

F R O S T & S U L L I V A N

FROST & SULLIVAN BEST PRACTICES AWARD

REMOTE CARDIAC MONITORING - NORTH AMERICA

Technology Innovation 2019

FROST & SULLIVAN

2019

BEST  
PRACTICES  
AWARD



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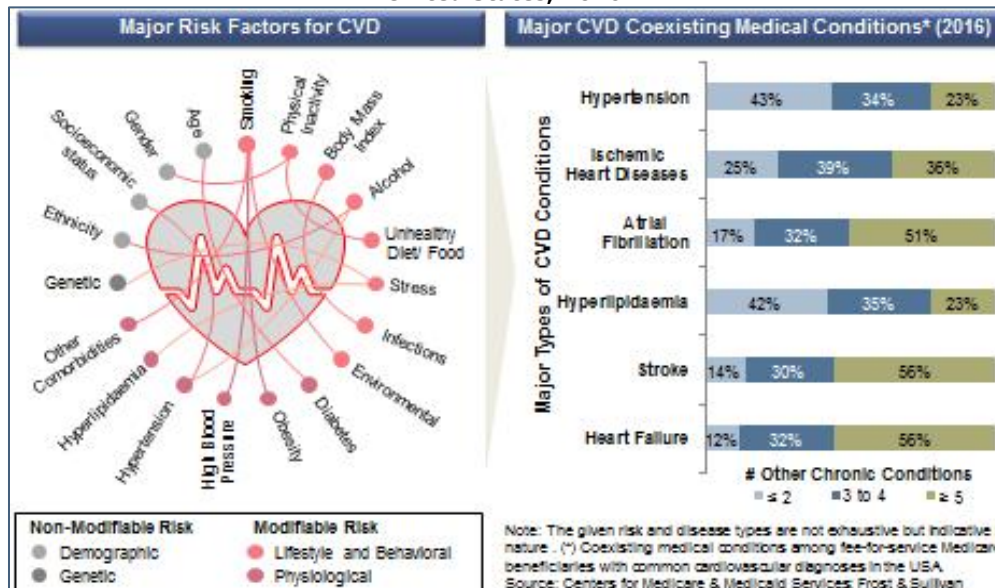
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## Background and Company Performance

### Industry Challenges

Over the last few decades, modernization-driven lifestyle changes have had major implications for people’s health and well-being. Specifically, the global disease burden has shifted from infectious diseases to lifestyle-based non-communicable diseases or chronic health conditions such as diabetes, hypertension, and cardiovascular disease (CVD). CVD is especially problematic, accounting for 31% of all deaths worldwide. In the United States (US) alone, 800,000 people succumbed to the disease in 2017—representing one out of every three deaths.<sup>1</sup>

**Cardiovascular Disease Major Risk Factors and Comorbidity, United States, 2016**



Source: Frost & Sullivan

As care for lifestyle-driven chronic diseases expands in scope, prevention and early diagnosis are becoming the new focus areas, apart from treatment. A Mayo Clinic study (2015) showed that digital health intervention among the early-stage CVD population could reduce by 40% the relative risk and by 7.5% the absolute risk of CVD events, hospitalizations, and deaths.

While wearable cardiac diagnosis systems are increasingly popular, most people still undergo routine cardiac checkups using traditional methods such as echocardiograms, computerized tomography (CT) scans, magnetic resonance imaging (MRI), and nuclear myocardial perfusion scans. Employing these methods require expensive technology and trained medical professionals.<sup>2</sup> Additionally, such clinical practices are labor-intensive, time-consuming, and require hospital visits by patients. In the mobility space, conventional

<sup>1</sup> <https://www.acc.org/latest-in-cardiology/ten-points-to-remember/2017/02/09/14/58/heart-disease-and-stroke-statistics-2017>

<sup>2</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5421671/>

devices such as Holter monitors are expensive, inconvenient, and subject to limited recording time—potentially leading to sub-optimal detection of arrhythmias.

Finally, related conditions such as classical atrial flutter (AFL) and paroxysmal atrial fibrillation (PAF) are hard to diagnose owing to the limited signal clarity possible with R-wave detection engineered electrocardiography (ECG) monitoring systems.

As a result, there is an increasing demand for innovative, inexpensive, and reliable continuous cardiac health monitoring systems. Frost & Sullivan research reveals that devices which are user-friendly, easy to operate, and provide an intuitive and customizable user interface will enjoy rapid adoption. At the same time, the rising comorbidity of CVD with other health complications and disease conditions necessitate multi-parameter monitoring beyond the ECG to make cardiac care more targeted and efficient.

