

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

2024 TECHNOLOGY INNOVATION LEADER

*IN THE NORTH AMERICAN
POINT-OF-CARE
BIOIMPEDANCE
SPECTROSCOPY INDUSTRY*

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

2024
BEST
PRACTICES
AWARD

impedimed®

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. ImpediMed excels in many of the criteria in the point-of-care bioimpedance spectroscopy space.

AWARD CRITERIA	
<i>Technology Leverage</i>	<i>Business Impact</i>
Commitment to Innovation	Financial Performance
Commitment to Creativity	Customer Acquisition
Stage Gate Efficiency	Operational Efficiency
Commercialization Success	Growth Potential
Application Diversity	Human Capital

The Critical Need for Precision in Health Monitoring

In today’s healthcare landscape, where monitoring disease progression and early disease detection play vital roles, the demand for precise, real-time, and point-of-care health monitoring solutions is rising.

“ImpediMed’s bioimpedance spectroscopy (BIS) solution differentiates fluid types with high precision, offering an L-Dex® score to detect early changes in the fluid for clinical intervention in breast cancer-related lymphedema, and HF-Dex to support the management of heart failure. This precision is due to ImpediMed’s refined approach to measure impedance at 256 different frequencies up to 1,000 KHz. These accurate measurements provide a comprehensive view of fluid and tissue composition and help clinicians make efficient, data-driven decisions.”

– Dr. Isai Pratha Karthik Ph.D.
Senior Research Analyst

Chronic diseases such as cancer-related lymphedema, heart failure, and metabolic disorders have become increasingly prevalent. These conditions cause accumulation of bodily fluids in the tissues, resulting in swelling (edema). Subtle changes in the extracellular or intracellular fluid volume can indicate the onset or progression of these diseases, necessitating a reliable method to measure the fluid volume precisely.

The Heart Failure Society of America states that about 6.7 million people in the United States suffer from

heart failure, which is projected to double by 2050.¹ Beyond heart failure, fluid accumulation is prevalent in breast cancer survivors. There are 4.1 M breast cancer survivors in the US, with female breast cancer survivors representing 22% of cancer survivors in the US². About 65% of the patients treated for breast cancer develop breast cancer-related lymphedema (BCRL) between 0 and 11 years after surgery.³ It is often considered best to detect lymphedema before the symptoms are evident to enable early intervention before it progresses to a chronic condition, which can directly affect the physical and emotional well-being of breast cancer patients and survivors.

ImpediMed's SOZO® Digital Health Platform with L-Dex® represents a breakthrough in breast cancer-related lymphedema monitoring using a simple and non-invasive bioimpedance spectroscopy (BIS) method. The L-Dex score provides clinicians with quantifiable metrics to track changes in the extracellular fluid volume in the affected region of the limb. The SOZO platform utilizes BIS technology to provide insights into a patient's total body water, intracellular and extracellular fluid, skeletal muscle mass, fat mass, and other vital measurements within 30 seconds.

Thus, the early fluid changes detected by the SOZO platform empower clinicians to intervene early, monitor treatment progress, and support patient-specific care, opening a new era of precision in health monitoring.

SOZO® Digital Health Platform: A Transformative Innovation in Fluid & Tissue Composition Analysis

ImpediMed's SOZO platform can replace conventional fluid analysis like pitting tests, volumetric analysis, weight and girth measurements, which provide limited insight into the tissue fluid level. These methods fail to distinguish between extracellular and intracellular fluids, a crucial distinction for conditions like lymphedema and heart failure, where extracellular fluid accumulation can indicate disease onset and progression.

Advanced technologies such as magnetic resonance imaging and lymphoscintigraphy involve radioactive tracers and can be painful during injections. Also, these technologies are often used only after the prominent onset of symptoms like swelling, pain, and difficulty in moving the limbs.

Breast cancer-related lymphedema may be reversed when diagnosed at stage 0 or 1; upon further progression, lymphedema can become a lifelong, chronic condition.

