NICE National Institute for Health and Care Excellence

NICE guidance

SEM Scanner 200 for preventing pressure ulcers

HealthTech guidance
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www.nice.org.uk/guidance/htg556

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces MIB182 and MTG51.

1 Recommendations

More research is needed

1.1 SEM Scanner 200, with visual skin assessment, shows promise for preventing pressure ulcers. However, there is not enough good-quality evidence to support the case for routine adoption in the NHS.

What research is needed

1.2 A randomised controlled trial is recommended to address uncertainties about the clinical benefits of using the scanner compared with standard risk assessment. This should assess:

- using the scanner plus visual skin assessment compared with visual skin assessment alone for identifying pressure ulcer risk
- whether changes in clinical decision making from using the scanner reduce pressure ulcer incidence
- the clinical benefits and resource impact of using the scanner in different care settings
- the clinical benefits for different skin tones
- how well the scanner works across populations with a range of comorbidities
- patient-related outcome measures.

Why the committee made these recommendations

Inflammation occurs when tissue is damaged. Increased moisture under the skin is thought to reflect inflammation and may mean an increased risk of pressure ulcer formation. SEM

Scanner 200 is a device that measures differences in moisture under the skin of the heels and the area around the base of the spine (sacrum). Using SEM Scanner 200 could mean that measures to prevent pressure ulcers can be taken before visible or tactile signs of tissue damage develop.

SEM Scanner 200 is used with standard care in studies looking at its effect on pressure ulcer incidence. This makes it difficult to distinguish between the effect of SEM Scanner 200 alone and that of increased awareness of preventing pressure ulcers. Also, standard care is poorly described in the studies. More evidence is needed on how using SEM Scanner 200 affects clinical decision making and whether this benefits patients.

2 The technology

Technology

2.1 SEM Scanner 200 is a portable, hand-held skin assessment device. It detects an increased risk of pressure ulcers developing by identifying early pressure-induced tissue damage at the heel and sacrum. Published evidence suggests that damage to underlying soft tissues can happen 3 days to 10 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 subepidermal moisture. As damage increases, so does the level of subepidermal moisture. SEM Scanner 200 measures variation in subepidermal moisture across a small area. Healthy tissue has little variation, whereas inflamed or dead tissue has more variation. The variation is reported as a 'delta' value, with healthy tissue giving a low numerical reading and inflamed or dead tissue giving a higher numerical reading. A subepidermal moisture delta value of 0.6 or more is thought to represent clinically significant levels of tissue damage.

Innovative aspects

2.2 SEM Scanner 200 uses a novel method of identifying subepidermal moisture in the tissue of the heels and sacrum. SEM Scanner is the only CE marked device that assesses the anatomical risk of pressure ulcer formation before pressure-induced damage happens.

Intended use

2.3 SEM Scanner 200 is intended to be used on the heels and sacrum of people who are at risk or at high risk of developing a pressure ulcer. Risk categories are defined in NICE's guideline on pressure ulcers: prevention and management.

2.4 SEM Scanner 200 is used by healthcare professionals on hospital admission, during the patient's stay and on discharge. Users need training to use the device and interpret the results. For information on how to use the technology see the SEM Scanner 200 information for use document.

Costs

2.5 SEM Scanner 200 costs £5,835 per device.

For more details, see the website for SEM Scanner 200.

3 Evidence

Clinical evidence

The main clinical evidence comprises 7 studies

3.1 The evidence assessed by the external assessment centre (EAC) included 7 studies; 3 were full text peer reviewed publications (Gefan et al. 2018; O'Brian et al. 2018; Raizman et al. 2018) and 4 were abstracts (Hancock and Lawrance 2018; Okonkwo et al. 2017; Okonkwo et al. 2018; O'Keefe et al. 2019). The studies included 2,213 patients at risk of developing pressure ulcers in secondary care. Two of the studies were before-and-after comparative studies, the remaining 5 studies were single-arm observational studies. For full details of the clinical evidence, see section 3 of the assessment report.

