



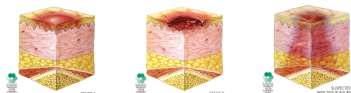
The SEM Scanner™:
Making Pressure Ulcer Prevention Possible

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Revision B

The SEM Scanner™: Making Pressure Ulcer Prevention Possible

BBI has developed the SEM Scanner™, a hand-held, portable, diagnostic device that detects early, pressure induced tissue damage – including pressure ulcers – up to 10 days before the damage becomes visible at the skin's surface.



Pressure ulcers are a common and critical medical problem. Also known as bedsores, pressure ulcers are localized injuries to the skin that result from pressure, shear, and/or friction.



Early detection, which has previously been an elusive goal for practitioners, can lead to targeted interventions, reduced severity, earlier recovery, and decreased hospital days.

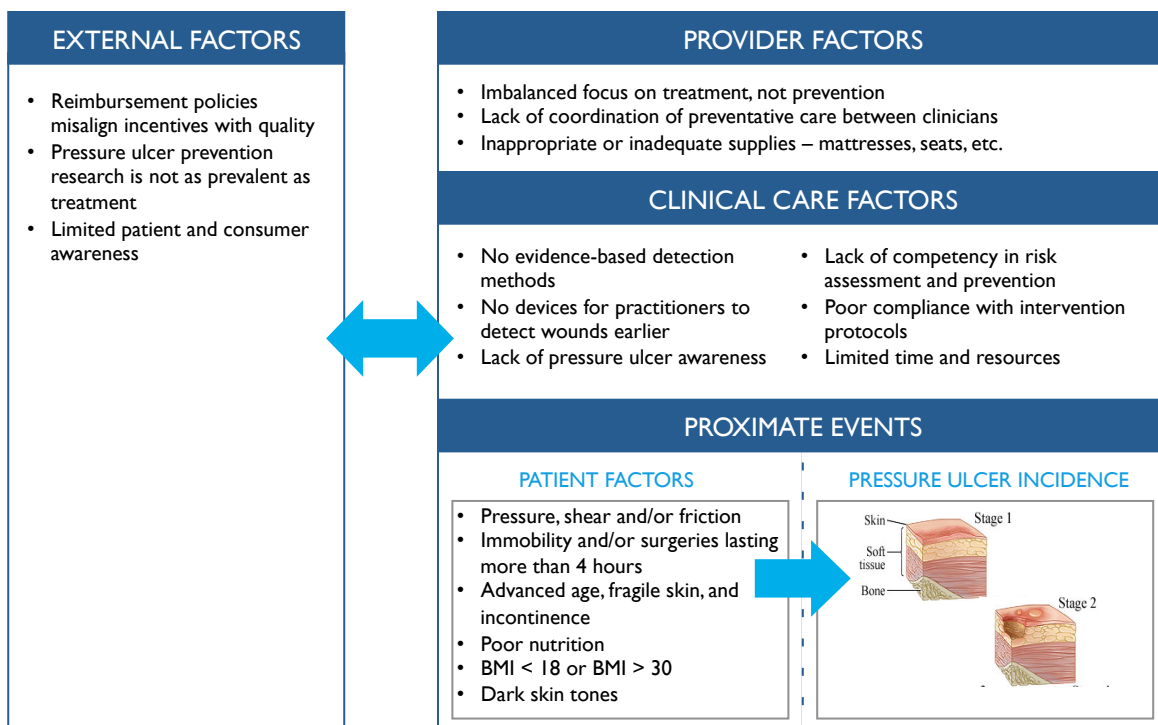
Pressure Ulcers are an Urgent, Clinical Problem

Across Europe, pressure ulcer prevalence ranges between 18.1% and 23% in nursing homes and hospitals, through it can be as high as 57% in critical care units. Hospital patients are often particularly vulnerable because of restricted mobility and poor health. Pain, disfigurement, and secondary complications leading to increased hospital stays ranging from 28 to 154 days are common.

In the UK alone, pressure ulcers cost the healthcare system €2.1 billion annually.*

Pressure Ulcer Incidence is the Result of Systemic Failure

Multiple interrelated factors contribute to the onset of a pressure ulcer.



