

## Device Description

The SEM Scanner™ is a hand-held, portable, tissue assessment device that interrogates the skin's underlying tissue to detect changes in sub-epidermal moisture (SEM), a biophysical marker associated with localised oedema in the inflammatory phase, and has been found to indicate tissue damage 3-10 days before visual skin damage or pressure ulcer formation.

The SEM Scanner™ is intended to provide information that a clinician can utilise as an adjunct to the standard of care for the detection of pressure induced tissue damage, including pressure ulcers and suspected deep tissue injury.



## Device Technology

The SEM Scanner™ uses the principles of bioimpedance technology. An integrated sensor emits a low frequency current to measure relative tissue capacitance. This measure of capacitance is translated into a calibrated SEM value. An increase in the presence of moisture (i.e., localised tissue oedema) is reflected as an increase in tissue capacitance and thereby a higher SEM value.

## Product Specifications

FEATURE	DETAILS
Device Classification	Class IIa (CE Approved: CE 0120)
Applied Part	Type BF
Battery Life	3 hours (typical)
Method of Disinfection	Surface Disinfectants - Low Alcohol (e.g., Metrex CaviWipes 17.2%) or Low Bleach (e.g., PDI Sani-Cloth 1:10 dilution)
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	100-240 V

## Technical Support & Customer Service

EU-based Customer Support team is available 8:30AM to 5:00PM Monday to Friday. This team is authorised to issue replacements of any non-functional SEM Scanner within 48 hours of service request.

## Warranty

Bruin Biometrics LLC (BBI) warrants the SEM Scanner against defects in materials and workmanship for three (3) years from the date of purchase from BBI or its subsidiaries. Under this warranty, BBI will provide for repair, or at its option, provide a replacement product for non-functioning devices. This warranty is given only to the original purchaser of the SEM Scanner™. BBI is not responsible for damage resulting from abuse or neglect.

\*Warranty terms may differ by geography. Please consult with your Product Specialist for details