ECG-based signal analysis technologies  
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**Record Status**  
This is a bibliographic record of a published health technology assessment from a member of INAHTA. No evaluation of the quality of this assessment has been made for the HTA database.

**Citation**  

**Authors' conclusions**  
The horizon scan identified seven ECG-based devices used to diagnose CAD or detect acute myocardial infarct. Of these devices, the PRIME ECG, the Cardio3KG, and the 3DMP appear to be commercially available at this time, with only the PRIME ECG and 3DMP having obtained FDA clearance for marketing. Our original search of the English-language literature identified only six studies that reported on performance characteristics of a single ECG-based signal analysis device (the PRIME ECG) in outpatients with chest pain. An expanded search strategy that allows for the inclusion of studies on patients at higher risk of CAD identified an additional seven studies. The PRIME ECG appears to be the only relevant device in the published literature that has been evaluated in patients with acute chest pain, but it was compared to an incomplete reference standard that only detected acute myocardial injury. Even these studies enrolled subjects at higher risk than the target population for this report. The available published evidence suggests that the PRIME ECG demonstrates slightly more favorable performance characteristics compared to the standard ECG among patients with ischemic-type chest pain, with myocardial injury as assessed by biomarkers as the reference standard. We were unable to identify any published evidence about the performance characteristics of the PRIME ECG among the patient population of interest (e.g., persons at low to intermediate risk of CAD). Limited published evidence suggests that the 3DMP may have adequate retest reliability, but studies are needed that fully evaluate inter-rater reliability and include electrode placement as a potential source of variability. Test performance characteristics for this device appear to be generally good, but the findings from the published studies do not apply to the target population for this report.

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