

FROST & SULLIVAN

MEDTRONIC – SONARMED™ SYSTEM

2022
NEW
PRODUCT
INNOVATION

*NORTH AMERICAN
NEONATAL CARE INDUSTRY*

Best Practices Criteria for World-Class Performance

Frost & Sullivan applies a rigorous analytical process to evaluate multiple nominees for each award category before determining their final award recipient. The process involves a detailed evaluation of best practices criteria across two dimensions for each nominated company. Medtronic excels in many of the criteria in the neonatal care space.

AWARD CRITERIA	
<i>New Product Attributes</i>	<i>Customer Impact</i>
Match to Needs	Price/Performance Value
Reliability	Customer Purchase Experience
Quality	Customer Ownership Experience
Positioning	Customer Service Experience
Design	Brand Equity

Medtronic

Founded in 1949 and headquartered in Dublin, Ireland, Medtronic is a developer of healthcare technology solutions. With over 90,000 employees across 150 countries, it designs breakthrough treatment solutions for more than 70 complex conditions. By harnessing data, artificial intelligence, and extensive expertise in the human body, the company extends, supports, and saves lives through insight-driven care. Medtronic has served 72 million patients globally.¹

The company develops, acquires, and distributes unique solutions to support the neonatal care ecosystem. As part of its respiratory care portfolio for neonatal patients, it built the first-of-its-kind airway monitoring system, a novel endotracheal tube (ETT) airway monitor that provides real-time visualization for accurate troubleshooting. The unique technology assists in reducing unplanned extubations (UE) during mechanical ventilation in the neonatal intensive care unit (NICU).

Redefining ETT Monitoring for Reducing UE and Heightening Neonatal Care

Medtronic invests heavily in research and development (R&D) and leverages market insights to ensure its solutions align with customer needs. With over \$2.5 billion invested in R&D activities,² the company gains market insights through customer surveys and explores technology to advance its commitment to new solution development.

¹ (<https://europe.medtronic.com/xd-en/our-company/key-facts.html>), accessed August 2022

² Ibid

Medtronic's needs-based approach inspired it to create an airway monitoring system for precise ETT monitoring at the patient's bedside to prevent UE, a vital safety concern in the NICU.

UE can lead to respiratory deterioration or fatal events such as hypoxemia, slow heart rate, increased infection risk, and physiological stress. Reportedly, nearly one in five neonates experience UE globally, a phenomenon that occurs randomly.³ However, the current guidelines to limit UE are substandard, which include ETT repositioning, tape removal, suctioning, reintubation, and continuous positive airway pressure therapy. These and other clinical interventions can potentially affect long-term neonatal

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*- Utkarsha Soundankar,
Senior Research Analyst*

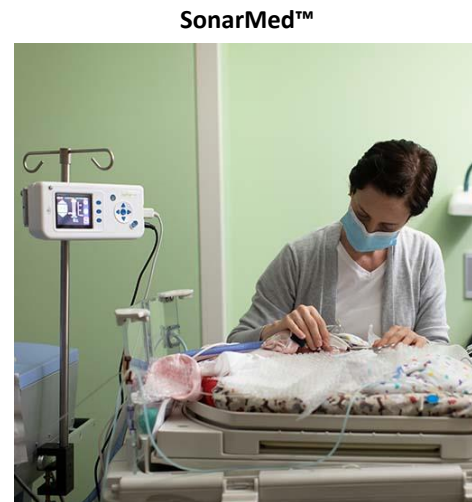
development and cause patient stress.⁴ Additionally, studies report pediatric patients with UEs lead to increased hospital costs (\$36,692/case) and a length of stay (LOS) of 6.5 days/case.⁵

Hence, Medtronic developed a solution for real-time ETT position and patency visualization. It enables accurate troubleshooting through timely alerts and precise measurements to handle a potentially critical event (tube movement or occlusion) and reduce UE.

SonarMed™ is the first and only Food and Drug Administration (FDA)-approved airway monitoring system designed to provide heightened patient safety, cost savings, and quality measures while lowering average LOS in the NICU.

