



BioSig[™]
technologies

PUREEP[™]
SEE MORE, CLEARLY

LOOKING BACK ON 2021

OFFICIAL COMPANY NEWSLETTER | ISSUE 8

BIOSIG TECHNOLOGIES, INC.
A YEAR IN REVIEW



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Metrics that matter

TOTAL PURE EP PATIENT CASES

END OF 2021

1800+

END OF 2020

425

TOTAL PURE EP UNITS IN THE FIELD

END OF 2021

15

END OF 2020

7

TOTAL EMPLOYEES

END OF 2021

60+

END OF 2020

31

A MESSAGE FROM OUR CEO

By Ken Londoner, CEO & Co-Founder, BioSig Technologies, Inc.

2021 was a landmark year that laid a strong foundation for our commercial and operational growth.

Despite the many challenges created by the pandemic, our novel technology for arrhythmia care, the PURE EP™ System, has been adopted by over 70 physician users who conducted nearly two thousand patient cases across the country. We expanded our clinical footprint in all three of our key strategic regions—Texas, Florida, and the Northeast—where the clinical need is significant and patient volumes - high. After 2020 when elective procedures were deferred for the substantial part of the year, 2021 marked a renewed return to hospitals and continued advancement of our mission to improve arrhythmia care—a condition that has only gotten more severe in the wake of COVID-19.

Looking ahead, we are poised for continued growth driven by recent catalysts, including our new manufacturing partnership with Plexus Corp., a global leader in medical device manufacturing; and the recent appointment of Access Strategy Partners (ASPI), a leading healthcare management firm that brings a wealth of experience to medical device sales and commercialization. I look forward to working closely with both partners as we build on our foundational efforts and enhance our commercial strategy for the next phase of our market release.

On the clinical side, we have delivered solid results from our most recent, multi-center clinical study, which surpassed expectations and reinforced the clinical benefits of the signals acquired with PURE EP™. We look forward to expanding our portfolio of clinical data and publications this year.

As an organization, we have doubled our team in the past year, including new appointments to our commercial, regulatory, and human resources leadership and Board of Directors. As we gear up for the next phase of our commercial roll-out, we look forward to continued organizational growth in the coming year.

From accelerating our installation footprint, delivering novel software solutions, presenting at the leading-edge industry conferences, contributing thought leadership and clinical publications to new progress and partnerships in emerging fields like artificial intelligence and bioelectronic medicine, there is much to cover from 2021 and even more to come!

Enjoy our year-in-review and stay tuned for what's coming next!

We are wishing everyone a happy and healthy New Year!



2021 Clinical Milestones & Commercial Growth

EXCEEDING OUR CASE VOLUME ESTIMATES

Due to increased adoption and commercial activity, we have more than tripled the number of PURE EP™ patient cases conducted over the last twelve months. Having started the year of 2021 with a little over 400 patient cases at the end of 2020, we were hoping to reach 1000 procedures by the end of 2021. However, we raised our case volume targets twice this year and exceeded them yet again, closing the year with a record 1,760 patient cases performed using our technology.

COMMERCIAL SALES TO LEADING MEDICAL CENTER OF EXCELLENCE

In April, Mayo Clinic, a world-class healthcare institution and one of our longstanding clinical partners, adopted PURE EP™ Systems across multiple clinical campuses.

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We are thrilled to see our technology's adoption across all three Mayo Clinic campuses, which includes Florida, Arizona, and Minnesota. As the number one hospital in the world and a national leader in cardiovascular care, Mayo's support for and adoption of our technology speaks to the clinical advantages PURE EP brings to the EP practice.”

~Ken Londoner, CEO & Co-Founder, BioSig Technologies, Inc.

OUR TARGETED COMMERCIAL LAUNCH

In 2021, we signed over eight installation agreements and delivered on our commercial strategy of expanding our clinical footprint across the three strategic regions we are focused on in our targeted commercial launch: the Northeast, Texas, and Florida -- areas with some of the largest clinical footprints in the country.

THE NORTHEAST

We entered the New York market through an agreement with a leading New York hospital, New York-Presbyterian / Weill Cornell Medical Center.

We also expanded our clinical footprint in two leading centers in Boston, MA— the number one state in the country for hospitals—where we started conducting patient cases at St. Elizabeth's Medical Center and Beth Israel Deaconess Medical Center (BIDMC).

FLORIDA & TEXAS

In Texas, we brought our technology to Medical City North Hills in North Richland Texas, and Methodist Hospital in San Antonio, an HCA-operated Medical City Heart Hospital in Dallas, to complement our existing commercial footprint in Austin, Texas. In Florida, we were delighted to add another busy HCA-operated facility: Westside Regional Medical Center in Plantation, FL .

