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BIOSIG TECHNOLOGIES, INC.

OFFICIAL COMPANY NEWSLETTER: A SPECIAL HEART MONTH ISSUE

MESSAGE FROM OUR CEO

BY KEN LONDONER, FOUNDER, CHAIRMAN & CEO, BIOSIG TECHNOLOGIES, INC.

We dedicate this month's newsletter to February's hallmark health awareness campaign: American Heart Month. Heart disease is the number one killer in the U.S., accounting for over 659,000 deaths each year.* *Atrial fibrillation (Afib) is one of the most common, yet under diagnosed and overlooked, heart conditions, affecting over 6 million people in the U.S. and 33 million worldwide.**

As an organization committed to preventing the life-threatening consequences of this condition, we want to elevate public awareness of Afib. We recognize the tremendous efforts by all physicians that work tirelessly to provide necessary treatment to their patients suffering from cardiovascular disease and honor the millions of lives it continues to claim.

The risk of developing an irregular heart rhythm increases with age. *The studies have established that those over the age of 80 have a 30% higher risk of stroke.* Even more worrying are the results of a Harris Poll survey that found that *over 61% of adults over the age of 40 are unaware of the condition.**

The need for increased awareness and understanding of this potentially deadly heart condition cannot be overstated, especially because it often strikes without warning. *Nearly 40% of all Afib patients experience little to no symptoms, often leading to much more severe health outcomes.**

Thank you for supporting this critical campaign and the year-round efforts to keep healthy hearts beating in our country and around the world. Despite the therapeutic advances of recent years, much more must be done to improve the standards of care for this challenging condition, but it fundamentally begins with continued self-education and patient awareness—our most powerful weapon in the fight against cardiovascular disease.

We hope you find this special edition helpful.
Happy Heart Month, and a warm welcome to March!

What is Afib – and Why Should I Take it Seriously?

Atrial Fibrillation, or Afib—the most common heart rhythm disturbance—affects over 33 million people across the globe.* Afib is caused by abnormal electrical activity in the heart and can lead to serious health consequences, including blood clots, stroke, or sudden cardiac arrest. The growing prevalence of Afib and other types of cardiac arrhythmias is startling. Afib is responsible for over 750,000 hospitalizations and over 158,000 deaths annually in the U.S. alone. At this rate, experts believe that Afib occurrences will exceed 12.1 million in the U.S. by 2030.



AN ESTIMATED
12.1 MILLION PEOPLE
WILL BE DIAGNOSED WITH AFIB BY 2030

A 5X Increase in Stroke

According to the American Heart Association, Afib is present in almost one out of every five strokes, leading to other neurological disorders, including a 50% increased risk of dementia and a 30% increased risk of Alzheimer's. Due to blood stagnation and turbulence in the fibrillatory atrium, Afib also increases the risk of heart failure by three-fold.*

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I never knew when an episode would strike — I might be washing the dog or out walking or even on a conference call, and was always afraid.”

~Melanie Truehills, Afib Survivor; Founder & CEO, StopAfib.Org

Symptoms That are Easy to Miss

Many people equate heart conditions with classic symptoms such as chest pain or a noticeably rapid heart rate. However, not all signs and symptoms of heart-related diseases are so readily apparent. Many people live with such dangerous heart conditions and may only be experiencing minor symptoms or remain entirely asymptomatic.

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The lifetime risk of developing A-fib is greater than 20 percent, yet many people don't even know they have it.”

~Jane Brody, Health Columnist, New York Times
("A Common Heart Problem That's Easy to Miss")

Time for your Next Doctor's Visit?