The system detects ETT tip movement and direction and alerts the physicians about potential ETT migration through custom alarms set to adjust each infant's needs. Unlike conventional techniques, where periodically prescribed suctioning adds to neonatal stress, the monitor (installed at the bedside) has an obstruction indicator to display the exact location and severity of ETT blockage, enabling optimized suctioning and secretion removal based on patient need. It also provides real-time feedback if the removal efforts are successful.

SonarMed™ measures the tracheal circumference change, providing clinicians with an early warning of a potential airway obstruction during ventilation for early intervention. At the same time, an easy-to-read monitor flashes instant ETT fluctuations and monitors the dislodged tube's repositioning, unlike other standard-



<https://www.medtronic.com/covidien/en-us/products/airway-monitoring-systems/sonarmed-airway-monitoring-system.html>

³ (<https://www.medtronic.com/covidien/en-us/products/airway-monitoring-systems/sonarmed-airway-monitoring-system.html>), accessed August 2022

⁴ Peng NH, Bachman J, Jenkins R, et al. Relationships between environmental stressors and stress biobehavioral responses of preterm infants in NICU. *J Perinat Neonatal Nurs.* 2009;23(4):363–371. doi:10.1097/JPN.0b013e3181bdd3fd.

⁵ (<https://pubmed.ncbi.nlm.nih.gov/25901542/>), accessed August 2022

of-care spot check techniques, e.g., chest X-rays, visual inspection, or opening the isolette during every assessment done twice a shift.

The system applies a non-invasive approach, heightens care, and limits radiation exposure from daily

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**- Supriya Lala Kundu,
Best Practices Analyst**

chest X-rays. It is the only solution to leverage acoustic reflectometry technology (which emits sound waves through the ETT). SonarMed™ analyzes the time between echoes (measures distance) and intensity of echoes (measures blockage) to determine ETT position, movement, and patency during ventilation, sending immediate sound alerts if abnormal.

The system-enabled real-time, continuous remote airway monitoring (compatible with any standard ETT) avoids physically checking on the patients, eliminating

sleep disturbance, which is vital for neonatal development. Simultaneously, it relays timely critical information to the care staff, lowering undue clinical interventions. Additionally, the system enhances the standard of care as timely alerts promote skin-to-skin contact (Kangaroo Care), established as the most suitable healing environment for newborns.

Furthermore, the technology benefits the patient, caregiver, and staff by seamlessly integrating with the existing clinical workflow without causing operational disruptions and not requiring advanced user training, providing a unique competitive advantage to SonarMed™.

A Customer-centric Approach Driving Unmatched Client Experience

With its customer-centric corporate philosophy, Medtronic operates on the central tenet that its success depends on customer satisfaction. This philosophy permeates the company’s daily practices.

The data from the system provides the clinicians the confidence to open for earlier kangaroo care while offering additional assurance for the parents through real-time ETT monitoring during skin-to-skin contact. At the same time, it lowers the care team’s anxiety when transferring the baby from the isolette into the mother’s arms.

Medtronic’s cost calculator estimates the SonarMed™ airway monitoring system’s average cost savings by potentially reducing UEs in the NICU, justifying the product cost and promising high market adoption.

A Quest to Near Zero UEs

A study published by the Solutions for Patient Safety, a network of over 145 children’s hospitals, considered 40 ICUs (including NICU and pediatric intensive care units) and recommended ICUs achieve at or near zero UEs per 100 ventilator days with care bundle implementation. However, as current quality measures are insufficient, it propelled several NICUs to apply care bundles and assess a solution to achieve a zero UE rate.

In this scenario, SonarMed™ emerges as a promising solution, further validated by positive feedback from early adopters. Remarkably, the company’s first customer, California-based Huntington Hospital,

implemented the system with measurable results. For instance, the hospital significantly lowered the number of X-rays performed (lessening radiation exposure, cost, and time) and noted substantial progress in effective airway suctioning.

The Huntington Hospital states that, as the new standard of care for their intubated babies, the system renders additional assurance to the care team and parents regarding correct ETT positioning during Kangaroo care.⁶

In a second case, SonarMed™' introduction at the Children's Hospital, located in Illinois, lowered their UE rate from 1.5 to below 0.6 per 100 ventilator days in six months.⁷ Additionally, the hospital improved bedside staff's care-taking standards by observing the ETT movement (real-time) and associated after-effects during baby's nursing to adjust care accordingly.