Our focus remains on bringing our PURE EP™ Systems to the centers with the highest volumes of cardiac ablation procedures across the country.

Accelerating Commercialization & Sales



Appointed to Enhance Market Access Strategy

We closed the year with the exciting appointment of a leading healthcare management firm, Access Strategy Partners, to advise on the next phase of our commercial roll-out.

Led by medical device sales experts, ASPI brings deep expertise in commercialization, contract management, execution, and value proposition optimization. Jim Walker, Co-Founder, and President of ASPI, is a healthcare executive with more than 30 years of experience in sales, marketing, sales operations, and national accounts management in some of the leading companies in the medical device sector, including Boston Scientific Corporation (BSC) and Johnson & Johnson.

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ASPI was founded to provide strategic relationship management for emerging medical device companies. Our sales conversations are all about delivering excellent clinical and economic value. BioSig and its breakthrough PURE EP(TM) product bring meaningful benefits to physicians and patients that we are thrilled to introduce to healthcare providers.”

~Jim Walker, Co-Founder & President,
Access Strategy Partners

Our New Manufacturing Partnership with



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We are fundamentally proud to partner with Plexus on our mission to advance therapies through technological innovation. Their engineering and manufacturing capabilities and outstanding expertise in building complex medical devices make Plexus a foundational cornerstone to support BioSig's growth objectives now and well into the future.”

~Ken Londoner, CEO & Co-Founder,
BioSig Technologies, Inc.

In September, we announced our new manufacturing and agreement with Plexus Corp. (Nasdaq:PLXS), a global leader in complex product design, manufacturing, supply chain, and aftermarket services.

Plexus counts healthcare and life sciences as one of its largest market sectors representing nearly 40% of annual revenue. Their engineering and manufacturing capabilities and outstanding expertise in building complex medical devices make Plexus a foundational cornerstone to support our company's growth objectives now and well into the future.

Our Growing Organization

Welcoming Seasoned Industry Executives and Directors to Our Leadership Team



Gray Fleming

Chief Commercial Officer

This past month, we appointed Gray Fleming as our Chief Commercial Officer. Mr. Fleming brings over 20 years in the healthcare industry, including tenure at Abbott Laboratories, where he served as Vice President of Cardiac Sales. Mr. Fleming will lead our commercial efforts as we continue to expand our clinical footprint.



Brenda Castrodad

Director of Human Resources

We also welcomed Brenda Castrodad, BioSig's Director of Human Resources. An experienced medtech executive, Ms. Castrodad has been paramount to our company's efforts to scale up organizational development, source, and retain the best talent for our company.



James J. Barry, PhD

Director

In September, we were thrilled to welcome medical device industry leader Dr. James Barry, Ph.D., to our Board of Directors. As former President and CEO at InspireMD and Sr. Vice President of Corporate Technology at Boston Scientific, Dr. Barry brings a wealth of knowledge and experience to our board.

This past year, we not only grew commercially, but we also grew significantly as an organization. We had 31 employees at the end of 2020 and have ended 2021 with over 60 employees, more than doubling our team.

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I am extremely excited to be returning to the electrophysiology arena and, most importantly, dedicating effort and energy towards supporting the fight against Atrial Fibrillation. I look forward to leading the team that can provide the cleanest signal in every electrophysiology laboratory in the world.”

~Gray Fleming, Chief Commercial Officer, BioSig Technologies, Inc.

“

This past year, BioSig's team has been growing at an accelerated pace. The enthusiasm that our new hires bring to the workplace is contagious and we are highly privileged to have all of them on our team.”

~Brenda Castrodad, Director of Human Resources, BioSig Technologies, Inc.

“

Electrophysiology is a space that can benefit greatly from innovation, and I am impressed with the PURE EP System, which appears to be a meaningful advance in signal detection and should have a positive impact on procedure time and cost.”

~James J. Barry, PhD., Director, BioSig Technologies, Inc.

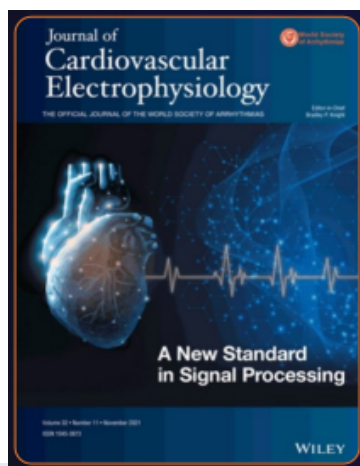


The PURE EP 2.0 Study

This past year, we announced the PURE EP 2.0 study results, a multi-center, blinded, and randomized clinical trial. The trial enrolled 51 patients and was conducted by leading physicians across three of our nation's top medical centers: Texas Cardiac Arrhythmia Institute at St. David's Medical Center in Austin, TX; Mayo Clinic Florida Campus in Jacksonville, FL, and Massachusetts General Hospital in Boston, MA.