SOZO's bioimpedance spectroscopy solution differentiates fluid types with high precision, offering an L-Dex score to detect early changes in the tissue fluids. This precision is due to ImpediMed's proprietary approach to measure impedance at 256 different frequencies up to 1,000 kHz. Each SOZO measurement automatically generates six Cole plots to confirm quality of the measurement, representing body segments like arms, legs, and the whole body. These accurate measurements provide a comprehensive view of fluid and tissue composition to help clinicians make efficient, data-driven decisions.

¹ <https://hfsa.org/>

² : American Cancer Society. Cancer Treatment & Survivorship Facts & Figures 2022-2024. Atlanta: American Cancer Society; 2022.

³ <https://doi.org/10.1016/j.suronc.2024.102124>

ImpediMed's SOZO platform, which integrates graphical visualizations and multi-frequency BIS, represents a significant advancement in point-of-care fluid analysis to diagnose and track disease progression.

SOZO L-Dex Analytics: Tracking Trends for Early Intervention

SOZO's L-Dex Analytics is an intuitive platform for healthcare professionals to track the trends of patients' L-Dex scores over time, offering a longitudinal view of fluid changes. With SOZO, clinicians can assign a

"ImpediMed has over 500 systems placed and reached 1 million patient tests in 2024, setting a solid footprint in the US healthcare landscape. This number will likely rise steadily with over 4 million breast cancer survivors in the US and the increase in both private and silent coverages by payors in the United States. Europe is ImpediMed's next focus region, with initial efforts in the United Kingdom and Ireland. With growing global adoption and strong clinical evidence, the SOZO platform is poised to become a standard of care tool for breast cancer patients in different geographies."

**– Dr. Isai Pratha Karthik Ph.D.
Senior Research Analyst**

baseline measurement prior to cancer treatment and monitor any fluctuations over time that may indicate subclinical onset of lymphedema.

The SOZO app, operated on a mobile tablet, is the user interface that controls the device's measurements. Stored in a MySOZO Cloud, all patient data can be accessed by clinicians across care locations. This online platform not only enhances accessibility but also integrates with patients' existing electronic health records, improving operational efficiency and supporting efficient patient management in large healthcare facilities.

SOZO's role-based access feature limits data visibility to healthcare professionals directly involved in patient care. ImpediMed assures its HITRUST-Certified, HIPAA-compliant cloud solution's data security and

privacy using end-to-end encryption in motion and at rest. Thus, ImpediMed's SOZO system provides advanced health monitoring without compromising security protocols, positioning it as a trusted technology for patients and healthcare providers.

SOZO Digital Health Platform: A Versatile Health Monitoring Solution

ImpediMed's BIS technology has proved its efficacy in a large-scale clinical trial, PREVENT, which included over 1,200 breast cancer patients from 10 healthcare facilities in the United States and Australia. The PREVENT trial, which began in 2014, longitudinally monitored patients for 3 years in different time frames, identifying patients for breast cancer-related lymphedema.

The study found that 92% of patients detected for lymphedema using ImpediMed's BIS technology at an early stage did not progress to the chronic state, thus preventing complex and painful treatments like decongestive physiotherapy, pneumatic pumps, and surgery. Research studies using the data from the PREVENT trial on the importance of a follow-up lymphatic screening program emphasize its implementation in clinical settings in the United States and Australia.⁴ These clinical validations and research activities reinforce SOZO's value, paving the way for its adoption as a standard preventive tool at oncology clinics worldwide.

⁴ <https://doi.org/10.1200/OP.23.00060>

FDA clearance, CE mark, and TGA approval for different applications underscore SOZO's global impact. This allows SOZO to reach healthcare providers and patients in North America, Europe, and Asia-Pacific countries like Australia and New Zealand. ImpediMed's key opinion leaders in these geographic markets and its internal oncology advisory board enable the company to evolve the solution with continuous feedback. These insights ensure SOZO applications remain user-focused and clinically effective, advancing the platform according to real-world clinician needs.

SOZO Vs Bioimpedance Analysis: Unique Advantages in Lymphedema Monitoring

ImpediMed's SOZO platform is unique in the bioimpedance technology landscape for its use of a proprietary bioimpedance spectroscopy solution that can measure 256 frequencies between 3 and 1,000 kHz. Conventional bioimpedance analysis (BIA) can measure only between 1 and 8 frequencies from 1 to 1,000 kHz.