Technology plays a pivotal role in the much-anticipated transformational journey of the healthcare industry towards outcome-based preventive care practices. Frost & Sullivan projects that emerging multi-parameter biosensor technologies combined with mobile health (mHealth) platforms will democratize the current diagnostics industry, unlocking new values by displacing high-cost gatekeepers and previously inaccessible segments.

### *Technology Attributes and Future Business Value of Bardy Diagnostics*

Founded in 2013 and headquartered in Seattle, Washington, Bardy Diagnostics (BardyDx) is a medical technology firm specializing in innovative heart monitoring technologies.

Recently, the company launched the Carnation Ambulatory Monitory (CAM™) patch, a first-of-its-kind P-wave centric surface ECG monitor and arrhythmia detection device. Combined with low-frequency and amplitude electrical signal detection, BardyDx provides industry-leading arrhythmia detection.

The patch's use of advanced engineering and design allows it to detect different arrhythmias occurring at the same time, positively impacting patient management, especially when the arrhythmias require different treatment decisions. For example, the CAM™ patch can accurately detect the occurrence of classic AFL and PAF. With a typical monitor, AFL may be obscured by the presence of AF, resulting in inadequate treatments and increased costs and risks to the patient. CAM™ patch was developed to provide optimal detection and clear recording of the often difficult to detect P-wave, the signal of the ECG waveform that is essential for accurate arrhythmia diagnosis and subsequent patient management.

Frost & Sullivan appreciates BardyDx's advances in novel detection technology leveraging advanced machine learning (i.e., a deep convolutional neural network, which can sequence millions of ECG samples and P-wave centric arrhythmia annotations) that will be

**Bardy Diagnostics' CAM™ patch**



Source: Bardy Diagnostics

incorporated in future generation CAM releases. BardyDx has successfully validated an automated AF detection technology against samples consisting of persistent atrial fibrillation (AF), paroxysmal AF, and no findings of AF.<sup>3</sup> This AI-enabled technology is achievable solely because of the CAM patch's unique ability to accurately detect a broad array of arrhythmias, including those commonly mistaken for AF by commercially-available, R-wave focused automated detectors.

### **Leveraging Innovative Engineering to Pioneer Advancements in Arrhythmia Diagnostics**

Among other best practices, CAM™ patch's novel circuit design and signal capture technologies result in accurate and clear P-wave detection and recording. As a result, the CAM™ patch delivers improved ECG resolution and diagnostic accuracy while simultaneously providing continuous data on the heart's rhythm. Patched along the sternum directly over the heart, the lightweight CAM™ patch captures P-waves (in addition to the more easily visualized QRS complex)—generating excellent atrial signal quality. As a result of its best-in-class engineering, the non-invasive BardyDx CAM™ ECG patch monitor can accurately detect arrhythmias, thereby optimizing opportunities for early detection and targeted treatment while minimizing risk. The device is also slim and lightweight—17.5 centimeters (cm) in length, 0.94 cm in breadth, and 13 grams in weight—enabling usage during activities of daily living, including exercising and bathing. In addition, the hourglass-shaped form factor of the monitor was specifically designed to be female-friendly and rest comfortably in the cleavage. The CAM™ patch offers up to seven days of extended wear and is suitable for both adult and pediatric patients.

Furthermore, CAM™ patch's ease-of-use promotes patient compliance and streamlines clinical workflows. To further simplify diagnostics and reporting, BDxCONNECT, a companion patient management portal, provides healthcare professionals with a single system for creating, accessing, and managing patient CAM™ reports. Through linking the CAM™ patch to a suite of ECG analysis services and tools, BDxCONNECT can provide a single platform for sharing patient ECG data and reports, resulting in improved workflow and convenience for clinicians.

The data generates a unique and proprietary CAM™ report that offers exceptionally detailed ECG trace interpretation based on actionable ECG events. As a result, providers can accurately identify specific arrhythmias to aid clinical decision-making. Turnaround time is significantly improved, and the company generates real-time notifications and alerts when reports are ready. Finally, BardyDx's augmented intelligence and visualization technologies will accelerate delivery of information and clinically meaningful insights to clinicians while enhancing operational efficiencies. Frost & Sullivan research further reveals that competitive analysis against leading peers demonstrates BardyDx's solution superiority. In a recent

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<sup>3</sup> <https://www.prnewswire.com/news-releases/bardy-diagnostics-announces-validation-of-ai-enabled-automatic-screening-technology-for-atrial-fibrillation-300645117.html>

clinical validation study, physicians found that the CAM™ exhibited significantly higher ECG clarity and improved rhythm diagnosis versus competing devices.<sup>4 5</sup>

As a result, the company is experiencing wide interest from investors, including some of the largest healthcare venture capital firms. Frost & Sullivan appreciates that many of the top US health systems are already using the CAM™ patch. Furthermore, the device is one of only a few monitors that is suitable for pediatric applications (i.e., children weighing more than 22 lbs or 10 kg). Additionally, BardyDx is working with some of the largest group purchasing organizations in the US market, providing increased access to large networks of hospital and health systems. Currently, the CAM™ patch is only available via prescription; however, the company has direct-to-consumer plans to further increase market access. BardyDx also offers multiple pricing models to suit end-user needs.

