



BIOTRONIK Recognized for

2021

Enabling Technology Leadership

Global Implantable Cardiac
Monitoring Device Industry
Excellence in Best Practices

Best Practices Criteria for World-Class Performance

Frost & Sullivan applies a rigorous analytical process to evaluate multiple nominees for each Award category before determining the final Award recipient. The process involves a detailed evaluation of best practices criteria across two dimensions for each nominated company. BIOTRONIK excels in many of the criteria in the Global implantable cardiac monitoring device space.

AWARD CRITERIA	
<i>Technology Leverage</i>	<i>Customer Impact</i>
Commitment to Innovation	Price/Performance Value
Commitment to Creativity	Customer Purchase Experience
Stage Gate Efficiency	Customer Ownership Experience
Commercialization Success	Customer Service Experience
Application Diversity	Brand Equity

Introducing an Insertable Cardiac Monitor to Enable Continuous Monitoring With Maximum Precision

Cardiac monitoring is required to diagnose heart rhythm disorders or monitor treatment in patients suffering from atrial fibrillation, unexplained fainting, unexplained stroke and other heart conditions. External cardiac monitors such as Holter Monitors and Wearable Patches can be used to diagnose a patient’s heart condition. However, their recording duration may be too short to capture intermittent arrhythmias and skin irritation, the device, cables and attachments can limit how long they can be worn. Implantable cardiac monitors (ICMs) enable more accurate diagnostics and a better patient experience by recording and transmitting heart rhythm disturbances for longer periods - without disrupting patients’ daily lives.

“BIOTRONIK’s BIOMONITOR III_m offering allows physicians to monitor cardiac patients’ irregular heart rhythm, temperature, and activity remotely. The device’s unique BIOvector design and RhythmCheck algorithm enable maximum precision in recorded rhythm disturbance, reducing false positives. Accuracy is, therefore, higher compared to competing implantable cardiac monitors. The device also has an industry-leading battery life of five and a half years, compared to other implantable cardiac monitoring devices.”

**- Dr. M. Sneha Maria,
Senior Research Analyst**

Frost & Sullivan notes that the increasing prevalence of cardiac disease coupled with patients’ demand for

a high quality of life increases the need for implantable cardiac monitoring devices. BIOTRONIK, a medical device company founded in 1963, focuses on cardiovascular and endovascular medical technologies. To that end, the company has developed the [BIOMONITOR III_m](#), an insertable cardiac monitor, to track irregular heart rhythms remotely. BIOMONITOR III_m is a miniature ECG device that can record, store and transmit heart rhythm irregularities for an extended time. It has an industry-leading battery life of five and a half years, compared to other implantable cardiac monitoring devices. The device is injected subcutaneously under local anesthesia and its flexible antenna allows the device to adapt to the patient's body.

The BIOMONITOR III_m's leverages the company's unique BIOvector design to obtain 99% noise-free signals, allowing it to optimize signal quality. As a result, the device can provide high-definition ECGs and maximum precision in the recorded rhythm disturbance. False positives are thus significantly reduced, in contrast with other competitors' implantable cardiac monitors. Furthermore, the device uses RhythmCheck, an intelligent algorithm that recognizes and eliminates ectopic beats. Such an approach is quite important as ectopic beats are often misinterpreted as atrial fibrillation, making them responsible for 52% of false positives¹. RhythmCheck prevents approximately 72% of false positive detections for patients with ectopic beats. The innovative algorithm adapts to each patient's unique heart rhythm, resulting in higher accuracy than competing implantable cardiac monitoring devices.

Moreover, physicians can remotely monitor patients implanted with the BIOMONITOR III_m via the BIOTRONIK Home Monitoring® solution. Recorded rhythm disturbances are transmitted wirelessly to the company's CardioMessenger Smart device every night, which then sends the data to the Home Monitoring Service Centre. Transmission is entirely automated, unlike competitive remote monitoring solutions which require set-up and interventions by the clinic or patient. An evaluation, called a CardioReport, is generated at the centre and accessed by the physician through a webpage. As a result, clinicians can monitor patients' cardiac rhythms every 24 hours from anywhere. Frost & Sullivan points out that BIOTRONIK's Home Monitoring's transmission compliance rate is 98%, the highest in the industry. Moreover, BIOTRONIK Home Monitoring has been shown to detect abnormalities up to 34 days earlier than competing technologies, resulting in a 45% reduction in face-to-face visits², 73% decrease in hospitalizations³, and a 60% reduction in mortality⁴ when used with BIOTRONIK cardiac monitoring devices. Such efficacy has proven useful, especially during the COVID-19 pandemic, as physicians can continually monitor patients for warning signs without hospital visits.