The 2 before-and-after studies are relevant to the decision problem and report pressure ulcer incidence

3.2 Both studies compared pressure ulcer incidence before and after using SEM Scanner 200 as a risk assessment tool to be used alongside standard care. Both studies reported reduced pressure ulcer incidence after using SEM Scanner 200. One study reported that pressure ulcer incidence reduced from 2.17% to 0.95% (Hancock and Lawrance 2019) and the other reported a reduction from 13% to 1% (Raizman et al. 2018). Neither study included a detailed description of the protocol used for assessment and management in the standard care arm. Also, there was heterogeneity in the reporting of pressure ulcer incidence, with only 1 study including stage 1 pressure ulcers. These limitations made it difficult to be certain about how well SEM Scanner 200 works when used as the only test.

Diagnostic accuracy is reported in 3 of the observational studies but they use an inappropriate reference standard

3.3 All 3 studies reporting the diagnostic accuracy of SEM Scanner 200 used visual skin assessment (a standard clinical measure for detecting pressure ulcers based on visual signs of skin deterioration) as a reference standard. SEM Scanner 200 is intended to detect subepidermal moisture changes before visible signs of pressure ulcers are present and is not a diagnostic test for pressure ulcers. The EAC noted that using visual skin assessment for measuring the diagnostic accuracy of SEM Scanner 200 may underestimate its specificity. This is because non-visible damage correctly identified by SEM Scanner 200 would be recorded as a false positive.

In 3 of the observational studies SEM Scanner 200 detects subepidermal moisture changes earlier than visual skin assessment

3.4 All 3 studies reported that subepidermal moisture changes indicating pressure-induced damage were detected earlier than visible signs of skin deterioration reported by visual skin assessment. The studies provided no additional information about the effect of these findings on clinical management or on the clinical benefits of earlier detection.

Cost evidence

The company's model compares the costs of using SEM Scanner 200 plus standard care with using standard care alone

3.5 The company submitted 10 studies relevant to the economic assessment of SEM Scanner 200. The EAC reviewed the literature and found 1 study (Burns et al. unpublished) that it considered to be relevant to the decision problem. The company used a decision tree, based on standard care as defined by NICE's guideline on pressure ulcers: prevention and management, to assess the effect of

SEM Scanner 200 on the cost of preventing pressure ulcers, over a 1-year time horizon. In this model, the heels and sacrum of each patient were assessed and categorised as low risk, at risk or at high risk. Patients assessed to be at risk or at high risk had repositioning every 6 hours or 4 hours, respectively. The key clinical parameters were:

- an assumed pressure ulcer incidence of 4.09% in the at-risk group
- a pressure ulcer incidence of 1.637% in the standard care arm and 0.509% in the SEM Scanner 200 arm (a 68% reduction).

  These parameters were from the unpublished Hancock and Lawrance (2018) before-and-after study.

3.6 The company used a cost of £18 per hour for band 5 nursing time as stated in NICE's costing statement for pressure ulcers published in 2014. The EAC considered this source to be outdated and updated the cost to £37 per hour (Curtis and Burns 2018). The EAC also added a 3.5% depreciation rate for the device, which had not been included in the company submission.

The updated company model results in cost savings of £59 per person from reduced pressure ulcer incidence

3.7 The updated company model resulted in cost savings of £59 per patient. Sensitivity analyses applied to the assumed percentage pressure ulcer reduction found SEM Scanner 200 to be cost-neutral at a 28% reduction in pressure ulcer incidence. The model included the costs of 1 scanner per 9 beds for 210 beds. The model showed that the increased costs for preventive measures were offset by cost savings related to the reduced need for pressure ulcer treatment. Results were reported to be robust to sensitivity analyses, however, the results were not presented. The EAC noted there was uncertainty around estimates from an unpublished study used to populate the company model.

The EAC's model shows that SEM Scanner 200 is cost incurring by £45 per person

3.8 The EAC used its preferred assumptions to calculate a pressure ulcer incidence of 8.05%. These assumptions were the predicted number of positive stage 1 pressure ulcers, the prevalence of pressure ulcers and the diagnostic accuracy of SEM Scanner 200 plus visual skin assessment. The model assumed that 50% of stage 1 pressure ulcers would progress to stage 2 without diagnosis and treatment and that 36.5% would do so with diagnosis and treatment. The EAC acknowledged that this model did not adequately capture any potential benefit of earlier identification of pressure-induced damage. The EAC's base case resulted in SEM Scanner 200 plus visual skin assessment being cost incurring by £45 per person when compared with visual skin assessment alone.

