sup>i</sup> Kadish Ah, et al. ACC/AHA Clinical Competence Statement on Electrocardiography and Ambulatory Electrocardiography: A Report of the ACC/AHA/ACP-ASIM Task Force on Clinical Competence. *J. Am. Coll. Cardiol.* 2001;38;2091-2100.

<sup>ii</sup> Kligfield P, et al. Recommendations for the Standardization and Interpretation of the Electrocardiogram: Part I The Electrocardiogram and Its Technology. *J. Am. Coll. Cardiol.* 2007;49;1109-1127.