FROST & SULLIVAN

Cardiologs
AI serving cardiology

2018 Global ECG Analysis Software New Product Innovation Award

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2018 BEST PRACTICES AWARD

GLOBAL ECG ANALYSIS SOFTWARE NEW PRODUCT INNOVATION AWARD

2018

BEST PRACTICES

AWARDS

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Cardiovascular disease is the leading cause of death worldwide, according to the World Health Organization (WHO). Arrhythmia is a common cardiovascular condition, wherein the heart beats too fast, too slow, or irregularly, with the most common type being atrial fibrillation (AFib). The US Centers for Disease Control and Prevention (CDC) estimates that about 2.7 to 6.1 million people in the United States have AFib, and the condition affects about 33 million people worldwide. AFib costs the United States about $6 billion each year, and AFib patients are five times more likely to have a stroke, making this condition extremely dangerous.

Because AFib is often asymptomatic and does not occur at fixed intervals, it is not always detected during a doctor's visit using a point-of-care electrocardiogram (ECG) machine. Therefore, cardiologists often prescribe the use of ambulatory monitors (e.g. Holter devices) to record cardiac electrical activity, typically over a period of 24 to 48 hours, to detect instances of AFib. Aided by recently published clinical evidence demonstrating higher diagnostic yield of longer ambulatory recordings, there is a trend to conduct longer ambulatory monitoring studies lasting up to 14 days, with manufacturers coming out with more advanced devices with a patient-friendly form factor. In combination with the proliferation of wearable devices that are capable of recording ECG, there is a substantial increase in the amount of ECG data that is available to clinicians to diagnose arrhythmias such as AFib. This increase in analyzable data is calling for new software solutions that can analyze vast amount of information to provide timely and clinically meaningful analysis on which cardiologists can act.

ECG recordings must be analyzed by clinicians to identify the clinically relevant episodes and glean insights to guide future medical treatment. Such analysis is done with the help of ECG analysis software by the hospital based clinician or staff. Increasingly, to save time and hospital resources, hospitals may outsource this ECG analysis to external vendors which employ certified cardiac technicians for preparing medical reports that clinicians can review. These technicians work on ECG analysis software and use a variety of diagnostic tools to capture and highlight instances of arrhythmia. With the increase in the number of patients being prescribed continuous cardiac monitoring solutions, as well as the increase in recording duration, there is a need to increase the throughput of ECG analysis while maintaining clinical accuracy. Compounding the problem of growing demand is the challenge that afflicts the entire healthcare industry: the shortage of skilled personnel, including qualified cardiac technicians who can analyze ECG recordings.

Even though existing software enables the analysis process, current conventional tools are not fast or sophisticated enough to process the amount of data coming in, which is where artificial intelligence (AI) is expected to play a role. In general, one of AI's expected roles is in healthcare to help doctors process more information and increase throughput. While solutions are currently being developed that explore the use of AI for image processing in imaging modalities, only a few companies are working on using AI for analyzing patient data.

Deep learning is an AI technology that is based on the input of millions of data points, often in nested hierarchy, that help train software to extract meaning from complicated, large volumes of data; detect complex trends; and identify patterns that can indicate a medical condition. In addition, deep learning technology has the inherent ability to incorporate new data or usage patterns to perform better in the future. This technology has tremendous potential to increase throughput and predict the occurrence of medical events, thus potentially saving lives and healthcare costs.

Therefore, deep learning-enabled software holds great potential to drive growth in the patient monitoring market. Such software can bring needed efficiency to the complex and high-impact ECG monitoring space, where the number of ECG recordings to be analyzed will rise, yet the supply of qualified technicians will struggle to keep up with the increased demand.

New Product Attributes and Customer Impact

Founded in 2014, France-based Cardiologs is a revenue-stage venture-funded company, with additional operations in the United States (Boston, MA). The company has developed a cloud-based, AI-powered ECG analysis platform that is cleared for use in both the United States and Europe as a Class II medical device to detect instances of AFib and other cardiac arrythmias. The company's platform enables clinicians and cardiac technicians to perform ECG analysis considerably faster, enabled by better sensitivity and specificity than current standard ECG analysis software.