The cost of SEM Scanner 200 increases if healthcare assistants do the repositioning

3.9 The EAC's base case assumed that 2 band 5 nurses were needed for repositioning. Experts advised the committee that repositioning can be done by other healthcare professionals. The EAC's sensitivity analyses reported that reducing the cost of repositioning had a considerable effect on the cost of SEM Scanner 200 and standard care. If repositioning was done by 1 nurse and 1 healthcare assistant or 2 healthcare assistants, SEM Scanner 200 would cost an additional £38 or £30 per person respectively, compared with standard care. The costs used in these analyses reflect a hospital setting.

4 Committee discussion

Clinical-effectiveness overview

SEM Scanner 200 can reduce pressure ulcer incidence but there are considerable uncertainties

4.1 The committee noted that the published evidence suggested that using SEM Scanner 200 could result in statistically significant reductions in pressure ulcer incidence. But the clinical experts explained that the size of this benefit was greater than they would expect from their own clinical experience. One clinical expert commented that using SEM Scanner 200 had substantially reduced pressure ulcer incidence in their hospice, but not to the same degree as reported in the studies. The committee also considered that it was unclear from the studies whether reduced pressure ulcer incidence was because of:

- the scanner results guiding care management decisions or
- increased attention to pressure ulcer prevention from greater patient engagement by healthcare professionals.

It concluded that the evidence was unclear about whether changes in clinical decision making from using SEM Scanner 200 reduce pressure ulcer incidence.

Research is needed on whether using preventive measures earlier affects pressure ulcer incidence

4.2 The clinical experts considered that SEM Scanner 200 provides information that could affect decisions about when to intensify preventive measures. These measures include improving the specification of the foam mattress, doing more regular repositioning of the patient, or other pressure-relieving measures. One clinical expert said that using SEM Scanner 200 allows nurses to intensify

preventive measures earlier than when using clinical judgement alone. The committee acknowledged that using SEM Scanner 200 may result in preventive measures being introduced or intensified earlier. It noted that there was no evidence to show the effect of earlier interventions on pressure ulcer incidence. The committee concluded that research is needed to assess the effect of introducing preventive measures earlier on pressure ulcer incidence.

SEM Scanner 200 assesses the risk of pressure ulcers developing

4.3 The company explained that SEM Scanner is not intended to diagnose pressure ulcers but to diagnose the risk of pressure ulcers developing. Correspondence with the Medicines and Healthcare products Regulatory Agency confirmed that SEM Scanner 200 is used to identify patients at an increased clinical risk of pressure ulcers and should be seen as a diagnostic risk assessment tool.

Further research on using SEM Scanner 200 for pressure ulcer risk assessment is needed

4.4 The company acknowledged there is no appropriate reference standard for measuring subepidermal moisture and that this limited the assessment of diagnostic accuracy. The clinical experts also said that using visual skin assessment as a reference standard would confound the results. This was because SEM Scanner 200 is designed to assess the risk of pressure ulcers developing before any visible signs, such as redness, appear whereas visual skin assessment records visible pressure injuries. The committee concluded that further research is needed on the use of SEM Scanner 200 plus visual skin assessment compared with visual skin assessment alone for pressure ulcer risk assessment.

The evidence does not address how SEM Scanner 200 performs across different populations

4.5 The clinical experts explained that part of the visual skin assessment is to identify

redness, which may not be visible in people with dark skin. Using a non-visual method such as SEM Scanner 200 for people with dark skin may offer advantages and could address an unmet need. The committee also considered that comorbidities and conditions associated with skin damage or swelling may influence subepidermal moisture levels and affect the clinical accuracy of SEM Scanner 200 to identify pressure ulcer risk. The committee concluded that further research should be done to assess the efficacy of SEM Scanner 200 in preventing pressure ulcers for patients with dark skin and for those with comorbidities.

Relevance to the NHS

There is NHS interest in SEM Scanner 200 because community and hospital-acquired pressure ulcers remain a significant problem

4.6 The NHS safety thermometer report states that from April 2014 to March 2015 approximately 25,000 patients developed new pressure ulcers. The proportion of people with a stage 2 to 4 pressure ulcer in the UK is estimated to be 5%. The clinical experts explained that, in view of the continued clinical challenges of preventing pressure ulcers in the community and in hospitals, there is increasing interest in using SEM Scanner 200 across the NHS.