The Standard of Care in Pressure Ulcer Prevention is Insufficient

The current standard of care in pressure ulcer prevention is based on risk assessment and periodic monitoring for changes with **visual assessment** of skin in areas where pressure ulcers are most likely to occur. There are well-accepted challenges of visual assessment:

1. Differentiating between epidermal irritation and sub-epidermal injury **lacks evidence-based** measures;
2. Surface discoloration associated with Stage I pressure ulcers is **less evident** in patients with dark skin tones;
3. Pressure ulcers often occur suddenly **without visual cues** appearing in time to prevent them;
4. It is particularly **difficult** to detect Deep Tissue Injury that develops according to the “Bottom-Up” pressure ulcer formation model.

By the time damage is visually evident, significant tissue damage has already occurred.

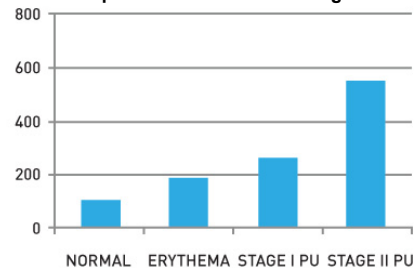
Subepidermal Moisture: A Clinical Breakthrough

Increased relative capacitance is a reflection of increased water in the skin and tissue known as **subepidermal moisture (SEM)**. SEM can serve as a **biophysical marker** associated with the inflammatory response to injury indicative of impending skin damage and pressure ulcer formation.

In clinical studies, SEM has been found to:

- Reliably differentiate between erythema and Stage 1 pressure ulcers, even in subjects with dark skin tones.
- Accurately identify local tissue edema related to inflammatory changes that occur up to 10 days before damage is visible on the skin's surface.

Relative Capacitance and Wound Progression



Bates-Jensen B, McCreath H, Kono A, et al. Sub-epidermal Moisture Predicts Erythema and Stage I Pressure Ulcers in Nursing Home Residents: A Pilot Study. *Journal of the American Geriatric Society*, 2007; 55:1199-1205.

The Most Innovative Technology in Pressure Ulcer Detection

The SEM Scanner™ uses sensor technology to measure inflammatory responses of the skin and tissue by emitting low amplitude signals from electrode structures placed on the subject's skin. The surface electrical capacitance value can be used to indicate the presence of subepidermal moisture.

The SEM Scanner™ was developed by one of the world's leading wound care experts.

The device is a low-cost solution that fits seamlessly into the current workflow of clinicians when used in conjunction with current skin assessment modalities. Advantages of the SEM Scanner™ include:

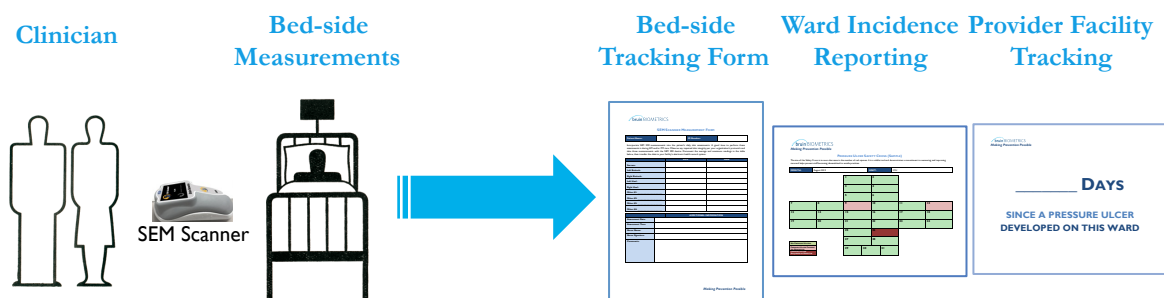
- Objective, **evidence-based** measurements
- Non-invasive, rapid results
- Relative **low cost** to other diagnostic modalities
- Applicability across all skin colors
- Clear risk assessment **documentation**
- Usable by nurse technicians and medical assistants
- Minimal technical skills for operation: 94% of nurses are able to accurately use the device with only **10 minutes of training**

The Missing Link in Effective Pressure Ulcer Management

The SEM Scanner™ makes pressure ulcer prevention possible with a comprehensive, **multidisciplinary** approach that **efficiently engages** clinical staff in **driving incidence down**.

