

# SEM Scanner for pressure ulcer prevention

Medtech innovation briefing

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## Summary

- The **technology** described in this briefing is SEM Scanner. It is used for detecting changes in sub-epidermal moisture (SEM) to show pressure-induced tissue damage which can become a pressure ulcer.
- The **innovative aspects** are that SEM Scanner uses a non-visual tissue assessment and is the only technology available that assesses SEM for pressure ulcer risk.
- The **intended place in therapy** would be alongside current techniques for risk and visual assessment in people at risk of developing a pressure ulcer.
- The **main points from the evidence** summarised in this briefing are from 7 studies (3 prospective studies, 1 pilot study and 3 abstracts) involving 1,870 adults. They show that SEM Scanner can detect early signs of tissue damage and might do this earlier than visual assessment or ultrasound.
- **Key uncertainties** around the evidence or technology are that it is unclear if this technology should be used in all patients at risk of a pressure ulcer, or only those at high risk. Further evidence comparing SEM Scanner and other non-invasive tests would also be beneficial, especially from an NHS perspective.
- The **cost** of SEM Scanner is £5,835 per unit (exclusive of VAT). The **resource impact** would be greater than standard care. However, it could offer resource benefits by avoiding hospital-acquired pressure ulcers.

## The technology

SEM Scanner (Bruin Biometrics) is a hand-held, skin tissue assessment device that detects early, pressure-induced tissue damage. This includes pressure ulcers and deep tissue injuries. Published evidence suggests that damage to underlying soft tissues can happen some days before tissue damage shows at the epidermis ([Moore et al. 2017](#)). Tissue inflammation is the first response to damage and causes increased dilation and permeability of surrounding blood vessels. This leads to leakage of plasma and fluid, creating a layer of moisture under the skin called sub-epidermal moisture (SEM). As damage increases, so does the level of SEM. SEM Scanner measures SEM and might give an early sign of tissue damage and its severity. The technology consists of 2 concentric coplanar electrodes and an integrated pressure sensor to measure SEM around an area. In-built software works out a 'delta' value from these measurements and shows the information on a screen. The clinician compares the delta value to a threshold to see if the tissue is likely to become a pressure ulcer.

## *Innovations*

The company claims that SEM Scanner can be used to identify areas of tissue damage at risk of becoming a pressure ulcer before visible clues are noticeable and across all skin tones.

## *Current care pathway*

NICE's guideline on [pressure ulcers](#) recommends that a documented risk assessment for pressure ulcers should be done in at-risk adults. It recommends using a validated scale to support clinical judgement, and that risk is reassessed if the patient's clinical status changes.

The guideline recommends strategies to prevent pressure ulcers, including regular patient repositioning, foam mattresses and pressure redistribution cushions.

## *Population, setting and intended user*

SEM Scanner can be used in any care setting where people are at risk of developing pressure ulcers. This includes acute facilities, community hospitals, hospices, care homes and community care settings.

SEM Scanner can be used by any trained healthcare professional. The company provides all training. The company has collected user feedback from nurses showing that they found the device simple to use. The company claims that SEM Scanner is used at the same time as usual care

procedures. This means that there is a limited effect on the patient and nursing time. The device must be cleaned for each patient.

The company advises that SEM Scanner is being used in around 10 NHS facilities in the UK.

## Costs

### Technology costs

The cost per scanned patient for an episode of care of 5.6 days (average inpatient length of stay) is approximately £1.54.

Description	Cost	Additional information
SEM Scanner unit	£5,835 (excluding VAT)	Device is reusable. There is a 3-year warranty. The company recommends that each SEM Scanner should have annual testing to check performance. This is a short checklist done by the clinical operator at no extra cost.

### Costs of standard care

There was no estimate identified for the overall cost of existing standard care for detecting pressure ulcers. However, the cost of treating a pressure ulcer increases with severity ([Dealey et al. 2012](#)). The average cost of treating pressure ulcers in the NHS is:

- £1,214 (category I)
- £5,241 (category II)
- £9,041 (category III)
- £14,108 (category IV).

NICE's guideline on [pressure ulcers](#) estimated costs for repositioning based on the staff time involved and depending on ulcer category.