### *Conclusion*

Heart disease is a leading cause of mortality worldwide. Current heart monitoring solutions lack portability while limited diagnostic abilities hinder efficacy. Bardy Diagnostics' (BardyDx) Carnation Ambulatory Monitor (CAM™) patch leverages state-of-the-art engineering and design to provide a groundbreaking monitoring solution. With its unique P-wave centric ECG monitor, BardyDx offers unmatched signal clarity and superior arrhythmia detection. Lightweight and user-friendly, the company also furnishes a companion system, BDxCONNECT, to provide invaluable support for healthcare professionals and millions of heart patients.

With its thought leadership, unparalleled innovation, and disruptive potential, Bardy Diagnostics earns Frost & Sullivan's 2019 Technology Innovation Award in the North America remote cardiac monitoring market.

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<sup>4</sup> Rho R., et al. Comparison of two ambulatory patch ECG monitors: The benefit of the P- wave and signal clarity. American Heart Journal. Manuscript Accepted Online. March 2018. DOI: <https://doi.org/10.1016/j.ahj.2018.03.022>

<sup>5</sup> Smith WM., et al. Comparison of diagnostic value using a small, single channel, P-wave centric sternal ECG monitoring patch with a standard 3-lead Holter system over 24 hours. American Heart Journal. March 2017. DOI: <https://doi.org/10.1016/j.ahj.2016.11.006>

## Significance of Technology Innovation

Ultimately, growth in any organization depends upon finding new ways to excite the market and upon maintaining a long-term commitment to innovation. At its core, technology innovation, or any other type of innovation, can only be sustained with leadership in three key areas: understanding demand, nurturing the brand, and differentiating from the competition.



## Understanding Technology Innovation

Technology innovation begins with a spark of creativity that is systematically pursued, developed, and commercialized. That spark can result from a successful partnership, a productive in-house innovation group, or a bright-minded individual. Regardless of the source, the success of any new technology is ultimately determined by its innovativeness and its impact on the business as a whole.

## Key Benchmarking Criteria

For the Technology Innovation Award, Frost & Sullivan analysts independently evaluated two key factors—Technology Attributes and Future Business Value—according to the criteria identified below.

### *Technology Attributes*

#### **Criterion 1: Industry Impact**

Requirement: Technology enables the pursuit of groundbreaking ideas, contributing to the betterment of the entire industry.

#### **Criterion 2: Product Impact**

Requirement: Specific technology helps enhance features and functionalities of the entire product line for the company.

#### **Criterion 3: Scalability**

Requirement: Technology is scalable, enabling new generations of products over time, with increasing levels of quality and functionality.

#### **Criterion 4: Visionary Innovation**

Requirement: Specific new technology represents true innovation based on a deep understanding of future needs and applications.

#### **Criterion 5: Application Diversity**

Requirement: New technology serves multiple products, multiple applications, and multiple user environments.

### *Future Business Value*

#### **Criterion 1: Financial Performance**

Requirement: Potential is high for strong financial performance in terms of revenue, operating margins, and other relevant financial metrics.

#### **Criterion 2: Customer Acquisition**

Requirement: Specific technology enables acquisition of new customers, even as it enhances value to current customers.

#### **Criterion 3: Technology Licensing**

Requirement: New technology displays great potential to be licensed across many verticals and applications, thereby driving incremental revenue streams.

#### **Criterion 4: Brand Loyalty**

Requirement: New technology enhances the company's brand, creating and/or nurturing brand loyalty.

#### **Criterion 5: Human Capital**

Requirement: Customer impact is enhanced through the leverage of specific technology, translating into positive impact on employee morale and retention.



## Best Practices Recognition: 10 Steps to Researching, Identifying, and Recognizing Best Practices

Frost & Sullivan analysts follow a 10-step process to evaluate Award candidates and assess their fit with select best practice criteria. The reputation and integrity of the Awards are based on close adherence to this process.

