



2015 European Pressure Ulcer Diagnostics
New Product Innovation Award



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



50 Years of Growth, Innovation & Leadership

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Background and Company Performance

Industry Challenges

Pressure ulcers (PUs), commonly known as bedsores, are localized injuries to the skin and/or the underlying tissue. They are usually present over a bony prominence, such as a heel or an elbow, and occur as a result of pressure in combination with shear and friction. PUs can occur in any patient; however, they are more likely to occur in high-risk groups, such as the elderly, the obese, the malnourished, and in patients with underlying conditions. Pressure ulcers represent a severe health problem in European countries and in the United States, impacting up to 25% of patients across acute and long-term care settings. In the United States alone, approximately 60,000 patients die per year due to infections or complications resulting from PUs. Additionally, pressure ulcers represent a significant financial burden. On average, a PU can result in 6 to 10 additional hospital days and can cost an incremental \$13,000 per patient episode in Europe. In the United Kingdom, PUs cost the healthcare system around \$2.0 billion per year. These costs are incurred as a result of the increased nursing time to monitor, assess, and dress wounds, along with the utilization of suitable treatment therapies added to the increased duration of the hospital stay.

The current standard of care for PU prevention includes risk assessment tools—such as the Waterlow, Norton, or Braden Scale—and visual skin inspection (VSA). Visual inspection is, at present, considered the gold standard in assessing the presence of PUs in patients. Unfortunately, the accuracy of visual skin inspection is subjective and highly dependent on the skill of the caregiver, and ultimately, it is unreliable because PUs can occur without visual cues. Additionally, visual assessment is less effective on patients with dark skin tones and with a deep tissue injury (DTI), a specific type of pressure ulcer, where visual cues may be ambiguous. Furthermore, visual assessment is untimely as by the time damage is visually evident, significant tissue damage has already occurred. Risk assessment tools usually involve clinicians evaluating the patient against different parameters, such as mobility, nutrition, and skin moisture, and assigning a risk score. However, these tools demonstrate a wide range of specificity and sensitivity, leading to missed opportunities for early detection and prevention.

Frost & Sullivan's research clearly shows that an innovative diagnostic tool is needed that can accurately identify the presence of PUs prior to tissue damage, while simultaneously overcoming the above-mentioned limitations. Companies that offer accurate, non-invasive, easy-to-use, and cost-effective diagnosis solutions are best positioned to stay ahead of competition in the European pressure ulcer diagnostics market.

New Product Attributes and Customer Impact

Product Matched to Market Needs

Pressure ulcers can develop at any time during the course of a patient's care. However,

studies show that majority of the pressure ulcers begin to develop within 2 to 4 days after a patient's admission and immediately followed prolonged surgical procedures. Most PUs are considered preventable and reversible, if identified in the early stages (Stages I and II). As pressure ulcers are preventable, insurers across the United States and Europe have adopted stringent reimbursement restrictions and have deemed advanced hospital-acquired Stage III and Stage IV pressure ulcers as avoidable and non-reimbursable.

Founded in 2009 and headquartered in Los Angeles, California, Bruin Biometrics is a privately-held medical device company that designs and develops diagnostic solutions, specifically in the fields of wound care and orthopedics. Cognizant of the major challenges plaguing the pressure ulcer diagnostics market, the company developed its unique SEM Scanner™ (Sub-Epidermal Moisture). The device, which obtained the CE mark in 2013, is designed to detect the early warning signs of pressure-related skin damage days before it is visible to the naked eye, allowing a tissue viability nurse (TVN) and physicians to take swift preventative action. Frost & Sullivan's competitive analysis shows that the SEM Scanner™, when compared with the current standard of care in pressure ulcer risk assessment, can drastically minimize the incidence of pressure ulcers.

Superior Product Quality and Reliability

One of the important factors that determine the success of a device is its clinical outcome. The SEM Scanner™ is an innovative, sensor-based diagnostic solution designed for the detection of early stage pressure ulcers and suspected deep tissue injuries. In the clinical studies conducted by Bruin Biometrics, the SEM Scanner™ demonstrated high reliability rates regardless of the device used or the operator handling it. In addition, Frost & Sullivan notes that this revolutionary device has been found to accurately identify local tissue edema related to inflammatory changes that occur up to 10 days before damage is visible on the skin's surface. Given the limitations of the currently available diagnostic solutions to prevent and detect pressure ulcers, the SEM Scanner™ is a reliable tool for assessing the presence of pressure ulcers.

Enhanced Price and Performance Value

On average, 42% of patients with Stage I pressure ulcers progress to higher stages of ulceration. Associated with this is the treatment cost, which quadruples from Stage I (approximately \$1,966) to Stage II (approximately \$8,485). Hence, it is necessary to prevent and treat PUs at the earlier stage. The SEM Scanner™ can detect changes in SEM which occur up to 10 days before the tissue damage is visible on the skin surface. Product evaluation trials indicate that the deployment of the SEM Scanner™ within the clinical workflow can reduce the incidence of PUs by 40% per year, which translates into significant cost savings for the hospital. Additionally, in the trials conducted by UK NHS' Wrightington, Wigan and Leigh trust, it was found that by utilizing SEM Scanner™, they achieved zero pressure ulcers incidence (compared to 2-3 in previous periods achieved using currently available solutions in the European market) and recorded a savings of £50,000 per month.