BIOMONITOR III_m can be used to diagnose and monitor several cardiac arrhythmia conditions, namely atrial fibrillation, bradycardia, a sudden heart rate drop, a high ventricular rate and asystole. Due to the use of the RhythmCheck algorithm, the device's atrial fibrillation episode sensitivity is 99.1%, while sensitivity to episodes of high ventricular rate, bradycardia, asystole and sudden heart rate drop is 100%. The device also measures patients' temperature and activity rate, allowing for enhanced

¹ Afzal. Et al. Incidence of false-positive transmissions during remote rhythm monitoring with implantable loop recorders. *Heart Rhythm* 2020;17:75–80.

² Varma. Et al. Efficacy and Safety of Automatic Remote Monitoring for Implantable Cardioverter-Defibrillator Follow-Up. *Circulation* 2010; 122: 325.

³ Guedon-Moreau. Et al. Effectiveness and Costs of ICD Follow-up Schedule with Telecardiology. *European Heart Journal* 2013; 34: 605-614.

⁴ Hindricks Et al. Influence of Home Monitoring on the Clinical Status of Heart Failure Patients. *The Lancet* 2014; 384: 583-590.

monitoring. As a result, physicians can identify warning signs early, allowing for timely and appropriate interventions. Such an approach is quite critical as systemic illnesses can cause adverse outcomes in patients with cardiac conditions.

Overall, Frost & Sullivan believes that the BIOMONITOR III_m can improve patients' outcomes due to its clinically actionable ECGs, temperature and activity measurement. As a result of its superior features, high precision and industry-leading battery life, Frost & Sullivan expects the device to disrupt the insertable cardiac home monitoring market.

Exceptional Customer Experience

Injecting the BIOMONITOR III_m device into patients is a minor in-patient procedure involving simple tools, allowing patients to return to their normal activities immediately. The incision, injection and tool removal takes only around 39 seconds. The absence of cables and attachments, in contrast to

“Physicians can remotely monitor patients implanted with the BIOMONITOR III_m device via the BIOTRONIK Home Monitoring solution. By allowing patients' recorded cardiac rhythm disturbance to be automatically and wirelessly transmitted to physicians, the solution enables 24-hour monitoring from anywhere. The transmission compliance rate is 98%, the highest in the industry.”

**- Dr. M. Sneha Maria,
Senior Research Analyst**

conventional wearable monitors, allows patients to carry on with their routine activities (without any lifestyle restrictions). The device is safe around most household electronic appliances. The company's optional Remote Assistant III device further allows patients to record additional ECGs after suspicious events. When held over the BIOMONITOR III_m with the trigger key pressed for three seconds, the Remote Assistant III enables the device to record the last seven minutes of the heart rhythm. The resulting ECG helps physicians correlate symptoms with the heart rhythm. Above all, the device's ability to transmit ongoing data to physicians, irrespective of location,

gives patients confidence and improves their quality of life. A study regarding patients' experience of BIOTRONIK Home Monitoring demonstrated 98% patient satisfaction.⁵

Frost & Sullivan research reveals that, in addition to enabling physicians to diagnose and monitor treatments in cardiac patients effectively and remotely, BIOTRONIK's technology reduces false positives, thus decreasing clinicians' workload. CardioReport's "traffic light system" supports alert-based patient care and efficient triage, while BIOTRONIK Home Monitoring's QuickCheck feature allows current patient data to be triggered within 3 to 4 minutes. As a result, physicians have more time to concentrate on patients requiring immediate care. BIOTRONIK also trains physicians via hands-on educational programs and offers 24/7 technical and in-person support. The company also attends to patient questions and concerns. Frost & Sullivan lauds the exceptional ownership and service experience provided by BIOTRONIK to physicians and patients.

⁵ Ricci PR Et al. Long-term patient acceptance of and satisfaction with implanted device remote monitoring. *Europace* 2010; 12: 674–679.