Match to Needs

One of the key advantages of Cardiologs' ECG analysis solution is that it increases the throughput of ECG data analysis that can, in effect, improve the efficiency of a cardiology department and increase the number of patients that are screened for arrhythmias without increasing staffing costs. For example, a technician analyzing Holter readings using traditional ECG analysis software can process about two standard (24-48 hour Holter) recordings in an hour, and a seven-day Holter reading in one to two hours. In contrast, technicians using Cardiologs' AI-powered solution take on average 5 minutes to analyze a standard Holter recording and only about 15 minutes to analyze the same seven-day Holter reading.

With Cardiologs' solution, a cardiologist can upload a digital ECG from any compatible cardiac monitoring device, such as a Holter monitor, smartwatch, ECG patch, or even a connected T-shirt, to the Cardiologs cloud and conduct the analysis quickly and efficiently. With this solution, a patient can receive a diagnosis and treatment information in the same visit when returning the ambulatory monitor (or downloading data from the connected wearable device), instead of returning a few days later. Cardiologs' solution saves patients and clinicians time and allows for quicker diagnosis in cases of AFib and other dangerous arrhythmias, thereby potentially preventing any adverse events before the start of treatment.

Frost & Sullivan applauds Cardiologs' vision in enabling physicians to spend more time on diagnosing and treating patients rather than on taking hours to pore over large amounts

of patient data. In addition, Frost & Sullivan commends the company's ability to bring AI into the hands of the physician, thus ultimately improving healthcare outcomes.

Reliability

Cardiologs uses state-of-the-art deep learning, and its neural network has been trained with more than 1.4 million ECGs to recognize patterns in a cardiac signal and generate precise predictions of arrhythmias, all in the same intuitive manner as cardiologists. The algorithm's extensive training is reflected in its superior performance over conventional software solutions.

When defining the reliability of diagnosing AFib and other arrhythmias, Positive Predictive Value (PPV) refers to the percentage of true positive cases among the total cases detected. A higher PPV indicates that the solution is more accurate, and cardiologists can thus express more confidence in the diagnosis. As Cardiologs notes in its regulatory submission to the US Food and Drug Administration (FDA), its AI-based solution has a PPV of about 91%, which is significantly higher than that of conventional ECG analysis software solutions that have a demonstrated PPV of less than 59%, thereby making the Cardiologs solution naturally better at preventing misdiagnoses, and especially false positives that may result in unnecessary further diagnoses or unneeded and possibly risky medical treatment.

Other parameters used when comparing Cardiologs' solution with other solutions include sensitivity and specificity. The solution's sensitivity in detecting AFib (percentage of positives truly identified) has been reported to be about 97% and is superior to conventional 'state-of-the-art' software-based methods of detecting AFib and other arrhythmias. On the other hand, specificity is the ability to identify correctly any individuals without the condition, such as accurately identifying true negatives. Cardiologs' solution has shown an AFib detection specificity of about 99.2%, compared to 80% for conventional software used by ECG technicians.

Frost & Sullivan acknowledges that Cardiologs has helped raise the standard of cardiac care by developing ECG analysis services that are more accurate than current solutions, thus improving clinical diagnostic accuracy and ultimately positively impacting medical treatment.

Quality and Positioning

Cardiologs' platform is cleared in both the United States and Europe as a medical device and, thus, complies with regulatory and industry standards, with all software development processes audited twice a year. The company releases a software update almost every month (that goes through a complete QMS (ISO 13485) cycle) to enhance user experience. This upgrade frequency is rare for a Class II medical device or medical software, especially because software upgrade timelines are even longer in the healthcare space. Moreover, the company's first-to-market deep learning solution to analyze ECG data is protected by a combination of patents and trade secrets. While other market participants are working on enhancing their cardiac monitor predictive capability by employing machine learning technology, they are still in the research phase or are using

the technology specifically for their cardiac monitoring devices, limiting widespread adoption.