[Frost & Sullivan firmly believes that the SEM Scanner™ provides superior service value to its customers by preventing unnecessary treatments. It is common for a clinician to be uncertain of the exact stage of a particular PU with the traditional visual technique and whether that PU should be actively treated or not. Hence, the clinician may suggest a costly treatment solution even though it is not required. This is prevented by using the SEM Scanner™ system as it identifies at the early stage of the PU enabling the clinician to make the right call.

Strong Product Positioning

Recognizing the enormous untapped potential of the global pressure ulcer diagnostics market, Bruin Biometrics introduced the novel SEM Scanner™ solution intended to detect pressure-induced tissue damage beneath the skin's surface. The SEM Scanner™ facilitates an evidence-based, objective method to detect PUs, enabling early intervention to treat tissue damage, and ultimately, prevent the formation of pressure ulcers.

Pressure ulcers are painful, slow to heal, and can cause complications—such as serious infections, like MRSA, sepsis and cellulitis, and cancer—drastically increasing the hospital-acquired conditions and in turn, increasing the re-admission rates. Studies show that within Europe, the prevalence of PUs is higher in long-term care than in the acute care settings. This is because the patients in the long-term care are primarily aged 65 years and older, and thus, are more likely to develop PUs. Similarly, the overall pressure ulcer prevalence in US hospitals was 13.5% in acute care settings and 22% in long-term care facilities. Globally, there is a marked shift from hospitals and clinical settings to home care settings in order to reduce healthcare expenditures. Frost & Sullivan expects that these factors will aid in the effective adoption of the SEM Scanner™ within the home care and the long-term care settings.

Innovative Product Design

The SEM Scanner™ is a hand-held portable device that rapidly confirms the existence of early stage pressure ulcers non-invasively. The scanner works by measuring changes in subepidermal moisture (SEM), a biophysical marker that is correlated with pressure ulcer formation and healing. By detecting SEM build-up under the skin, clinicians can take preventive action before skin ulceration. In Frost & Sullivan's opinion, providers can also easily adopt the SEM Scanner™ into existing workflows. The SEM Scanner™ can be easily utilized in diverse clinical settings with minimal investments to train existing staff and provides reliable assessment of PUs irrespective of the clinician performing the assessment.

Excellent Customer Ownership Experience

Bruin Biometrics uses a classical approach in its product development procedures, wherein it identifies clients' needs and develops solutions that cater to these specific needs. After clinical validation, these solutions are marketed accordingly. In line with this approach,

the company introduced the SEM Scanner™, which when integrated by the hospitals into pressure ulcer prevention protocols, can eliminate the occurrence of PUs. Tremendous support for the adoption of the SEM Scanner™ has arisen, particularly from nurses and tissue viability nurses who see this scanner as a “game changer” in the diagnosis of pressure ulcers. Frost & Sullivan anticipates, with no direct competitors, Bruin Biometrics’ revenue in the European pressure ulcer diagnostic market will grow significantly in 2016.

Conclusion

Recognizing Bruin Biometrics’ dedication to preventing avoidable pressure ulcers, Frost & Sullivan applauds the enhanced value that the company provides to its broad-based European customers through its unique SEM Scanner™. Frost & Sullivan's independent analysis of the Pressure Ulcer market clearly shows that innovation is the company’s key to success, and the company consistently ensures maximum return on investment (ROI) to its customers by improving workflows and enhancing the quality of care for patients. Furthermore, by maintaining close relationships with customers, Bruin Biometrics focuses on developing innovative products to effectively address prevailing industry challenges and to cater to evolving customer requirements.

Because of its strong overall performance, Bruin Biometrics has earned Frost & Sullivan’s 2015 New Product Innovation Award.

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

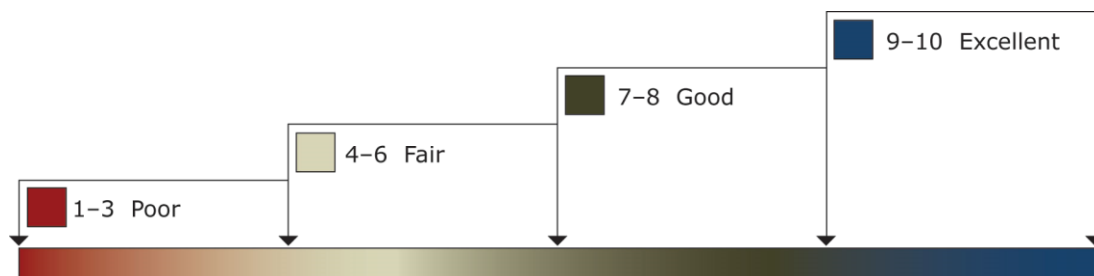
- Criterion 1: Price/Performance Value
- Criterion 2: Customer Purchase Experience
- Criterion 3: Customer Ownership Experience
- Criterion 4: Customer Service Experience
- Criterion 5: Brand Equity

Best Practice Award Analysis for Bruin Biometrics, LLC

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., the overarching categories for all 10 benchmarking criteria; the definitions for each criteria 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, Frost & Sullivan chose to refer to the other key players as Competitor 2 and Competitor 3.

