NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance scope

SEM Scanner 200 for pressure ulcer prevention

1 Technology

1.1 Description of the technology

SEM Scanner 200 (BBI Europe Ltd) is a portable, hand-held, skin tissue assessment device that detects increased risk of pressure ulcer development by identifying early, pressure-induced tissue damage at the heel and sacrum. This includes pressure ulcers and deep tissue injuries. Published evidence suggests that damage to underlying soft tissues can happen 3-10 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 moisture under the skin called sub-epidermal moisture (SEM). As damage increases, so does the level of SEM. SEM Scanner measures SEM and intends to give an early sign of tissue damage and its severity.

The technology consists of a single electrode sensor and an integrated pressure sensor. The SEM Scanner 200 assesses biocapacitance, a measure of the fluid content in the skin tissue using electrical capacitance, and displays a correlating SEM value between 0.3 and 3.9. To assess an area the SEM scanner 200 should be held against the tissue until an SEM value is reported, the pressure sensor guides the clinician to ensure the appropriate pressure is applied for an accurate reading. A minimum of 3 SEM measures are needed before the SEM scanner can report the SEM 'delta', the calculated difference between the minimum and maximum SEM values in the set of readings taken, of any given anatomical location. A delta value of greater than or equal to 0.6 suggest the anatomical site being assessed is at an increased risk of

developing a pressure ulcer. The results, as well as device status, are displayed on the device screen.

1.2 Relevant diseases and conditions

The SEM Scanner 200 is intended for use in the people at increased risk of developing pressure ulcers.

Pressure ulcers are injuries to the skin and underlying tissue, primarily caused by prolonged pressure on an area of the skin which is capable of impairing the skin's blood supply.

People with mobility issues and/or ageing skin are vulnerable to pressure ulcers, particularly people aged 70 years and over, those with disabilities affecting their physical, mental or cognitive capacities.

An NHS Safety Thermometer report states that from April 2014 to the end of March 2015, just under 25,000 patients developed a new pressure ulcer within the NHS in England. It is estimated that just under half a million people in the UK will develop at least one pressure ulcer in any given year. The NHS Stop the Pressure campaign (Midlands and East) launched in 2012 found measures to avoid the development of pressure ulcers resulted in a 50% reduction in pressure ulcer incidents in the first year. The national proportion of patients with a category 2-4 pressure ulcer in the UK in August 2012 was 6.0% and fell to 4.3% in August 2015. In July 2019 this proportion was reported to be 5.0%.

The NICE guideline on pressure ulcers: prevention and management notes that adults considered to be 'at high risk' of developing pressure ulcers will usually have multiple risk factors (such as significantly limited mobility, nutritional deficiency, inability to reposition themselves, and significant cognitive impairment) identified during risk assessment with or without a validated scale. Also considered to be at high risk are patients who have a history of pressure ulcers or those who already have a pressure ulcer.

1.3 Current management

NICE's guideline on pressure ulcers: prevention and management recommends that a documented assessment for pressure ulcer risk is carried out in adults, neonates, infants, children, and young people being admitted to secondary care, or care homes (adults), or tertiary care (neonates, infants, children, and young people), in which NHS care is provided; or receiving NHS care in other settings (such as primary and community care and emergency departments), if they have a risk factor. It recommends using a validated scale to support clinical judgement in those identified 'at risk' of developing pressure ulcers, and that risk is reassessed if the patient's clinical status changes. The guideline further defines a 'high risk' group for developing a pressure ulcer as those who usually have multiple risk factors such as significantly limited mobility and nutritional deficiency.

The guideline recommends strategies to prevent pressure ulcers, including regular patient repositioning, foam mattresses and pressure redistribution cushions. It also recommends the use of barrier creams to prevent damaged skin in people at high risk of developing moisture lesion or incontinence-associated dermatitis.

1.4 Regulatory status

The SEM Scanner 200 received a CE mark in November 2014 as a class IIb medical device for pressure ulcer prevention at the heel and sacrum only.

