

A novel cardiac signal processing system for electrophysiology procedures: early insights from the pure ep 2.0 study

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Background: Intracardiac electrogram data remain one of the primary diagnostic inputs guiding complex ablation procedures. However, the technology to collect, process, and display intracardiac signals has remained relatively unchanged for the past two decades.

Purpose: We test a new platform, the PURE EP™ 2.0 system (PEP; BioSig Technologies) for signal processing and display.

Methods: Identical electrocardiographic and intracardiac signal data were recorded during 15 AF ablation procedures from the PEP system, the signal recording system, and the 3D mapping system (Figure). The collected signals underwent blinded, controlled evaluation by three independent electrophysiologist reviewers to determine whether the PEP signals are a viable alternative to conventional sources and if it provides additional or clearer diagnostic information. Reviewers were asked to record the quality of each signal sample on a scale of 1–10 and select a rationale for their

rating in a dropdown menu. Each paired signal rating was collected and unblinded for the analysis. If the reviewer rated the samples in the set within 1 point of each other, the PEP sample was deemed equivalent to the control. Using a 2+1 statistical method, the ratings from the three reviewers were then compared looking for at least two positive reviews for each PEP sample.

Results: Based on the ratings for each pair of signals, a cumulative total of 29 PEP signals out of 34 (85.3%) were rated as statistically equivalent or better for this dataset. In 35.5% of samples, the reviewers selected PEP because "more signal components were visible".

Conclusion: The PURE EP 2.0 system is able to produce reliable and high-quality signals when compared to available standard of care systems. Further studies with larger dataset across multiple sites are needed to validate these results.