**Table 1 Treatment cost per patient per day and treatment cost per patient per episode of care, by category of ulcer and by health state (from NICE's guideline on [pressure ulcers](#))**

	Normal healing	With critical colonisation	With cellulitis	With osteomyelitis
<b>Category 1</b>				
Cost/day (£)	42.73	-	-	-
Cost/episode (£)*	1213.58	-	-	-
Probability**	100%	-	-	-
<b>Category 2</b>				
Cost/day (£)	46.90	62.24	138.05	374.42
Cost/episode (£)	4398.79	4834.46	5779.32	35,849.90
Probability	90%	5%	2.5%	2.5%
<b>Category 3</b>				
Cost/day (£)	56.77	70.70	372.26	374.42
Cost/episode (£)	7232.93	7727.82	10,955.51	38,684.04
Probability	80%	10%	5%	5%
<b>Category 4</b>				
Cost/day (£)	56.77	70.70	372.26	374.42
Cost/episode (£)	8782.85	70.70	372.26	40,233.96
Probability	60%	10%	10%	15%
* An episode is the length of treatment needed to heal an ulcer (average 5 to 8 days).				
** Probability is the proportion of patients with a particular category of ulcer expected to be in a particular health state.				

## Resource consequences

Using SEM Scanner would represent an additional cost compared with standard care. However, this could be offset if using the SEM Scanner allowed earlier detection of tissue damage. This could allow preventive interventions to be used earlier to resolve damage and avoid pressure ulcer development.

## Regulatory information

SEM Scanner is a CE-marked class IIa medical device.

## Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

Category I pressure ulcers are identified by visual assessment of a non-blanching area of redness. In people with darker skin tones, it may not be possible to identify pressure ulcers by visual assessment. SEM Scanner assesses moisture levels and avoids subjective tests of skin colouration so may allow for earlier detection of tissue damage in people with dark skin tones.

## Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the [interim process and methods statement](#). This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting [mibs@nice.org.uk](mailto:mibs@nice.org.uk).

### *Published evidence*

There are 7 studies summarised in this briefing, involving 1,870 people.

The studies included in this briefing are 1 large prospective controlled study (284 people), 1 prospective cohort study of 15 people, 1 prospective observational study of 47 people and 1 pilot study on the reliability of SEM Scanner results.

Three abstracts (1,493 people) are also included. There are several published conference posters and abstracts on SEM Scanner that have not been included in this MIB because they give limited additional information. These include an abstract that reports an economic evaluation based on the pressure ulcer prevention pathway described in NICE's guideline on [pressure ulcers](#). The results of

this state that in the first year of using SEM Scanner cost savings of up to £56 per patient are achievable (based on a 210-bed facility).

Table 2 summarises the clinical evidence as well as its strengths and limitations.

### *Overall assessment of the evidence*

The studies included in this briefing suggest that SEM Scanner is a reliable method of tissue damage detection. It might be able to identify areas of damage at risk of developing pressure ulcers earlier than other methods (visual assessment and ultrasound). However, only 1 study compares SEM Scanner with ultrasound. It would be desirable to have further evidence validating SEM Scanner results against other non-invasive tests.

None of the studies were done in the UK which may limit the generalisability of the evidence to the NHS. The company note that data collected in the UK are due to be published in an upcoming study. One pilot study recruited healthy people and the SEM Scanner was operated by non-healthcare professionals. Despite these limitations, the standard care comparators described in the studies are similar to those used in the NHS. The pilot study provides useful outcomes relating to the device rather than the patients.

### **Table 2 Summary of selected studies**

<u>Raizman et al. (2018)</u>	
Study size, design and location	Prospective controlled study of 284 hospital patients at risk of hospital-acquired pressure ulcers. Location: Canada.
Intervention and comparator(s)	SEM Scanner and standard of care (assessment and interventions). The study was done in 2 phases, in both phases all patients had SEM Scanner and standard of care. In phase 1 only standard of care was used to determine any intervention, in phase 2 both standard of care and SEM Scanner were used to determine any intervention.
Key outcomes	Phase 1 (standard of care) 12/89 (13.5%) people developed pressure ulcers (4 stage I ulcers, 6 stage II, 1 stage III and 1 deep tissue injury). Phase 2 (standard of care and SEM Scanner) 2/195 (1%) people developed pressure ulcers (1 stage I and 1 stage II). This represented a 93% reduction in hospital-acquired pressure ulcers compared with phase 1.