Results showed a **93% consensus rating** across all EP reviewers, including a **75% improvement in signal quality** and an **83% increase in confidence** in signal interpretation.

Results from the study were published in the Journal of Cardiac Electrophysiology, titled: "Evaluation of a novel cardiac signal processing system for electrophysiology procedures: the PURE EP 2.0 study."



[Read the Publication](#)

FROM CLINICAL DATA TO CLINICAL APPLICATION

A LIVE ROUNDTABLE WEBINAR

To learn more about the clinical value of the PURE EP 2.0 Study results, view our physician-led roundtable to hear from experts at the heart of the clinical study.

[View the Webinar](#)

“

We are electrophysiologists because we aren't interested in just targeting something anatomically. What we really want is to understand the physiology of what we're doing, and being able to see signals and electrograms clearly is critical in that effort.”

~Wendy Tzou, M.D, Director of Electrophysiology, University of Colorado

PARTICIPATION IN LEADING INDUSTRY CONFERENCES

In 2021, we presented our technology and clinical data at prestigious industry conferences, including the 26th Annual AF Symposium, Kansas City Heart Rhythm Symposium, Heart Rhythm 2021, and the Annual Symposium on Ventricular Arrhythmias.

HEART RHYTHM 2021

One of the highlights was our participation in the Annual Heart Rhythm 2021 Conference, which took place in one of our nation's leading MedTech hubs: Boston, MA. At the event, we had the opportunity to showcase the PURE EP System through live system demos and host scientific post presentations from several physician users.

Watch Dr. Christopher McLeod's Presentation

STANFORD BIODESIGN NEW ARRHYTHMIA TECHNOLOGIES RETREAT

Our presentation highlighted the key areas of differentiation of the PURE EP™ System, including demonstrations of our newest software version, which we released in April 2021.



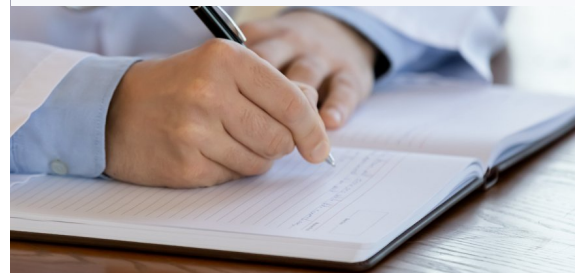
Watch
Presentation

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PURE EP Software Version 4 is the result of a collaborative effort between our engineering team and our physician customers to identify the most critical needs and translate those into innovative advancements. Our comprehensive product portfolio consists of a series of commercial software upgrades and novel software modules, and we are dedicated to driving the innovation as we accelerate commercial.”

~Olivier Chaudoir, Sr. Director of Marketing,
BioSig Technologies, Inc.

PUBLICATIONS IN CUTTING-EDGE MEDICAL JOURNALS

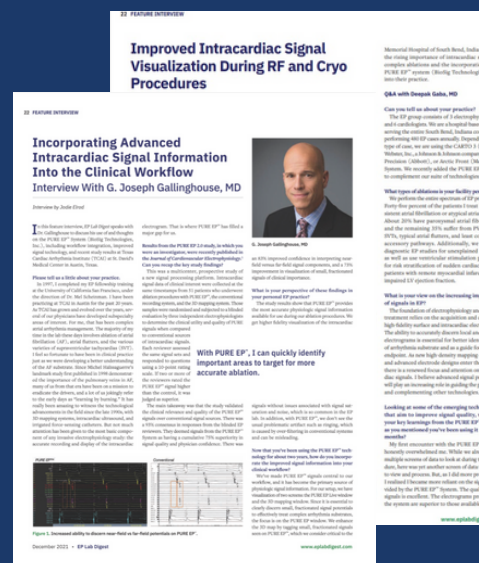


In 2021, our technology was featured by many of our clinician partners and experts in electrophysiology in interviews and articles in EP Lab Digest and The Journal of Cardiac Electrophysiology.

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PURE EP™ signals are at the center of many discussions these days, and it is great to see the engagement of everyone when it comes to discussing electrograms and how they can improve clinical outcomes.”