DECISION SUPPORT SCORECARD: NEW PRODUCT INNOVATION AWARD

<i>Measurement of 1–10 (1 = poor; 10 = excellent)</i>			
New Product Innovation	New Product Attributes	Customer Impact	Average Rating
Bruin Biometrics, LLC	9	10	9.5
Competitor 2	7	7	7.5
Competitor 3	6	6	6.0

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 functionality

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 like 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

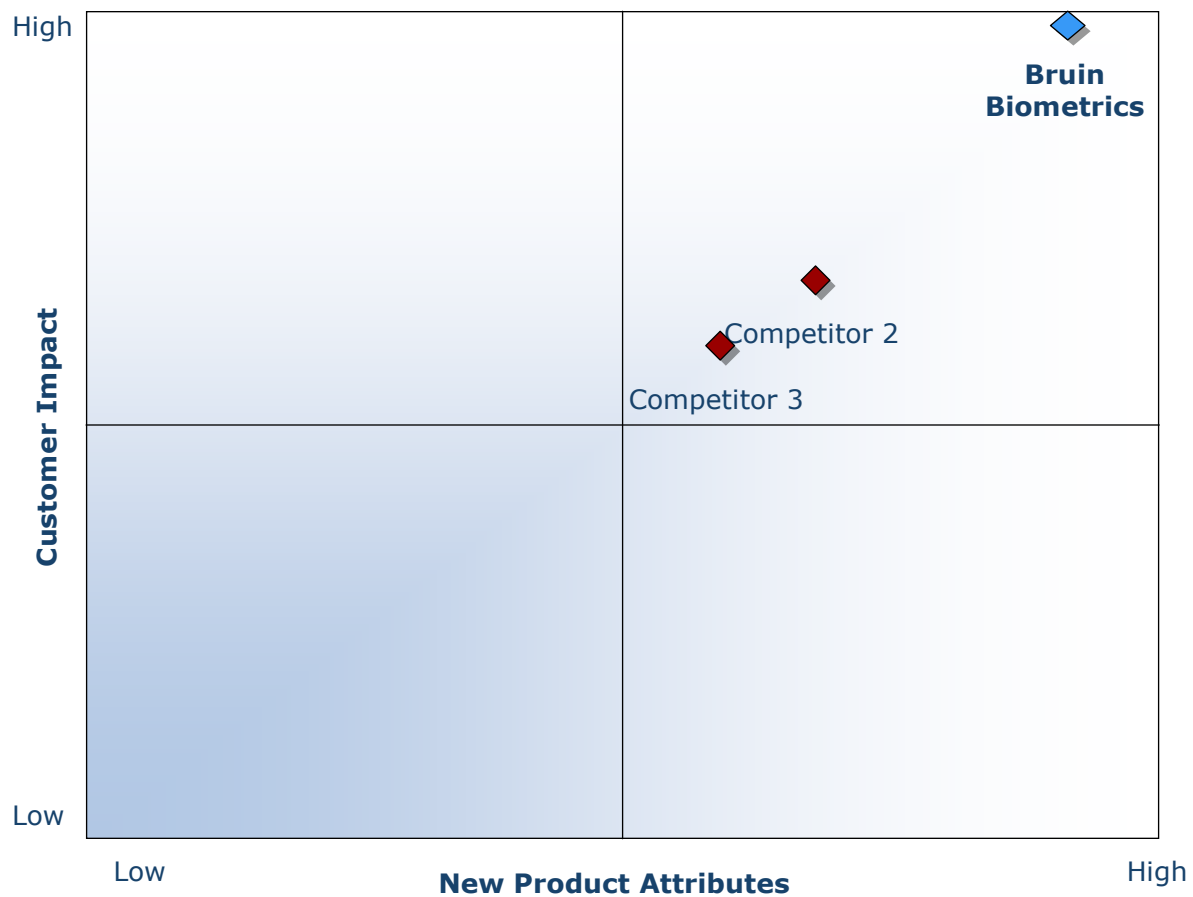
Criterion 5: Brand Equity

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 can 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.

DECISION SUPPORT MATRIX: NEW PRODUCT INNOVATION AWARD



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 players 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 over 50 years of experience in partnering with Global 1000 companies, emerging businesses and the investment community from 40 offices on six continents. To join our Growth Partnership, please visit <http://www.frost.com>.

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