Strengths and limitations	<p>The authors note that the people included in phase 2 of the study were at higher risk of developing pressure ulcers (more incontinent, less mobile, longer length of stay) compared with people included in phase 1.</p> <p>This study was funded by the company.</p>
<u>Gefen and Gershon (2018)</u>	
Study size, design and location	<p>Observational, prospective cohort study of 15 patients at risk of developing a pressure ulcer.</p> <p>Location: US.</p>
Intervention and comparator(s)	SEM Scanner and standard of care (including ultrasound) was used daily during hospital stay. SEM Scanner was used at 6 sites on the sacrum and 4 on the heels of each patient.
Key outcomes	There was consistent agreement between SEM Scanner and ultrasound for suspected deep tissue injuries. In 1 patient SEM Scanner readings indicated ulcer formation 2 days before any visible signs were present and 3 days before detection by ultrasound.
Strengths and limitations	<p>The mean age of people included in this study was 74±10.9 years, this is representative of elderly patients at risk of pressure ulcers.</p> <p>The authors note that 4 people included in the study had dark skin tone (Fitzpatrick scale of III and above) but did not perform separate subgroup analyses.</p> <p>This study was funded by the company.</p>
<u>O'Brien et al. (2018)</u>	
Study size, design and location	<p>Descriptive, prospective, observational study of 47 patients in an acute care setting.</p> <p>Location: Ireland.</p>
Intervention and comparator(s)	<p>SEM Scanner.</p> <p>Nurse visual skin assessment.</p>

Key outcomes	<p>There were 19 people who developed pressure ulcers, 100% of which had sustained elevated SEM.</p> <p>Compared with nurse visual skin assessment, SEM Scanner sensitivity was 100% and specificity was 83%.</p> <p>The mean number of days to detect tissue damage was 1.5 days (<math>\pm 1.4</math>; max 7, min 1) for SEM Scanner and 5.5 days (<math>\pm 2.5</math>; max 11, min 2) for nurse visual skin assessment.</p>
Strengths and limitations	<p>The people included in this study are likely to be considered at high risk of pressure ulcers because they were admitted to an acute care setting and had an average age of 74.7 years.</p> <p>Although the study did not take place in the NHS, the description of methods used for nurse visual assessment are representative of those used in the NHS.</p>
<u>Clendenin et al. (2015)</u>	
Study size, design and location	<p>Pilot, non-significant risk study of 31 healthy people.</p> <p>Location: US.</p>
Intervention and comparator(s)	<p>SEM Scanner.</p> <p>There were 3 operators using 3 SEM Scanner devices to collect readings from 4 anatomical sites.</p>
Key outcomes	<p>Inter-operator and inter-device agreement was good (mean difference ranged from -0.01 to 0.11) and inter-operator and inter-device reliability was high (over 0.8).</p>
Strengths and limitations	<p>People included in this study were healthy (not at risk of developing pressure ulcer) and young (29.8 years) and are not representative of the population SEM Scanner is likely to be used in. The operators using the device had no or minimal clinical training.</p> <p>This study was funded by the company.</p>
<u>Hancock and Lawrance (2019)</u>	
Study size, design and location	<p>Real world evidence results (abstract/poster) of 1129 patients.</p> <p>Location: 4 countries: UK, Canada, Spain and Belgium.</p>



Intervention and comparator(s)	SEM Scanner was used to measure changes in sub-epidermal moisture at 3 anatomical sites.
Key outcomes	For 983 patients at 13 acute care sites, average reduction in hospital-acquired pressure ulcer was 92%. 10 of the 13 sites reported zero pressure ulcers.
Strengths and limitations	This study includes data collected in the NHS. The results of this study are presented in abstract and poster format and therefore detail is very limited. This publication reports data from an ongoing real world evidence study. This study does not have a planned end date, but statistical analysis of the data collected is done every 3 months.
<u>Okonkwo et al. (2017)</u>	
Study size, design and location	Prospective longitudinal study (abstract/poster) of 189 patients. Location: UK and US.
Intervention and comparator(s)	SEM Scanner. Visual skin assessment.
Key outcomes	Compared with visual skin assessment (done by skin or wound care specialists) SEM Scanner detected damaged tissue on average (mean) 4.74 days earlier (standard deviation 2.39 days) across all anatomical sites. On the sacrum SEM Scanner detected damaged tissue on average (mean) 4.69 days earlier (standard deviation 2.59 days) than visual skin assessment, on the left heel SEM Scanner detected damaged tissue on average (mean) 5.06 days earlier (standard deviation 2.33 days) than visual skin assessment and on the right heel SEM Scanner detected damaged tissue on average (mean) 4.33 days earlier (standard deviation 2.39 days) than visual skin assessment.
Strengths and limitations	This study includes data collected in the NHS. The results of this study are presented in abstract and poster format and therefore detail is very limited. It is not clear how significance, sensitivity and specificity were calculated. The abstract reports data from the ongoing trial NCT02701101.
<u>Okonkwo et al. (2018)</u>	
Study size, design and location	Non-blinded case-control study (abstract/poster) of 175 patients. Location: US.