When it comes to heart-related conditions, prompt diagnosis and treatment are vital and, in some cases, lifesaving. One in five patients progresses from paroxysmal, or occasional Afib to persistent Afib in one year.* As the condition worsens, it can result in structural remodeling, exacerbating symptoms, and making it more challenging to treat.*

Silent Afib, or asymptomatic Afib, carries an increased risk of stroke or permanent Afib because symptoms alone often do not reflect the severity or complexity of one Afib diagnosis.* Unfortunately, asymptomatic patients are more likely to be diagnosed after experiencing the more severe consequences of Afib, such as a stroke, blood clots, and even heart failure.*



AFIB COSTS ARE EXPECTED TO REACH
\$55 BILLION BY 2030

COVID-19: A Heart Health Dilemma

The precedence of early Afib intervention reaches new levels in the wake of the COVID-19 epidemic. New research has indicated arrhythmia is a common symptom for COVID-19 patients. According to a recent survey conducted by the CDC, patients with Afib are at significantly higher risk of experiencing complications from COVID-19, including a 62% increased risk of suffering a major cardiovascular event, like heart failure and hospitalization. * Additionally, Afib carries a 40% increased risk of mortality for patients diagnosed with COVID-19 when compared to those without the heart condition. *



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We are expecting a tidal wave of cardiovascular events in the coming years from direct and indirect causes of Covid.”

~Donald M. Lloyd-Jones, President of the American Heart Association, [“Five Months After COVID, Nicole Murphy’s Heart is Still Doing Strange Things”(The Washington Post)]

Afib Management and Treatment

Historically, physicians have prescribed pharmacological therapy to manage atrial fibrillation and, ideally, restore and maintain a patient’s sinus rhythm with minimal side effects. However, the 21st century marked a critical turning point, shifting the paradigm in therapeutic approaches to managing and terminating Afib and other arrhythmias. The arrhythmia drug approach has since been challenged by discovering the various classifications of Afib (paroxysmal, persistent, permanent), and later, by establishing the different arrhythmia types (ventricular tachycardia, supraventricular arrhythmia, atrial flutter, etc.). The understanding that arrhythmia does not affect every patient in the same way has prompted a new commitment to more personalized, patient-centered approaches to treatment. *

Technological Solution

In the 1990s, the minimally invasive catheter ablation procedure was introduced to treat irregular heart rhythm conditions.* During an ablation, an electrophysiologist (EP) uses a catheter to guide them to the precise location of the arrhythmia within a patient’s heart to ablate ‘remove’ the harmful tissue disrupting a normal cardiac rhythm. While healthcare providers treat most people with medicine before considering an ablative solution, catheter ablation is often viewed as the first-line alternative for Afib patients because it can address the underlying arrhythmia and restore a healthy heart rhythm, especially when the intervention occurs early in the disease development.

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*Atrial fibrillation is associated with significant morbidity and an estimated two-fold increase in premature death. Unfortunately, patient outcomes are worse when ablation is delayed.” **

~Jason Andrade, M.D., FHRS, FRCPC, Assistant Professor, Université de Montréal; lead author of the EARLY-AF study.

An Unmet Clinical Need: Mixed Signals

During the catheter ablation, the physicians utilize many technologies, such as mapping and recording systems, that help them read cardiac signals and determine appropriate therapy delivery. Despite the therapeutic advancements and proven benefits of the catheter ablation procedure, long-term remission rates for arrhythmia remain suboptimal. Navigating and deciphering the multiple, intricate pathways of the heart’s electrical system is complicated and requires a physician to analyze a large amount of cardiac signal information in real-time. Like the challenge of trying to understand illegible handwriting, this information can be tough to read and interpret. The ability to identify the correct source of arrhythmia and distinguish it from the artifacts that often occur in busy environments with multiple technological solutions deployed simultaneously is critical to a successful procedure. Acquiring clean signals that carry significant diagnostic value is a common clinical challenge.

Recurrent Afib is still a problem today, with 20-50% of patients requiring a repeat ablation. *

The PURE EP™ System

See the Unseen



We developed the PURE EP™ System to address unmet needs in electrophysiology. PURE EP™ functions much like a professional translator of the heart, capable of revealing the full range of cardiac signals with precise, unaltered clarity so that physicians can make clinical decisions with more confidence and assurance.

Our PURE EP™ System's intelligent software and hardware were designed to preserve the purity of cardiac signals and minimize the presence of external noise or artifacts.

The PURE EP™ is the puzzle piece that can complete the entire cardiac picture. As physicians continue to utilize it daily, they help us uncover new clinical applications based on the small, often undetectable electrical signals causing the arrhythmia.