1.5 Claimed benefits

The following benefits to patients are claimed by the company as a result of a reduction in pressure ulcer incidence:

- Patient empowerment and engagement in care process
- Enabling rapid recovery and discharge
- Promoting functional recovery and mobility
- Increased ability to return to daily activities
- Maintenance of personal independence
- Reduced risk of social isolation

- Help to prevent patient distress
- Support prevention of patient pain
- Reduced risk of wound infection

The benefits to the healthcare system claimed by the company are:

- Consistent approach to risk assessment
- Objective and anatomically specific pressure ulcer data collection
- Reduced costs associated with medical and surgical interventions for treating pressure ulcers
- Reduced nursing and hospitalisation costs associated with the treatment of pressure ulcers

2 Decision problem

Population	People at risk of developing pressure ulcers at the heel or sacrum, including people with existing pressure ulcers
Intervention	SEM Scanner 200 used as an adjunct to standard NHS clinical practice.
Comparator(s)	Standard NHS clinical practice for patients considered 'at risk' or 'at high risk' of pressure ulcers. This may involve a combination of: • Standard risk assessment using visual, tactile and biomarker tools. • Frequent repositioning (at least 6 hourly in people considered to be at risk and 4 hourly in people considered to be at high risk) • Pressure redistribution using devices such as high-specification foam mattress or pressure redistributing cushions.
Outcomes	The outcome measures to consider include: Intermediate/diagnostic outcomes • Diagnostic accuracy • Time to test result • Number of inconclusive results (including occasions where it is not possible to take 3 readings) • Impact on clinical management decisions Clinical effectiveness

	•Incidence of pressure ulcers at the heel and sacrum •Incidence of skin breakdown at the heel and sacrum •Stage of pressure ulcer developed (stage I – IV, unstageable) •Device related adverse events •Rate of infection •Quality of Life, and associated outcomes e.g. pain and discomfort; patient mobility; patient/carer satisfaction; patient depression and anxiety Systematic impact •Rate of complications avoided from pressure ulcer prevention e.g. Infection, abscess, septicaemia, bone infections, meningitis. •Length of hospital stay as a result of pressure ulcers, including ICU and conventional ward bed days. •Costs of treating pressure ulcers and their complications e.g. nursing, hospital, surgical and treatment costs Additional outcomes to those relevant to the benefits claimed by the company: •Patient compliance with and the use of pressure ulcer prevention strategies •Ease of use of product, including training requirements
Cost analysis	Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be long enough to reflect differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.
Subgroups to be considered	People at high risk of developing pressure ulcers such as those with mobility issues, those with comorbidities affecting cognition and communication, people with spinal injury, those in residential homes and those with darker skin.
Special considerations, including those related to equality	People with restricted mobility are at an increased risk of developing pressure ulcers and would likely benefit from this device. Category 1 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.

Special considerations, specifically related to equality	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristic?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure the Medical Technologies Advisory Committee will have relevant information to consider equality issues when developing guidance?	No
Any other special considerations	Not applicable	

3 Related NICE guidance

Published

- The Debrisoft monofilament debridement pad for use in acute and chronic wounds. NICE medical technology guidance MTG17(2019). Available from www.nice.org.uk/guidance/MTG17
- Mepilex Border Heel and Sacrum dressings for preventing pressure ulcers. NICE medical technology guidance MTG40(2019). Available from www.nice.org.uk/guidance/MTG40
- Parafricta Bootees and Undergarments to reduce skin breakdown in people with or at risk of pressure ulcers. NICE medical technology guidance MTG20(2014). Available from www.nice.org.uk/guidance/MTG20
- Pressure Ulcers: prevention and management. NICE clinical guideline CG179(2014). Available from www.nice.org.uk/guidance/CG179.

In development

Not applicable

4 External organisations

4.1 Professional

The following organisations have been asked to comment on the draft scope:

- British Association of Dermatologists
- British Dermatological Nursing Group
- British Geriatric Society
- British Society for Dermatological Surgery
- Intensive Care Society
- Primary Care Dermatology Society (PCDS)
- Royal College of Nursing
- Royal College of Physicians
- Society of Chiropodists & Podiatrists (Feet for Life)
- Welsh Wound Network
- Wound Care Alliance UK

4.2 Patient

NICE's Public Involvement Programme contacted the following organisations for patient commentary and asked them to comment on the draft scope:

- British Skin Foundation (BSF)
- Leg Ulcer Charity
- Leonard Cheshire disability
- Pressure Ulcers UK