Frost & Sullivan appreciates Cardiologs' industry-first device-agnostic AI solution and its efforts to maintain a quality interface by reviewing periodic user feedback. In addition, Frost & Sullivan believes the company is well positioned to address the market's current and future challenges in meeting patient demand.

Design

Cardiologs has taken special care to ensure its platform is simple and intuitive to use, especially as users are often already overworked and have little time to learn new software. With the aim of providing a positive customer experience and with a robust user feedback mechanism in place, Cardiologs continues to improve its user experience with regular software updates. In addition, a cloud-based approach eliminates the need for any additional investments for high-processing power computers, thus allowing cardiologists to use the software on their existing computers and benefit from the seamless experience of accessing the cloud-based software using simple login credentials that adhere to HIPAA (Health Insurance Portability and Accountability Act) requirements and security best practices.

Furthermore, Cardiologs' software provides comprehensive and clinically relevant reports that address the diverse needs of different cardiology sub-specialties, so that physicians can make appropriate diagnoses quickly and easily, without having to search for additional information.

Conclusion

Cardiologs' first-to-market AI-based ECG analysis solution has been cleared in the United States and Europe as a Class II medical device that provides highly accurate solution for screening for AFib and other cardiac arrhythmias. The cloud-based solution's Web interface makes it a convenient tool for cardiac technicians and cardiologists, and enables a fast turn-around time for Holter analysis of about 5 minutes, compared to the 30 minutes (or one to two hours for 7-day studies) required by existing software. Cardiologs' powerful tool has the capability to increase ECG analysis service efficiency, reduce patient waiting time, and make better use of heavily burdened healthcare resources. Moreover, Cardiologs' vision is to bring down the expenditure associated with ECG analysis by increasing throughput, reducing false positives, and increasing diagnosing accuracy.

For its strong overall performance, Cardiologs has earned Frost & Sullivan's 2018 New Product Innovation Award in the global ECG analysis software industry.

Significance of New Product Innovation

Ultimately, growth in any organization depends upon continually introducing new products to the market and successfully commercializing those products. For these dual goals to occur, a company must be best-in-class in three key areas: understanding demand, nurturing the brand, and differentiating from the competition.

Understanding New Product Innovation

Innovation is about finding a productive outlet for creativity—for consistently translating ideas into high-quality products that have a profound impact on the customer.

Key Benchmarking Criteria

For the New Product Innovation Award, Frost & Sullivan analysts independently evaluated two key factors—New Product Attributes and Customer Impact—according to the criteria identified below.

New Product Attributes

Criterion 1: Match to Needs
Criterion 2: Reliability
Criterion 3: Quality
Criterion 4: Positioning
Criterion 5: Design

Customer Impact

Criterion 1: Price/Performance Value
Criterion 2: Customer Purchase Experience
Criterion 3: Customer Ownership Experience
Criterion 4: Customer Service Experience
Criterion 5: Brand Equity

Best Practices Award Analysis for Cardiologs

Decision Support Scorecard

To support its evaluation of best practices across multiple business performance categories, Frost & Sullivan employs a customized Decision Support Scorecard. This tool allows our research and consulting teams to objectively analyze performance, according to the key benchmarking criteria listed in the previous section, and to assign ratings on that basis. The tool follows a 10-point scale that allows for nuances in performance evaluation. Ratings guidelines are illustrated below.

RATINGS GUIDELINES
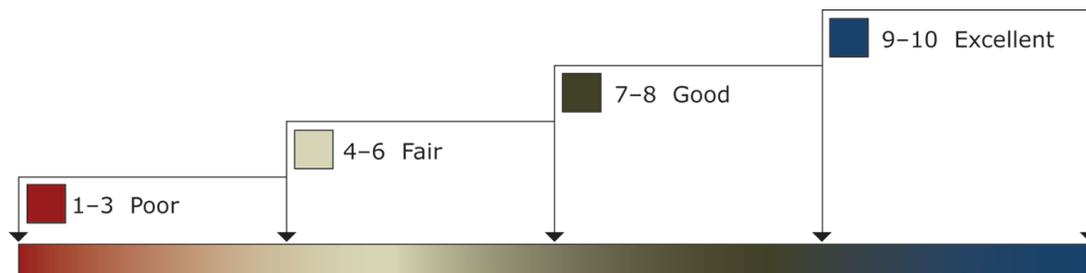
The Decision Support Scorecard is organized by New Product Attributes and Customer Impact (i.e., These are the overarching categories for all 10 benchmarking criteria; the definitions for each criterion are provided beneath the scorecard.). The research team confirms the veracity of this weighted scorecard through sensitivity analysis, which confirms that small changes to the ratings for a specific criterion do not lead to a significant change in the overall relative rankings of the companies.