While limited real-world clinical data exists to prove the efficacy of BIA in lymphedema, SOZO's BIS technology is FDA-cleared and has shown positive outcomes from many prospective clinical trials. This makes ImpediMed's SOZO Digital Health Platform not only an innovative technological advancement in early lymphedema detection but also a financially viable decision for healthcare providers.

Supported by unique CPT codes and expanding insurance coverage, the platform is gaining traction in the United States, Australia and New Zealand. ImpediMed has over 500 systems placed and reached its 1 million patient test mark in 2024, setting a solid footprint in the US healthcare landscape. This number will likely rise steadily with over 4 million breast cancer survivors and the increase in both private and silent coverages by payors in the United States.

Europe is ImpediMed's next focus region, with initial efforts in the United Kingdom and Ireland. With growing global adoption and strong clinical evidence, SOZO is poised to become a standard of care tool for breast cancer patients in different geographies.

Clinical Recognition and Advocacy: Shaping Breast Cancer-Related Lymphedema Care Guidelines

With positive clinical trial results, ImpediMed's BIS technology is establishing its leadership in this space.

Japan, the United States, Hong Kong, Canada, Italy, Denmark, Australia, Spain, and the United Kingdom are some regions involved in generating the Multinational Association of Supportive Care in Cancer (MASCC) guidelines. The guidelines published in *eClinicalMedicine*, a Lancet journal, emphasized the inclusion of BIS as a critical tool for the early detection of lymphedema in breast cancer patients.

BIS is a crucial modality included in the National Comprehensive Cancer Network® (NCCN®) Survivorship Guidelines. With its FDA clearance, SOZO became the only bioimpedance spectroscopy solution for the clinical assessment of lymphedema.

The National Accreditation Program for Breast Centers (NAPBC) is a quality program through the American College of Surgeons. The NAPBC Survivorship Standard reflects these evidence-based guidelines and specifies the use of BIS as part of a lymphedema prevention program that meets this accreditation standard.

Besides positioning the SOZO platform at the forefront in lymphedema management, ImpediMed continues to explore applications in further improving oncology survivorship through oncology body composition analysis and L-Dex for leg lymphedema. Clinical studies validating the SOZO platform's efficacy drive best practices in lymphedema care, adding credibility and supporting its integration into existing clinical practice.

These strategies and endorsements strengthen ImpediMed's position as a pioneer in digital health tools in early lymphedema detection and enable increased device adoption across diverse healthcare settings.

Conclusion

ImpediMed shows commitment to advancing healthcare through the SOZO Digital Health Platform, a BIS-based, non-invasive solution to address unmet needs in fluid analysis and point-of-care patient monitoring, particularly in lymphedema. By enabling early detection and proactive care, SOZO offers unique advantages over traditional methods, which often fail to distinguish between intracellular and extracellular tissue fluids. With multiple FDA clearances for applications like lymphedema, heart failure, malnutrition assessment, and body composition analysis, the SOZO platform has become a versatile tool catering to diverse clinical needs.

For its cutting-edge technology, clinical robustness, regulatory achievements, and strategic market expansion, ImpediMed is recognized with Frost & Sullivan's 2024 North American Technology Innovation Leadership Award in the point-of-care bioimpedance spectroscopy Industry.

What You Need to Know about the Technology Innovation Leadership Recognition

Frost & Sullivan's Technology Innovation Leadership Award recognizes the company that has introduced the best underlying technology for achieving remarkable product and customer success while driving future business value.

Best Practices Award Analysis

For the Technology Innovation 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

Business Impact

Financial Performance: Strong overall financial performance is achieved in terms of revenues, revenue growth, operating margin, and other key financial metrics

Customer Acquisition: Customer-facing processes support efficient and consistent new customer acquisition while enhancing customer retention

Operational Efficiency: Company staff performs assigned tasks productively, quickly, and to a high-quality standard

Growth Potential: Growth is fostered by a strong customer focus that strengthens the brand and reinforces customer loyalty

Human Capital: Commitment to quality and to customers characterize the company culture, which in turn enhances employee morale and retention

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)**

