

Innovations in EP: Interview with Greg Cash

Interview by Jodie Elrod

In this interview, *EP Lab Digest*[®] speaks with Greg Cash about the proprietary PURE EP™ technology platform, designed to improve the clinical outcomes of electrophysiology procedures. Greg Cash is the President and CEO of BioSig Technologies, Inc., located in Los Angeles, California.

What is the PURE EP System?

The PURE EP System is a multichannel electrocardiogram and intracardiac EP recording platform. It is designed to allow for precise, uninterrupted, real-time evaluations of electrocardiograms and electrograms during electrophysiology procedures ranging from simple diagnostic tests to catheter ablation for the most complex cases of arrhythmias.

How was the PURE EP System developed? Tell us about its concept validation and technology development.

The PURE EP System has been developed with the input of leading cardiac electrophysiologists from around the country. Initial concept discussions were held with Drs. Andrea Natale and Luigi Di Biase at Texas Cardiac Arrhythmia Institute (TCAI); proof of concept, as well as prototype testing, were carried out at the EP and animal

labs at UCLA Cardiac Arrhythmia Center with Dr. Kalyanam Shivkumar and his team. Valuable guidance has been provided by Dr. Mauricio Arruda from UH Case Medical Center in Cleveland. Clinical input has also been provided by Dr. Vivek Reddy from Mount Sinai Hospital in New York, Dr. David Haines from William Beaumont Hospital in Michigan, and Dr. Hiroshi Nakagawa from the Heart Rhythm Institute at the University of Oklahoma.

How does the proprietary PURE EP System compare with conventional EP recording systems currently available?

What disadvantages are there in current EP recording systems?

The PURE EP System preserves the patient's cardiac signal morphology by minimizing non-biologic signals such as noise, artifacts, and baseline wander through digital signal processing. Existing systems, many of which employ core technology nearly 20 years old, are unable to eliminate electrical interference without compromising signal quality.

In what ways can the PURE EP System help improve ablation procedures?

The technology employed in the PURE EP System was designed to

allow electrophysiologists to obtain signals' morphology currently masked by noise, such as early activation and late potentials in the case of ventricular tachycardia, and various atrial signals in the case of atrial fibrillation. Theoretically, this should allow for more precise ablation.

How have procedure times been affected using this system?

This has yet to be validated; however, the system employs confidence indexes aimed at improving procedural efficiency by eliminating the need for multiple maneuvers and retrospective data validation.

In what ways does the PURE EP System help workload and patient outcomes in the EP lab?

When validated, the software features and confidence indexes could result in time reduction of EP studies and ablation procedures, thereby increasing lab throughput. In terms of outcomes, the potential exists to improve success rates by identifying further ablation targets, in addition to anatomically based procedures such as the pulmonary vein isolation approach for atrial fibrillation ablation.

What studies are taking place using the PURE EP System?

We are planning animal studies with Drs. Samuel Asirvatham and K.L. Venkatachalam at the Mayo Clinic in Rochester as well as with Dr. Shivkumar at UCLA in Los Angeles. The clinical plan for human studies is currently under development.

What are the next steps? How soon could we see approval and commercialization of the PURE EP System?

The next steps involve the Mayo Clinic and UCLA animal studies and first-in-human studies at TCAI, followed by multicenter studies at leading arrhythmia centers. FDA approval to market could come as early as this time next year.

Can you share some of the history of BioSig Technologies? What brought you to the company?

BioSig was co-founded in 2009 by Ken Londoner, a serial entrepreneur in the medical technology field and former mutual fund manager in New York, and a team of biomedical engineers with expertise in biomedical signal processing. I joined the company for several reasons — I believe PURE EP represents a significant technological advance in the EP information and recording system segment, and provides the potential to improve patient outcomes as well as decrease procedure times; electrophysiology is one of the few medical device markets enjoying double-digit growth; and, we have a world-class scientific advisory board featuring many of the leading electrophysiologists in the field. ■

Disclosure: As disclosed in the article, Mr. Cash is the President & CEO of BioSig Technologies, Inc.

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