Introduction: The SentiAR engine uses a mixed reality head-mounted display (Microsoft HoloLens) for the display of real-time digital stereoscopic 3-dimensional electroanatomic models of patient-specific geometry with catheter locations within the body. Additionally, the system interface provides physicians with a sterile, hands-free, intuitive interface with which they can manipulate the model (rotation, zoom and alterations in transparency). The purpose of this study is to describe the first-in-human usability and accuracy assessment using the SentiAR system compared to a traditional electroanatomic mapping system (EAMS; EnSite Velocity).

Methods: Pediatric patients scheduled for electrophysiology (EP) studies were enrolled in the study protocol. During the procedural waiting phase, physicians were asked to perform a series of time-limited tasks under 2 conditions, randomized in sequence: (1) EAMS, (2) SentiAR. Tasks included: (1) creation of a cardiac chamber (maximum time limit of 5 minutes) and (2) point-by-point navigation (maximum time limit of 60 seconds/point). During point-by-point navigation, a series of 5 spatially disparate points were placed within the previously created geometry. Physicians were then asked to sequentially navigate to each point. Markers were placed in the EAMS at the successful site of navigation as defined by the physician. Target points were defined as ground truth. Coordinate x,y,z locations for each marker (both target and navigation points) were taken from the EAMS and used to calculate the Euclidian distance of each navigated point to the designated target point. Area, volume and sphericity were calculated.

Result: Nine patients were enrolled with diagnoses of atrioventricular nodal reentrant tachycardia (AVNRT) n=5, atrioventricular reentrant tachycardia (AVRT) n=3 and premature ventricular contractions (PVC) n=1. Eight right atrial geometries and 1 right ventricular geometry were created under both conditions; there was no difference in time to geometry creation between the conditions (4:21mins EAMS versus 4.43mins SentiAR, p=0.1) or time in point by point navigation (30sec EAMS versus 30sec SentiAR, p=0.9). When quantitatively comparing geometries, there was no significant difference in area (p=1), volume (p=0.8) or sphericity (p=0.5) between the models. For point by point navigation, 2 sets of points (n=4) were disqualified for the navigation task not being completed within the allotted timeframe, resulting in 86 points available for analysis. When using the EAMS, the average distance of marker lesions from the intended target point was 4.6±4.1mm; when using the SentiAR system, the average distance from the intended target point was 2.9±1.8mm (p=0.006).

Conclusion: Use of a mixed reality system, providing the physician with stereoscopic visualization as well as control of model views allowed for more point accurate navigation when compared to navigation using EAMS.