



2018 North American Perinatal Information Systems
New Product Innovation Award



2018
BEST PRACTICES
AWARDS

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Background and Company Performance

Industry Challenges

In North America, rising maternal age alongside increasing rates of diabetes, obesity, and hypertension contribute to one of the highest rates of maternal mortality and morbidity as well as neonatal mortality in the developed world.^{1,2} However, on careful review of these tragedies, large proportions are potentially preventable.³ Delayed recognition and response to signs of worsening clinical conditions were the leading human factor present in approximately 70% according to an extensive and recent review of maternal mortality in California.³ In parallel, a shortage of skilled nurses and the need for round-the-clock monitoring of high-risk labor and delivery (L&D) patients spurs the demand for intelligent monitoring equipment. Increasing awareness of the benefits of medical technology among computer-savvy patients and their healthcare providers reinforce the call for sophisticated and multi-parametric fetal and maternal monitoring devices.

Since its introduction in 1958, continuous electronic fetal heart rate monitoring (EFM) is commonly used to assess fetal well-being during labor with the goal to prevent metabolic acidemia—a condition associated with increased rates of neonatal brain injury and cerebral palsy. Intrapartum fetal heart rate monitoring is the most common obstetric procedure performed in the United States (US). In 2002, 85% of the approximately four million live births in the US were evaluated with EFM.⁴ Modern fetal monitors have additional sensors that measure maternal vital signs and her oxygenation status. Some use a new type of sensor that is not impeded by obesity.

With increasing expectations for a healthy outcome and decreasing availability of human resources, market participants offering artificial intelligence (AI)-based analytics that enhance decision support and drive optimal patient outcomes will gain a significant competitive edge. Wireless monitoring capabilities are equally sought as are cloud-based approaches that can extend the expertise of highly qualified personnel to remote locations. Finally, successful market participants must focus on cost containment due to the initial high capital outlay of purchasing EFM machines as well as ancillary costs, e.g., EFM software to display and store strips, maintenance, and staff certification programs.

¹ https://www.cdc.gov/nchs/data/nvsr/nvsr63/nvsr63_05.pdf

² Global, regional, and national levels of maternal mortality, 1990–2015: a systematic analysis for the Global Burden of Disease Study. *Lancet*. 2016 Oct 8; 388(10053): 1775–1812.

³ Main EK, McCain CL, Morton CH, Holtby S, Lawton ES. Pregnancy-related mortality in California: causes, characteristics, and improvement opportunities. *Obstet Gynecol*. 2015 Apr;125(4):938-47

⁴ Lisa Heelan, "Creating a Culture of Safety With Informed Choice," *The Journal of Perinatal Education* 22, no. 3 (Summer 2013): 156-165

New Product Attributes and Customer Impact of PeriGen

Founded in 1995 and headquartered in Cary, North Carolina, PeriGen is an innovator and pioneer of advanced early warning perinatal systems that provide fetal monitoring and clinical decision support. PeriGen focuses on improving standardization with a particular emphasis on creating an objective assessment process and enhancing situational awareness with concise long-term displays of critical information. The US Food and Drug Administration (FDA) has cleared the company's devices and the National Institutes of Health has verified the EFM pattern recognition module. PeriGen's most recent solution, PeriWatch™ Vigilance™ is an early warning obstetrics platform that automatically integrates its advanced analytics and monitoring capabilities with existing EFM systems.

Applying Industry-leading Expertise to Address Market Needs

PeriGen understands that poor L&D outcomes often result from medical staff not recognizing signs of worsening medical conditions in a timely manner, due in part to the difficulty of simultaneously monitoring, documenting, and conferring with colleagues as well as subjectivity in assessing the fetal heart rate or trends over long periods of time. Frost & Sullivan notes that while conventional perinatal monitoring systems focus exclusively on small windows of time and simple high-low alerts, PeriGen provides a single, time-aligned, color-coded view of critical data over many hours showing how the mother and baby are tolerating labor with respect to expected norms.

The analysis of fetal heart patterns is based on advanced AI algorithms which have been validated by the NICHD. PeriGen's Curve module assesses labor progression—accounting for several factors such as the frequency of contractions and epidural use. Standard perinatal systems merely record dilation entries over time. These powerful tools help clinicians standardize and automate checklists with tireless real-time analysis of dynamic patient data. The consolidated long-term displays reduce information overload or missing important deviations in vital signs and address human inconsistency and bias in reading fetal strips, by identifying concerning trends for both mother and baby. Frost & Sullivan appreciates the fact that PeriGen is using Google's Tensor Flow machine learning tools to advance some of its sophisticated algorithms. The software requires minimal integration and incorporates Health Level Seven International standards—providing seamless transfer of data to and from electronic medical records.