The results of this analysis are shown below. To remain unbiased and to protect the interests of all organizations reviewed, we have chosen to refer to the other key participants as Competitor 2 and Competitor 3.

Measurement of 1–10 (1 = poor; 10 = excellent)			
New Product Innovation	New Product Attributes	Customer Impact	**Average Rating**
Cardiologs	**9**	**9**	**9**
Competitor 2	8	9	8.5
Competitor 3	7	8	7.5

New Product Attributes

Criterion 1: Match to Needs
Requirement: Customer needs directly influence and inspire the product's design and positioning.

Criterion 2: Reliability
Requirement: The product consistently meets or exceeds customer expectations for consistent performance during its entire life cycle.

Criterion 3: Quality
Requirement: Product offers best-in-class quality, with a full complement of features and functionalities.

Criterion 4: Positioning
Requirement: The product serves a unique, unmet need that competitors cannot easily replicate.

Criterion 5: Design
Requirement: The product features an innovative design, enhancing both visual appeal and ease of use.

Customer Impact

Criterion 1: Price/Performance Value
Requirement: Products or services offer the best value for the price, compared to similar offerings in the market.

Criterion 2: Customer Purchase Experience
Requirement: Customers feel they are buying the most optimal solution that addresses both their unique needs and their unique constraints.

Criterion 3: Customer Ownership Experience
Requirement: Customers are proud to own the company's product or service and have a positive experience throughout the life of the product or service.

### Criterion 4: Customer Service Experience
Requirement: Customer service is accessible, fast, stress-free, and of high quality.

Criterion 5: Brand Equity
Requirement: Customers have a positive view of the brand and exhibit high brand loyalty.