STEP	OBJECTIVE	KEY ACTIVITIES	OUTPUT
1 <b>Monitor, target, and screen</b>	Identify Award recipient candidates from around the globe	<ul style="list-style-type: none"> <li>• Conduct in-depth industry research</li> <li>• Identify emerging sectors</li> <li>• Scan multiple geographies</li> </ul>	Pipeline of candidates who potentially meet all best-practice criteria
2 <b>Perform 360-degree research</b>	Perform comprehensive, 360-degree research on all candidates in the pipeline	<ul style="list-style-type: none"> <li>• Interview thought leaders and industry practitioners</li> <li>• Assess candidates' fit with best-practice criteria</li> <li>• Rank all candidates</li> </ul>	Matrix positioning of all candidates' performance relative to one another
3 <b>Invite thought leadership in best practices</b>	Perform in-depth examination of all candidates	<ul style="list-style-type: none"> <li>• Confirm best-practice criteria</li> <li>• Examine eligibility of all candidates</li> <li>• Identify any information gaps</li> </ul>	Detailed profiles of all ranked candidates
4 <b>Initiate research director review</b>	Conduct an unbiased evaluation of all candidate profiles	<ul style="list-style-type: none"> <li>• Brainstorm ranking options</li> <li>• Invite multiple perspectives on candidates' performance</li> <li>• Update candidate profiles</li> </ul>	Final prioritization of all eligible candidates and companion best-practice positioning paper
5 <b>Assemble panel of industry experts</b>	Present findings to an expert panel of industry thought leaders	<ul style="list-style-type: none"> <li>• Share findings</li> <li>• Strengthen cases for candidate eligibility</li> <li>• Prioritize candidates</li> </ul>	Refined list of prioritized Award candidates
6 <b>Conduct global industry review</b>	Build consensus on Award candidates' eligibility	<ul style="list-style-type: none"> <li>• Hold global team meeting to review all candidates</li> <li>• Pressure-test fit with criteria</li> <li>• Confirm inclusion of all eligible candidates</li> </ul>	Final list of eligible Award candidates, representing success stories worldwide
7 <b>Perform quality check</b>	Develop official Award consideration materials	<ul style="list-style-type: none"> <li>• Perform final performance benchmarking activities</li> <li>• Write nominations</li> <li>• Perform quality review</li> </ul>	High-quality, accurate, and creative presentation of nominees' successes
8 <b>Reconnect with panel of industry experts</b>	Finalize the selection of the best-practice Award recipient	<ul style="list-style-type: none"> <li>• Review analysis with panel</li> <li>• Build consensus</li> <li>• Select recipient</li> </ul>	Decision on which company performs best against all best-practice criteria
9 <b>Communicate recognition</b>	Inform Award recipient of Award recognition	<ul style="list-style-type: none"> <li>• Present Award to the CEO</li> <li>• Inspire the organization for continued success</li> <li>• Celebrate the recipient's performance</li> </ul>	Announcement of Award and plan for how recipient can use the Award to enhance the brand
10 <b>Take strategic action</b>	Upon licensing, company is able to share Award news with stakeholders and customers	<ul style="list-style-type: none"> <li>• Coordinate media outreach</li> <li>• Design a marketing plan</li> <li>• Assess Award's role in future strategic planning</li> </ul>	Widespread awareness of recipient's Award status among investors, media personnel, and employees

## The Intersection between 360-Degree Research and Best Practices Awards

### Research Methodology

Frost & Sullivan's 360-degree research methodology represents the analytical rigor of our research process. It offers a 360-degree-view of industry challenges, trends, and issues by integrating all 7 of Frost & Sullivan's research methodologies. Too often companies make important growth decisions based on a narrow understanding of their environment, leading to errors of both omission and commission. Successful growth strategies are founded on a thorough understanding of market, technical, economic, financial, customer, best practices, and demographic analyses. The integration of these research disciplines into the 360-degree research methodology provides an evaluation platform for benchmarking industry participants and for identifying those performing at best-in-class levels.

### 360-DEGREE RESEARCH: SEEING ORDER IN THE CHAOS



## About Frost & Sullivan

Frost & Sullivan, the Growth Partnership Company, enables clients to accelerate growth and achieve best-in-class positions in growth, innovation and leadership. The company's Growth Partnership Service provides the CEO and the CEO's Growth Team with disciplined research and best practice models to drive the generation, evaluation and implementation of powerful growth strategies. Frost & Sullivan leverages more than 50 years of experience in partnering with Global 1000 companies, emerging businesses, and the investment community from 45 offices on six continents. To join our Growth Partnership, please visit <http://www.frost.com>.