Medtronic meets with customers to assess their specific needs and develop tailored solutions with roadmaps for seamless execution. This foundational approach establishes customers' ongoing trust for long-lasting relationships throughout the product's lifecycle.

Positioned for Growth

Since its inception, Medtronic's sterling reputation and customer-centric framework led to its coveted preferred partner status. Over the years, it added a range of new customers to its established base.

In December 2020, the company acquired SonarMed, the system's decade-long original developer, refining the sensing technology and algorithms over time. Additionally, over five granted patents and others pending protect the system's intellectual property, bolstering customer trust. Medtronic focuses on level 3 and 4 NICU, targeting neonatologists and respiratory therapists as champions to drive product adoption.

Furthermore, therapies that provide data-driven insights into respiratory management are a vital growth engine for the system from a business angle. Medtronic aims to propel product adoption initially in the United States in partnership with a dedicated team of the country's top clinical specialists in neonatal care and an established clinical infrastructure. It plans to adjust production for global expansion in Japan, Australia, and New Zealand based on its initial sales. Besides advancing the system's research interest, the company operates a neonatology advertisement board in several countries to promote awareness.

With positive feedback from over 300 NICU clinicians, Medtronic focuses on scaling the technology for usage beyond the NICU, integrating the ventilator data into the information systems' ecosystem and exploring the potential of sensing technology's capabilities for additional monitoring and diagnostics. The company has received FDA approval for different system sizes (for adult patient use) and is preparing for subsequent product commercialization.

Medtronic's distinct positioning creates substantial market opportunities. With a one-of-a-kind system for neonatal care (respiratory division focused on ICU) and a strategic partnership with its patient monitoring

⁶ (<https://www.med-technews.com/news/latest-medtech-news/medtronic-launches-sonarmed-airway-monitoring-system-in-u-s/>), accessed August 2022

⁷ (<https://hcpresources.medtronic.com/blog/q-a-benefits-of-implementing-airway-monitoring-system-at-childrens-hospital-of-illinois>), accessed August 2022

division (for account targeting), the company can leverage the existing client relationship network as part of SonarMed™ market development and commercialization strategy.

Frost & Sullivan believes Medtronic is well-positioned to drive the neonatal care space into its next growth phase, capturing market share and sustaining its leadership in the coming years.

Conclusion

To create a new solution, a company must understand the market's needs and deliver a solid solution designed and embedded with high quality and reliable performance. Frost & Sullivan finds that Medtronic embodies this concept through its SonarMed™ airway monitoring system. The first and only Food and Drug Administration-cleared system leverages acoustic technology and sensors to inspect real-time endotracheal tube (ETT) movement, position, and obstruction. The SonarMed™ monitor displays changes in ETT position through an easy-to-read screen. It notifies the physicians to handle critical events such as ETT movement and migration, addressing issues related to patient safety, a vital concern in neonatal care.

High unplanned extubation (UE) rates globally in the neonatal intensive care unit result in adverse and long-term events during mechanical ventilation. SonarMed™ potential to significantly reduce UE will improve infant care outcomes, lower healthcare costs and length-of-stay, and lessen infants' exposure to radiation from periodic X-rays.

Furthermore, Medtronic integrates a customer-centric approach to ensure that its offering addresses the wants and needs of users by providing best-in-class neonatal care. For its strong overall performance, Medtronic earns Frost & Sullivan's 2022 North American New Product Innovation Award in the neonatal care industry.

What You Need to Know about the New Product Innovation Recognition

Frost & Sullivan's New Product Innovation Award recognizes the company that offers a new product or solution that uniquely addresses key customer challenges.

Best Practices Award Analysis

For the New Product Innovation Award, Frost & Sullivan analysts independently evaluated the criteria listed below.

New Product Attributes

Match to Needs: Customer needs directly influence and inspire product design and positioning

Reliability: Product consistently meets or exceeds customer performance expectations

Quality: Product offers best-in-class quality with a full complement of features and functionality

Positioning: Product serves a unique, unmet need that competitors cannot easily replicate

Design: Product features an innovative design that enhances both visual appeal and ease of use

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

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The Growth Pipeline Engine™

Frost & Sullivan's proprietary model to systematically create ongoing 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 6 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)**