BBI's comprehensive solution is composed of three core modules:

EDUCATION	EVIDENCE	EVALUATION
- On-site device training - Facility Awareness Posters - Patient Brochures	- SEM Scanner Measurements - SEM Scanner Analytics - Targeted Risk Assessment	- Maintain Compliance Rates - Measure Incidence Rates - Realize Cost and Risk Reduction



The SEM Scanner™ is Easily Adopted into Existing Workflows

STEP	ACTIVITIES
Project Kick-off	NEW: Conduct SEM Scanner Trainings & Involve Hospital Leadership - Conduct baseline pressure ulcer incidence rates - Assemble project champions and rollout plans
Conduct Holistic Risk Assessments & Skin Evaluations	NEW: Obtain and document SEM Scanner readings - Assess Patients for Pressure Ulcers Present on Admission - Perform Risk Assessment with Braden / Norton / Waterlow and Visual Inspection
Deploy Rapid Intervention & Prevention Methods	NEW: Refine at risk groups using SEM Scanner Analytics - Turn, float, lift, relieve pressure - Focus on patients in known risk groups
Manage the Patient Environment	NEW: Provide patient education on pressure ulcers & the SEM Scanner - Optimize Surfaces - Increase Mobility (Turn, Float, Lift, Relieve Pressure) - Manage Moisture & Incontinence - Ensure Proper Nutrition
Communicate Success & Be Rewarded	NEW: Instill risk management & get paid for quality - Publish assessments performed with bedside charts - Track pressure ulcer prevalence with the Unit Safety Cross

The SEM Scanner™ Product Fact Sheet

Device Description

The SEM Scanner™ is a hand-held, portable, diagnostic medical device that is able to interrogate the skin's underlying tissue to detect changes in sub-epidermal moisture (SEM), a biophysical marker that assesses the epidermal barrier function of the skin. The SEM Scanner™ is intended to provide information that a clinician can utilize as an adjunct to the current standard of care for the detection of pressure induced tissue damage, including pressure ulcers.

Device Function

The SEM Scanner detects and measures water below the stratum corneum (the uppermost layer of skin and the most influenced by outside surface moisture). While the stratum corneum of the epidermis is influenced by environmental moisture, the lower epidermal layers contain water generated from within the tissues and are not as affected by environmental moisture. The SEM Scanner employs a capacitive sensor that emits low amplitude RF signaling to measure the relative surface tissue capacitance. Results are displayed in SEM units. Higher values indicate increased water in the tissues and increased likelihood of tissue damage.

Cleaning, Disinfection, & Biocompatibility

To allow for sanitation, the electrode on the backside of the device is coated with a silicone conformal coating. This silicone coating protects the device from liquid, allowing for the use of disposable anti-bacterial wipes on the device for sanitation as needed.

Before using the SEM Scanner on a patient, the device should be wiped with CaviWipes™ disposable, cleaning and disinfectant towelettes for 2 minutes and allowed to air dry to ensure that infectious organisms are not transmitted from one patient to another. Other cleaning solutions or methods should not be used on the device, as these may damage the capacitance of the sensors or the flexible membrane at the bottom of the device.

The materials employed in the SEM Scanner comply with the applicable sections of ISO 10993; i.e., ISO 10993-5:2009 for cytotoxicity and ISO 10993-10:2010 for hypersensitivity and reactivity.

Product Specifications

FEATURE	DETAILS
Device Classification	Class IIa (CE Approved: CE 0120)
Rated Useful Life	At least 1 year, not to exceed 3 years
Applied Part	Type BF
Battery Life	3 hours (typical)
Method of Disinfection	Metrex CaviWipe™, Low Alcohol (17.20% isopropanol) Surface Disinfectants
Water Ingress Protection	IPX1
Duty Cycle	Continuous operation
Power Source	Internally powered equipment
SEM Value Range	0.5 to 7.0 SEM Value units
SEM Value Accuracy	+/- 0.4 SEM Value units
Storage	The SEM Scanner should only be stored at temperatures ranging from -4°F (-20°C) to 113°F (45°C) at 5% to 90% relative humidity (non-condensing).
Operating Conditions	The SEM Scanner should only be operated at temperatures ranging from 59°F (15°C) to 95°F (35°C) at 5% to 90% relative humidity (non-condensing).
Charging Mat AC Mains Voltage	100-240V



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