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Novel Computational Mapping System Accurately Localizes Arrhythmia Sources

# Forward-solution Computational Arrhythmia Source Mapping: The vMap Study

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## Background and Objective

The accuracy of arrhythmia source localization using a forward solution computational mapping system has not yet been evaluated in blinded, multi-center analysis. The study tested the hypothesis that a computational mapping system using a comprehensive arrhythmia simulation library would provide accurate localization of the site of origin for atrial and ventricular arrhythmias and pacing using the 12-lead ECG compared with the gold standard invasive electrophysiology study and ablation.

## Methods

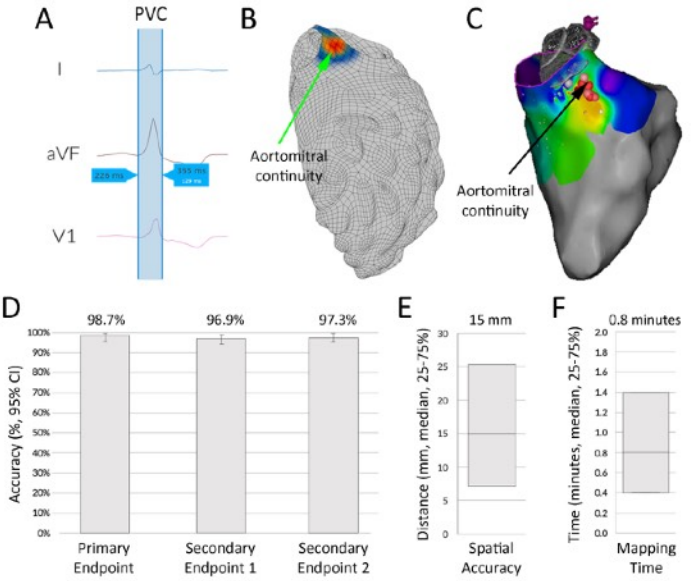
The vMap study was a blinded, multi-center evaluation with final data analysis performed by an independent core laboratory. Eligible episodes included atrial and ventricular: tachycardia (VT), fibrillation, pacing, premature complexes (PACs and PVCs; figure panel A); and orthodromic antrioventricular reentrant tachycardia. Forward-solution mapping system results (panel B) were compared with the gold standard of successful ablation or pacing during invasive study and ablation (panel C). Mapping time performance was assessed from timestamped analysis logs. Pre-specified performance goals were used for statistical comparison.

## Results

A total of of 255 episodes from 225 patients were enrolled from 4 study centers.

- Regional accuracy for VT and PVCs in patients without significant structural heart disease (n=75, primary endpoint) was 98.7% (95% CI: 96.0-100%, p<0.0001 to reject study null hypothesis, panel D).
- Regional accuracy for all episodes (secondary endpoint 1) was 96.9% (95% CI: 94.7-99.0%, p<0.001).
- Accuracy for the exact or neighboring segment for all episodes (secondary endpoint 2) was 97.3% (95% CI: 95.2-99.3%, p<0.001).
- Median center-to-center spatial accuracy was 15 mm (n=255, IQR: 7-25 mm, panel E).
- The mapping process was completed in a median of 0.8 minutes (IQR: (0.4-1.4 minutes, panel F).

**Analysis of vMap™ Results**




## Conclusion

Computational ECG mapping using a forward simulation approach exceeded pre-specified accuracy goals for arrhythmia source and pacing site localization. Spatial accuracy analysis revealed clinically actionable results. This rapid, non-invasive mapping technology may facilitate catheter-based and non-invasive arrhythmia therapies.

vMap™ is commercially available in the U.S.