Using devices for measuring subepidermal moisture is referenced in global clinical practice guidelines

4.7 The committee noted the recently updated US National Pressure Ulcer Advisory Panel (NPUAP), European Pressure Ulcer Advisory Panel (EPUAP) and Pan Pacific Pressure Injury Alliance (PPPIA) global clinical practice guideline in the treatment and prevention of pressure ulcers. This states that healthcare professionals should consider using a subepidermal or oedema measurement device in addition to routine visual skin assessment to assess the clinical risk of pressure ulcers. The committee also noted that, based on evidence, the guideline only proposed a weak positive recommendation for these devices when assessing risk in people

with dark skin.

NHS considerations overview

SEM Scanner 200 provides an objective measure of pressure ulcer risk, which would be an advantage

4.8 SEM Scanner 200 provides an objective measure of variations in subepidermal moisture. Current risk assessment involves the combined use of validated scales and clinical judgement. The clinical experts explained that the availability of an accurate and objective measure of risk would be an advantage, particularly for training staff in pressure ulcer risk assessment.

The rationale for using SEM Scanner 200 needs further clinical testing

4.9 The company explained that the SEM Scanner 200 delta value reflects a measure of relative difference between the subepidermal moisture recorded over the bony prominences and surrounding tissues of the heels or sacrum. The greater the variation in subepidermal moisture (and therefore the delta value), the greater the likelihood of underlying localised inflammation. Although the committee accepted the rationale for this hypothesis, it considered that patients may have oedema from other causes and the hypothesis needs to be further tested in well-constructed clinical studies. It further noted that the interrater reliability of the device was reported by the company to be 83%. The committee concluded that further research would help to understand the reproducibility of the result.

SEM Scanner 200 needs cleaning between patients

4.10 The SEM Scanner 200 is classified as having a medium risk of cross-contamination. The company explained that cleaning has been shown to be effective in addressing the risk of cross-contamination. The clinical experts advised that cleansing wipes are used to clean SEM Scanner 200 and this is in

keeping with NHS infection and control procedures. The company stated that there have been no reported cross-contamination adverse events with SEM Scanner 200.

SEM Scanner 200 has a battery life of 3 hours and a lifespan of over 3 years

4.11 The company explained that SEM Scanner 200 has a 3-year warranty but the battery life of the device may be longer than 3 years. The clinical experts advised that 3-hour battery capacity is adequate because SEM Scanner 200 is left on a charging station when not being used.

Training

The company provides free training

4.12 The clinical experts explained that the company provides free training in the use of SEM Scanner 200. The device is easy to use, and the clinical experts described that staff became comfortable and familiar with its use within 2 weeks or so.

Cost modelling overview

Uncertainties about the clinical benefit of SEM Scanner 200 result in uncertain cost effectiveness

4.13 The committee noted that the key cost drivers, the reduction in pressure ulcer incidence and specificity of the device, were subject to considerable uncertainty. It concluded that more research was needed to establish the clinical and cost benefits of SEM Scanner 200.

Further research

Further research is needed to address the uncertainty about the efficacy of SEM Scanner 200 in reducing pressure ulcer incidence

4.14 The committee concluded that further research was needed to address uncertainties about the efficacy of SEM Scanner 200 in reducing pressure ulcer incidence. This research should investigate using SEM Scanner with visual skin assessment compared with standard risk assessment alone in judging the risk of pressure ulcers. It should control for the effect of increased engagement with healthcare professionals on pressure ulcer incidence. Pressure ulcers occur in acute and community care so research should address the effect of adopting the scanner in each of these settings independently. Additional research should specifically address the possible benefit of using the scanner in people with dark skin and those with a range of comorbidities known to influence fluid levels in the subepidermis and underlying tissues. Clinical studies using the scanner should be clear about how it affects clinical decision making; what effect it has on clinical outcomes and patient-related outcome measures; and the cost implications of its use.

5 Committee members and NICE project team

Committee members

This topic was considered by NICE's medical technology advisory committee which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of the medical technology advisory committee, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

Each medical technologies guidance topic is assigned to a team consisting of 1 or more technical analysts (who act as technical leads for the topic), a technical adviser and a project manager.

Rebecca Owens
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Update information

Minor changes since publication

December 2025: Medical technologies guidance 51 has been migrated to HealthTech guidance 556. The recommendations and accompanying content remain unchanged.

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