

## Stability and performance of the EnSite Precision cardiac mapping system for electrophysiology mapping and ablation procedures: results from the EnSite Precision observational study

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**Background:** The EnSite Precision™ Cardiac Mapping System is a catheter navigation and mapping system capable of displaying the three-dimensional (3D) position of conventional and sensor enabled electrophysiology catheters, as well as displaying cardiac electrical activity as waveform traces and dynamic 3-D maps of cardiac chambers.

**Objective:** The EnSite Precision™ Observational Study was designed to quantify and characterize the use of the EnSite Precision™ Cardiac Mapping System for mapping and ablation of cardiac arrhythmias in a real-world environment and to evaluate procedural and subsequent clinical outcomes.

**Methods:** 1065 patients were enrolled at 38 centers in the U.S. and Canada between 2017–2018. Eligible subjects were adults undergoing a cardiac electrophysiology mapping and radiofrequency ablation procedures using the EnSite Precision™ System.

**Results:** Of 989 patients who completed the protocol, a geometry was created in 936 (94.7%). Most initial maps were created using Automap (n=545, 67.0%) or a combination of Automap and manually mapping

(n=151, 18.6%). Median time to create an initial map was 9.0 min (IQR 5.0–15.0), with a median number of used mapping points per minute of 92.7 (IQR 30.0–192.0). During ablation, AutoMark was used in 817 (82.6%) of procedures. The most frequent metrics for lesion color were Impedance Drop or Impedance Drop Percent (45.5% combined), time (23.9%) and average force (14.2%). At Canadian sites where LSI was an option, it was used as the color metric in 87 (45.8%) of cases (10.6% overall). The EnSite System was stable throughout 79.7% (n=788 of 989) of procedures. Factors affecting stability were respiratory change (n=88 of 989, 8.9%), patient movement (n=73, 7.4%), CS Positional Reference dislodgement (n=32, 3.2%), and cardioversion (n=19, 1.9%). Conscious sedation was used in 189 (19.1%) of patients. Acute success was reached based on the pre-defined endpoints for the procedure in 97.4% (n=963) of cases.

**Conclusion:** In a real-world study analysis, the EnSite Precision™ mapping system was associated with a high prevalence of acute procedural success, low mapping times, and high system stability.