Decision Support Matrix

Once all companies have been evaluated according to the Decision Support Scorecard, analysts then position the candidates on the matrix shown below, enabling them to visualize which companies are truly breakthrough and which ones are not yet operating at best-in-class levels.
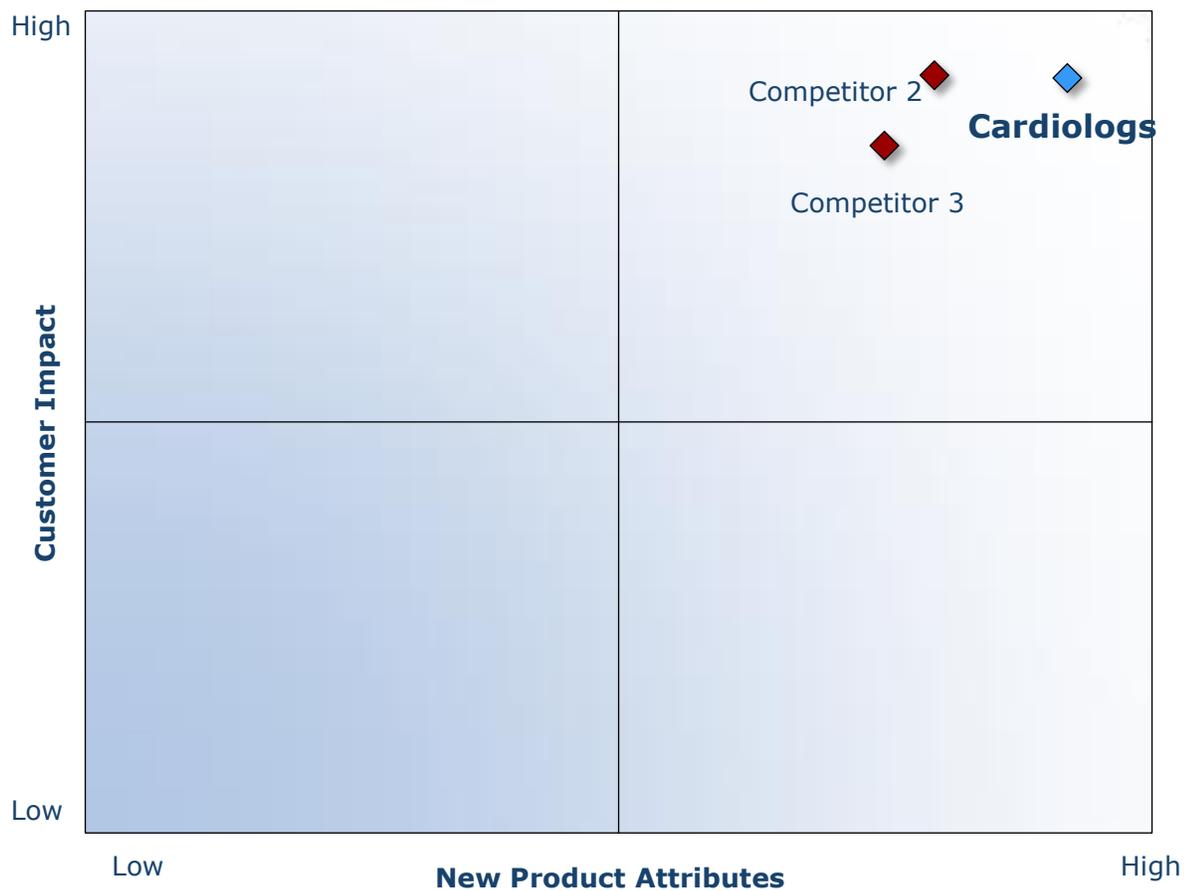
Best Practices Recognition: 10 Steps to Researching, Identifying, and Recognizing Best Practices

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	**Monitor, target, and screen**	Identify Award recipient candidates from around the globe	• Conduct in-depth industry research • Identify emerging sectors • Scan multiple geographies	Pipeline of candidates who potentially meet all best-practice criteria
2	**Perform 360-degree research**	Perform comprehensive, 360-degree research on all candidates in the pipeline	• Interview thought leaders and industry practitioners • Assess candidates' fit with best-practice criteria • Rank all candidates	Matrix positioning of all candidates' performance relative to one another
3	**Invite thought leadership in best practices**	Perform in-depth examination of all candidates	• Confirm best-practice criteria • Examine eligibility of all candidates • Identify any information gaps	Detailed profiles of all ranked candidates
4	**Initiate research director review**	Conduct an unbiased evaluation of all candidate profiles	• Brainstorm ranking options • Invite multiple perspectives on candidates' performance • Update candidate profiles	Final prioritization of all eligible candidates and companion best-practice positioning paper
5	**Assemble panel of industry experts**	Present findings to an expert panel of industry thought leaders	• Share findings • Strengthen cases for candidate eligibility • Prioritize candidates	Refined list of prioritized Award candidates
6	**Conduct global industry review**	Build consensus on Award candidates' eligibility	• Hold global team meeting to review all candidates • Pressure-test fit with criteria • Confirm inclusion of all eligible candidates	Final list of eligible Award candidates, representing success stories worldwide
7	**Perform quality check**	Develop official Award consideration materials	• Perform final performance benchmarking activities • Write nominations • Perform quality review	High-quality, accurate, and creative presentation of nominees' successes
8	**Reconnect with panel of industry experts**	Finalize the selection of the best-practice Award recipient	• Review analysis with panel • Build consensus • Select recipient	Decision on which company performs best against all best-practice criteria
9	**Communicate recognition**	Inform Award recipient of Award recognition	• Announce Award to the CEO • Inspire the organization for continued success • Celebrate the recipient's performance	Announcement of Award and plan for how recipient can use the Award to enhance the brand
10	**Take strategic action**	Upon licensing, company is able to share Award news with stakeholders and customers	• Coordinate media outreach • Design a marketing plan • Assess Award's role in future strategic planning	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.