Currently, the company has its L&D systems installed in 350 hospitals throughout the US and anticipates double-digit growth in 2019. PeriGen has over 30 patents and appears in over 50 peer-reviewed articles in leading journals. In addition, PeriGen extends its educational focus by presenting its technology at industry conferences throughout the world. PeriGen offers clients 24/7 support as well as a virtual user community. Frost & Sullivan firmly believes that the return on investment PeriGen offers to its clients is a strong suit for the company.

For example, MedStar, a leading Maryland-based health system, researched the impact of PeriGen's decision support software solutions as a key part of a system-wide process improvement program. Over a 10-year period, they found a 54% reduction in the use of cardiopulmonary resuscitation, assisted ventilation, or intubation; a 52% decline in unanticipated neonatal intensive care unit transfers, and stabilized Cesarean rates.⁵ Furthermore, upon implementing PeriGen's solutions, MedStar's obstetrics-related medical malpractice payouts dropped from nearly a third of the system's total to approximately 8%.

Improving EFM for All: Introducing PeriWatch™ Vigilance™

In 2018, PeriGen launched PeriWatch® Vigilance™, an early warning obstetrics platform that runs its advanced analytics and monitoring capabilities alongside existing EFM systems; thus, eliminating the need to replace legacy technology. At the heart of the system are the proprietary algorithms to analyze fetal heart rate patterns. PeriGen experts analyzed and subsequently fed thousands of hours of these fetal strips to machine learning programs to develop algorithms for fast and accurate pattern detection and interpretation. Now the company uses Google's Tensor Flow, a computational framework, for building its machine learning models. As a result, PeriGen systems can interpret fetal heart rate patterns in real time, with information taken directly from the medical device as opposed to relying on human analysis and data entry. PeriWatch Vigilance also tracks maternal vital signs and labor progression and will consistently alert clinicians when a patient exceeds limits set by the institution so that care protocols can be followed in a timely and standardized way.

Frost & Sullivan research reveals that PeriWatch Vigilance provides a range of unique capabilities that position the company for continued recognition and increased market penetration. First, Vigilance customers can now realize significant patient safety, process improvement, and efficiency gains through the use of this new, innovative AI-enabled solution for obstetrics data management and analytics. Second, PeriWatch Vigilance operates regardless of any existing EFM system, offering complementary capabilities in perinatal monitoring. Third, PeriWatch Vigilance can install within 45 days and does not require time-consuming workflow changes, complex interfacing, or additional documentation. The system is highly interoperable and can easily implement and integrate with multiple leading EHR systems including Allscripts, Cerner, Epic, Meditech, and others. Finally, PeriGen recently entered into a strategic partnership with Qualcomm Life to license and sell PeriWatch Vigilance. The partnership with Qualcomm is designed to accelerate PeriWatch Vigilance adoption and eventually extend PeriGen's market through collaborative product development. PeriGen continues to focus on continuous product development and improvement, which will further enhance the offering. The PeriWatch Vigilance proprietary algorithm is currently FDA-cleared for 36 weeks of gestational age and beyond, but the company is working to extend its capabilities to address patients over the entire last trimester, thus, positioning PeriGen for additional growth opportunities.

⁵ Samuel Smith MD, Lynette Philip RN, Adi Zmri MD, Emily Hamilton MD, Thomas Garite MD. "HIT and clinical synergy: A decade of decreasing NICU admissions & stabilizing cesarean rates," *Becker's Hospital Review*, 2016 Dec 20.

Conclusion

While electronic fetal monitoring (EFM) is the standard of care for obstetrics, inconsistent interpretations can lead to delayed or unnecessary surgical interventions, increased costs, and potential complications. PeriGen's PeriWatch Vigilance leverages advanced artificial intelligence to add objective, best-in-class analytics and monitoring capabilities to augment fetal monitoring systems. With its capacity to improve accuracy, reduce liability and enhance patient outcomes, PeriGen earns Frost & Sullivan's 2018 New Product Innovation Award in the North American perinatal information systems market.

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.

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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Present 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	<ul style="list-style-type: none"> • 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.



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>.