With over 2,000 patient cases conducted to date and a strong portfolio of clinical data, the PURE EP™ System is quickly gaining recognition as the much-anticipated technological solution to a known clinical challenge.

[Learn More](#)



Seamless Integration

PURE EP™ integrates seamlessly with existing EP labs and workflows. It is fully compatible and complementary with EP recording systems, mapping systems, robotic equipment, and multi-display panels

Validated the most clinically relevant source of signals for EP labs

75%

Improvement in signal quality and confidence in signal interpretation

83%

Improved confidence in interpreting multi-component signals

73%

Improved identification of small fractionated potentials

PURE EP 2.0 Clinical Study Results

PURE EP™ : Metrics That Matter



2,000+

Patient cases completed

70+

Physician Users

Resources

Initiatives & Organizations

- [The American Heart Association](#)
- [StopAfib.org](#)
- [Heart Rhythm Society](#)
- [Matter of Moments](#) (Sponsored by Pfizer)
- [Arrhythmia Alliance](#)
- [American Stroke Association](#)
- [American Heart Month Toolkits 2022](#) (Sponsored by the CDC)
- [#OurHearts](#) (Sponsored by the National Heart, Lung, and Blood Institute)

Quick Reads

- [Five months after COVID, Nicole Murphy's heart rate is still doing strange things](#) (The Washington Post)
- [Rehab for long COVID gives hope, while condition continues to puzzle](#) (American Heart Association News)
- [COVID-19 Linked with Key Cardiovascular Events: Study](#) (The Hindustan Times)
- [10 Sneaky Signs you May Have Heart Disease](#) (AARP)
- [A Common Heart Problem, That's Easy to Miss](#) (The New York Times)
- [One alcoholic drink raises risk of irregular heartbeat: study](#) (New York Post)
- [Is your heart skipping beats? If it's happening a lot, it could be Afib](#) (The Washington Post)
- [The Connection Between Diabetes and Heart Disease](#) (US News & World Report)

ABOUT BIOSIG TECHNOLOGIES, INC.

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.

Visit our website to learn more: www.biosig.com

Contact us: info@biosigtech.com



BioSig
technologies

Showing the Way to Better.

SOURCES

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- [Heart Disease in the United States \(CDC\),](#)
- [Atrial fibrillation: the current epidemic \(US National Library of Medicine National Institute of Health\), March 2017.](#)
- [Global epidemiology of atrial fibrillation: An increasing epidemic and public health challenge \(National Library of Medicine\), February 2021.](#)
- [Harris Poll Survey \(conducted by Bristol Myers Squibb\), May 9, 2019.](#)
- [Matter of Moments: Elevating Awareness of AFib and its Connection to Stroke Together with Yahoo! Lifestyle \(Sponsored by Pfizer\), \[www.pfizer.com\]\(http://www.pfizer.com\)](#)
- [Trends in Cardiovascular Mortality Related to Atrial Fibrillation in the United States, 2011 to 2018 \(Journal of the American Heart Association\), July 29, 2021.](#)
- www.getsmartaboutafib.com/afib-education
- [EARLY-AF: First-line Ablation Beats Meds for Recent Paroxysmal A-fib \(TCMD\), November 2020](#)
- [Prompt Diagnosis is “vital” in effective AF management,” \(Cardiac Rhythm News \), July 30, 2020](#)
- [Centers for Disease Control and Prevention, National Center for Health Statistics. Underlying Cause of Death, 1999–2018. Accessed March 12, 2020](#)
- [Estimation of Total Incremental Health Care Costs in Patients With Atrial Fibrillation in the United States \(Circulation\), May 2011](#)
- [Revisiting Antiarrhythmic Drug Therapy for Atrial Fibrillation: Reviewing Lessons Learned and Redefining Therapeutic Paradigms \(Frontiers in Pharmacology\), November 2020](#)
- [Persistent Atrial Fibrillation Often Requires Multiple Catheter Ablations \(\[stopafib.org\]\(http://stopafib.org\)\)](#)