# A novel cardiac signal processing system for electrophysiology procedures: early insights from the PURE EP 2.0 study

Carola Gianni, Amin Al-Ahmad, Bradley P Knight, Wendy Tzou, Pasquale Santangeli, MaryAnn Edzards, Kelsey Tarzia, James Lee, Avyaya Sharma, Julie Stephenson, Shane M Bailey, G Joseph Gallinghouse, Rodney P Horton, David Kessler, Andrea Natale

## Background

Intracardiac electrogram (EGM) 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

Herein, we tested a new platform, the PURE EP 2.0 system (BioSig Technologies) to determine whether the its signals are a viable alternative to conventional sources and if it provides additional or clearer diagnostic information.

## Methods

Electrocardiographic and bipolar EGM signal data were recorded during 15 atrial fibrillation ablation procedures in one center using the PURE EP system and a conventional signal recording system (CardioLab - formerly Prucka; General Electric). The bipolar EGMs were acquired with the following settings:

- CardioLab: 1 kHz sampling frequency, filtered between 30-500 Hz, with 5000 gain and notch pass filter on
- PURE EP: 2 kHz sampling frequency, filtered with an high pass of 30 Hz, "gain" (i.e., zoom) 2.88 to 4.0, no notch pass filter

For review, signals were displayed with a 100 mm/sec sweep speed.

The collected signals underwent blinded, controlled evaluation by three independent electrophysiologist reviewers. 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 PURE EP 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 PURE EP sample.

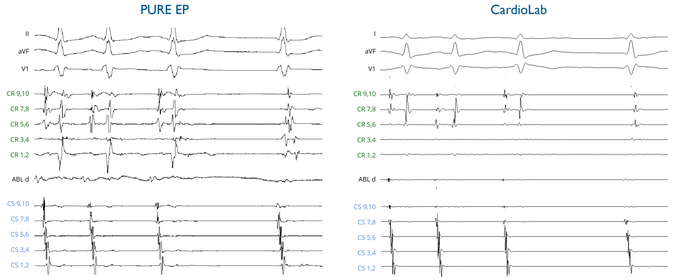
## Conclusions

The PURE EP 2.0 system is able to produce reliable and high-quality signals when compared to CardioLab. Further studies with larger dataset across multiple sites are needed to validate these results.

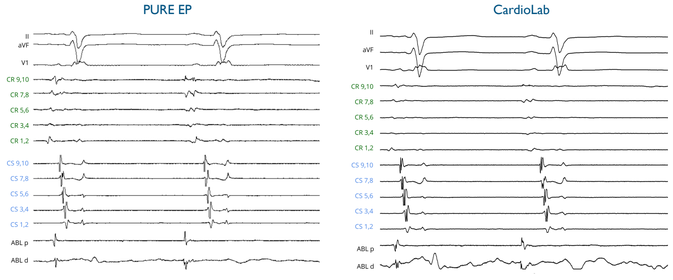
## Results

34 pairs of signals were evaluated by all reviewers. Based on the ratings for each pair of signals, a cumulative total of 29 PURE EP signals out of 34 (85%) were rated as equivalent or better for this dataset. In 36% of samples, the reviewers selected PURE EP because "more signal components were visible."

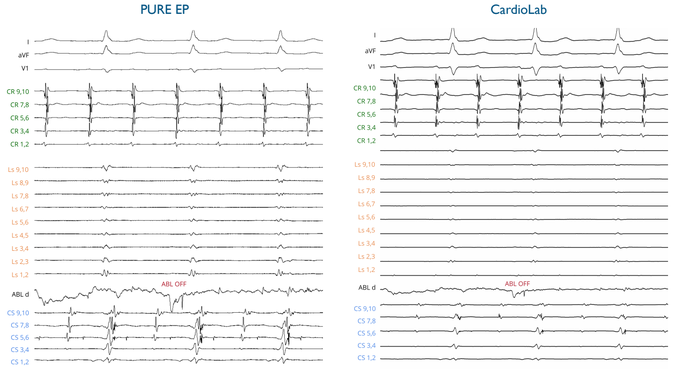
## Examples



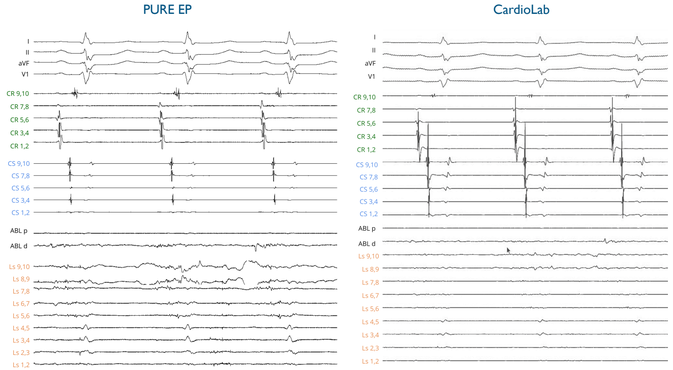

Example of electrograms on the distal ablation catheter (ABL d) and distal crista terminalis (CR) during termination of atrial flutter




Example of noise on the distal ablation catheter (ABL d) during RF ablation




Example of split electrograms on the proximal-mid coronary sinus (CS) catheter during atrial flutter ablation




Example of fragmented electrograms on the Lasso catheter (Ls, positioned in the LA) and distal ablation catheter (ABL d) during atrial flutter



carola.gianni@gmail.com