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Read Our Latest
Publications

EMERGING DIRECTIONS, CUTTING EDGE FIELDS

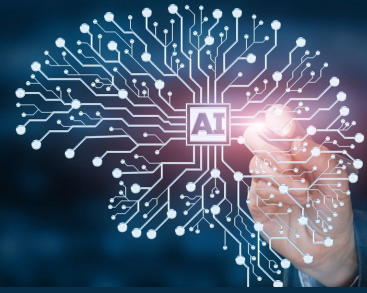
STRATEGIC INITIATIVES IN ARTIFICIAL INTELLIGENCE

We launched two strategic initiatives in artificial intelligence this past year. The first is with our longstanding partner and collaborator, Mayo Clinic, where we have commenced the development of next-generation AI- and machine learning-powered software for our PURE EP™ System.

More recently, we also started collaborating with Israel-based leading academic institution, Technion. This new program aims to utilize data acquired by the PURE EP™ System to develop targeted novel AI & machine-learning solutions for specific arrhythmia types.

We also accepted an invitation to join the Alliance for Advancing Artificial Intelligence in Healthcare (AAIH), a global advocacy organization for advancing and using artificial intelligence in healthcare. We are proud to contribute to the AAIH's efforts alongside other member organizations and AI leaders, including Amazon WS, Bayer, GE Healthcare, the Alliance for Regenerative Medicine, and many more.

[Learn More About Our Goals in AI](#)



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Artificial intelligence excels at analyzing and uncovering patterns in vast volumes of clinical data – a fundamental building block in improving patient care. BioSig is a company that is committed to providing superior technological solutions based on precise signal information. We believe that a joint effort between various healthcare community representatives is a much-needed step towards solving common challenges and accelerating the adoption of AI-powered solutions.”

~Ken Londoner, CEO & Co-Founder,
BioSig Technologies, Inc.

ADVANCING THE FIELD OF BIOELECTRONIC MEDICINE

Our non-profit initiative, the Alliance for Advancing Bioelectronic Medicine, hosted Bioelectronic Medicine Talks this past year. This live, three-part webinar series explored one of the most innovative fields in healthcare: Bioelectronic Medicine. Each episode featured a panel discussion between leaders at the heart of the field.

[Watch the Series](#)

“

Our field needs innovation. It needs bold ideas. It needs cutting-edge science. But to do all of these things right, it also needs partnerships. There are many lessons that we could draw from the pandemic, but in my opinion, the most important impact is cross-sector collaboration.”

~Natasha Drapeau,
Executive Vice President,
BioSig Technologies, Inc.,
Founding Member,
Alliance for Advancing Bioelectronic Medicine

BIOSIG IN THE NEWS

“

PURE EP is the puzzle piece that finally completes the entire cardiac picture. As physicians continue to discover its immense value, so too do they continue to discover the small, fractionated, erratic electrical signal causing the arrhythmia.”

~Ken Londoner, CEO & Co-Founder, OPED - *Medical Device News Magazine*,

“

It's exciting to be here right now because we are one part of a national company.”

~Sasha Gentling, BioSig's Director of Business Development & Investments, Feature Article, *MedCity Beat* - July 2021

“

The national Afib costs are estimated to range from \$6 to \$26 billion. We feel it is our duty to help improve this outlook by partnering with more physicians that are developing novel techniques that aim to relieve their patients and the broader communities from the burdens associated with arrhythmias.”

~Natasha Drapeau, BioSig's Executive Vice President, *Benzinga Exclusive Interview* - September 2021

Since 2018, when we were named one of the "50 Innovative Companies to Watch" by The Silicon Review, BioSig has received regular media mentions and journalist coverage spanning mainstream, trade, broadcast, and local news. Check out some of the cutting-edge pieces authored by or featuring our company this past year!

[Read Our Latest News Features](#)

ABOUT BIOSIG

We are the bioelectronic intelligence company on a mission to preserve the unaltered value of heart signals, gather and provide the real data physicians need to better control procedures today, and predict better treatment pathways for tomorrow. We are showing the way to help improve outcomes for every patient. As innovators in the electrophysiology (EP) space, our primary focus is addressing the unmet needs of the field. The PURE EP™ System is designed to improve the \$4 billion EP market through a powerful combination of hardware and software that makes better decision-making possible.

The PURE EP™ System offers a novel way to acquire and process cardiac signals. These are essential diagnostic signals that deliver high clinical value in all types of cardiac ablations. No other systems or technologies preserve the purity of signals physicians need to deliver better outcomes. PURE EP™ was designed to improve clinical decision-making by providing the full cardiac picture. When it comes to operating on a patient's heart, there is no room for uncertainty.



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SHOWING THE WAY TO BETTER ...