Intervention and comparator(s)	SEM Scanner readings were taken from patients with pressure injuries (66 sacral injuries and 59 heel injuries) and from 50 patients without pressure injuries or ulcers.
Key outcomes	The authors state that the difference between the cohorts was statistically significant (not reported) and that sensitivity and specificity exceeded 80% for both sacrum and heels.
Strengths and limitations	The results of this study are presented in abstract and poster format and therefore detail is very limited. It is not clear how significance, sensitivity and specificity were calculated. The abstract reports data from the ongoing trial NCT01965444.
Definitions: inter-operator and inter-device reliability: how much of the observed variation is because of between-subject variation compared with between-operator or between-device variation.	

### *Recent and ongoing studies*

- [Evaluation of the SEM Scanner 200 for the detection of early pressure ulcers: a multi-site longitudinal study](#). ClinicalTrials.gov identifier: NCT02701101. Status: completed, no results posted. Indication: pressure ulcers. Devices: SEM Scanner.
- [An investigational, non-significant risk study to collect data needed to analyse readings given by the SEM Scanner Point of Care 200 series \(SEM POC 200\) and its ability to detect sub-epidermal moisture](#). ClinicalTrials.gov identifier: NCT01965444. Status: completed (October 2013). Indication: pressure ulcers. Devices: SEM Scanner.

### **Specialist commentator comments**

Comments on this technology were invited from clinical specialists working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

There were 2 specialists familiar with the technology and 1 had used it before.

### *Level of innovation*

All specialists agreed that SEM Scanner was an innovative device and that the method of measuring SEM to assess early skin damage was a novel concept.

### *Potential patient impact*

All specialists agreed that if SEM Scanner can be used to detect early signs of skin damage, pressure ulcer prevention interventions can begin earlier. This will reduce the risk of pressure ulcer formation and the extent of tissue damage.

All noted that any patient at risk of developing pressure ulcers could benefit from use of SEM Scanner. One specialist commented that people in intensive care, people undergoing and recovering from high-risk surgery and people with diabetes are at high risk of developing pressure ulcers. Another specialist noted that SEM Scanner may offer additional benefits to people with dark skin tones as it does not rely on the visual signs of damage, which are more difficult to identify than in people with light skin tones.

### *Potential system impact*

All specialists agreed use of SEM Scanner could reduce the incidence of pressure ulcers through earlier introduction of preventive care. This would reduce the length of hospital stay, release staff productivity and costs and improve patient outcomes.

One specialist noted that the SEM Scanner provides an objective measurement of tissue damage compared with subjective visual assessment. This specialist also noted that visual assessment often confuses early tissue damage with incontinence-associated dermatitis (which needs different treatment). Use of SEM Scanner might help differentiate between tissue damage and incontinence-associated dermatitis.

All specialists agreed that initial and acquisition costs of SEM Scanner will be higher than current standard care. However, 2 specialists noted the potential for substantial downstream savings for the NHS. One specialist had done research that showed SEM Scanner can reduce costs because of released nursing time in hospital and community settings, reduced dressings and antibiotic costs, improved revenue loss in secondary care settings from lost bed days, reduced community nurse visits and a reduced need for expensive pressure relieving equipment over time.

All specialists agreed that training in how to use SEM Scanner was essential for NHS staff. One specialist felt only a brief training session would be needed. Another felt that on-site support would be needed at first, and that regular education and support sessions would be needed to ensure proper use.

## Specialist commentators

The following clinicians contributed to this briefing:

- Samantha Holloway, reader, Cardiff University, no conflicts of interest.
- Professor Michael Clark, Welsh Wound Innovation Centre, has provided consultancy services to several companies about wound management but not the manufacturer of this technology.
- Glenn Smith, nurse prescriber, St Helens Medical Centre, no conflicts declared.

## Development of this briefing

This briefing was developed by NICE. The [interim process and methods statement](#) sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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