Leveraging 58 Years of Excellence to Provide Best-in-Class Quality

BIOTRONIK's legacy of disruptive and life-saving innovations has resulted in improved patient outcomes for almost six decades. The company's strong research and development team and close collaboration with industry experts allow it to deliver precise, state-of-the-art cardiac rhythm management, electrophysiology and vascular intervention solutions. BIOTRONIK is committed to the highest quality standards to guarantee patient safety. Its products undergo stringent quality and validation checks and, to ensure control over the safety and reliability of its products, BIOTRONIK manufactures its critical components in-house. As a result, Frost & Sullivan recognizes how BIOTRONIK has gained remarkable trust among its customers, spurring brand loyalty and the quick adoption of its products.

Conclusion

BIOTRONIK's innovative and high-quality BIOMONITOR III_m offering is a miniature electrocardiogram (ECG) device that can record, store, and transmit heart rhythm irregularities. Its unique BIOvector design optimizes signal quality, resulting in high-definition ECGs and maximum precision in the recorded rhythm disturbance.

The BIOMONITOR III_m leverages the company's unique RhythmCheck algorithm to reduce false positives indicating atrial fibrillation. When used with the BIOTRONIK Home Monitoring[®] system, it enables the automated and wireless transmission of daily recorded rhythm irregularities to physicians. Aside from accurately monitoring multiple cardiac arrhythmia conditions, the BIOMONITOR III_m tracks patients' temperature and activity, garnering brand loyalty among customers.

With its exceptional ownership and service experience and disruptive life-saving cardiovascular and endovascular solutions, BIOTRONIK earns the 2021 Frost & Sullivan Enabling Technology Leadership Award.

What You Need to Know about the Enabling Technology Leadership Recognition

Frost & Sullivan's Enabling Technology Leadership Award recognizes the company that applies its technology in new ways to improve existing products and services and elevate the customer experience.

Best Practices Award Analysis

For the Enabling Technology Leadership Award, Frost & Sullivan analysts independently evaluated the criteria listed below.

Technology Leverage

Commitment to Innovation: Continuous emerging technology adoption and creation enables new product development and enhances product performance

Commitment to Creativity: Company leverages technology advancements to push the limits of form and function in the pursuit of white space innovation

Stage Gate Efficiency: Technology adoption enhances the stage gate process for launching new products and solutions

Commercialization Success: Company displays a proven track record of taking new technologies to market with a high success rate

Application Diversity: Company develops and/or integrates technology that serves multiple applications and multiple environments

Customer Impact

Price/Performance Value: Products or services provide the best value for the price compared to similar market offerings

Customer Purchase Experience: Quality of the purchase experience assures customers that they are buying the optimal solution for addressing their unique needs and constraints

Customer Ownership Experience: Customers proudly own the company's product or service and have a positive experience throughout the life of the product or service

Customer Service Experience: Customer service is accessible, fast, stress-free, and high quality

Brand Equity: Customers perceive the brand positively and exhibit high brand loyalty

About Frost & Sullivan

Frost & Sullivan is the Growth Pipeline Company™. We power our clients to a future shaped by growth. Our Growth Pipeline as a Service™ provides the CEO and the CEO's growth team with a continuous and rigorous platform of growth opportunities, ensuring long-term success. To achieve positive outcomes, our team leverages over 60 years of experience, coaching organizations of all types and sizes across 6 continents with our proven best practices. To power your Growth Pipeline future, visit Frost & Sullivan at <http://www.frost.com>.

The Growth Pipeline Engine™

Frost & Sullivan's proprietary model to systematically create on-going growth opportunities and strategies for our clients is fuelled by the Innovation Generator™.

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Key Impacts:

- **Growth Pipeline:** Continuous flow of Growth opportunities
- **Growth Strategies:** Proven Best Practices
- **Innovation Culture:** Optimized Customer Experience
- **ROI & Margin:** Implementation Excellence
- **Transformational Growth:** Industry Leadership



The Innovation Generator™

Our six analytical perspectives are crucial in capturing the broadest range of innovative growth opportunities, most of which occur at the points of these perspectives.

Analytical Perspectives:

- **Mega Trend (MT)**
- **Business Model (BM)**
- **Technology (TE)**
- **Industries (IN)**
- **Customer (CU)**
- **Geographies (GE)**

