

Provizio® SEM Scanner Achieves Expanded FDA Claims and CMS Procedure Code in the United States, and Drug Tariff Listing in the United Kingdom, Further Advancing Pressure injury* prevention for Patients and Providers.

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Bruin Biometrics LLC announces repeated formal recognition of the role of sub-epidermal moisture (SEM) in the identification of the increased risk of pressure injuries and of the Provizio SEM Scanner in the detection, and guided treatment of SEM for the prevention of broken skin pressure injuries.

Martin Burns, CEO of Bruin Biometrics, brings good news: "Leading national and expert guidelines now recognize SEM assessment for pressure injury prevention due to the latest data on the ongoing challenges of pressure injuries and the importance of their prevention".

Provizio is intended to mean "foresight". FDA, CMS, Provizio users and many others acknowledge the efficacy and utility of that clinical foresight, in real-time, at the bedside, by anatomy. That is acutely true for dark-skin-toned patients. Health economic modeling and time-motion analytical analysis underscores its cost-effectiveness while liberating precious nursing time."

In The United States

- The FDA has acknowledged that sub-epidermal moisture is the equivalent of persistent focal edema, localized edema, sub-epidermal moisture, which is measured and monitored by the Provizio SEM Scanner, accepting an expanded labeling (K231830, September 2023¹).
- The US Centers for Medicare and Medicaid (CMS) has approved the ICD-10 PCS procedure code, XX2KXP9, for the SEM scanning procedure, effective April 1, 2024, promoting standardization of the SEM scanning procedure linked to an existing diagnosis code. This was one of only approximately 40 codes issued across all clinical procedures this year. It recognizes the utility of the technology in measuring and monitoring SEM which, when treated, significantly aids in preventing pressure injuries and deep tissue injuries. This new code will play a significant role in promoting standardization of the procedure, especially for present on admission testing which is a major quality risk area for providers with consequential Medicare penalties for missed diagnoses.

In The UK

- The UK's Department of Health and Social and Social Care' Drug Tariff now provides payment for Scanner sensors at the point of care for all UK's at-home patients, the Provizio SEM Scanner Sensor is the first "pressure injury prevention sensor" to be added to the Drug Tariff.

After another year of groundbreaking clinical and health economic advancements with the Provizio SEM Scanner, the company and its collaborating practitioners and exclusive global distributor,

Arjo, continue to modernize the landscape of pressure injury prevention in the US and UK, with far-reaching positive effects for patients, globally.

These data show that pressure injuries develop microscopically, invisible to the naked eye and imperceptible to tactile assessment. Detection of developing pressure damage, which precedes and predicts tissue death, is clinically impossible without technology. Prevention – keeping the skin intact – is improbable under the current standard of care, particularly for dark skin toned patients.

Burns continued, “It is this mismatch of what is now acknowledged as the “contemporary understanding of etiology of pressure injuries and clinical practices overly reliant on risk-factors and macroscopic methods of detection which sharply bifurcates old from now.”

These developments have broad implications for clinical practice. In the US, the 1% Medicare penalty for hospital-acquired pressure injuries again applies to clinical practice for the fiscal year from October 1, 2023, to September 30, 2024. Because of these Provizio SEM Scanner related milestones, healthcare providers and practitioners have coded procedures and a powerful tool to support pressure injury prevention from admission to discharge.

For years, healthcare practitioners and policymakers have been frustrated from increased pressure injury incidence and associated resource burdens and treatment costs. From Bruin Biometrics’ point of the view the current status quo around pressure injuries is simply inadequate resulting in too much avoidable patient suffering.

Burns concluded, “These approvals and authorizations are proverbial breaths of fresh air in a clinical area frustrated by detection, treatment and prevention methods not grounded in contemporary etiology and pathophysiology. We have moved beyond the era of pressure injury risk-tools and visual and tactile skin assessments alone, and into an era where objective, microscopic measures guide practitioners’ understanding of their patients’ skin and tissue status.”

For more information, please visit [Bruin Biometrics CEO Martin Burns Shares an Important Update](#) or contact Kate Hancock, EVP External Communications, at +447827315347 or khancock@bruinbiometrics.com.

Media contact details:

Joanna Dodd, Alicia Barkle Rochester PR Group : joanna.dodd@rochesterprgroup.com
alicia.barkle@rochesterprgroup.com

About Bruin Biometrics

Bruin Biometrics LLC is a pioneer in modernizing healthcare with biometric sensor technology for early detection and monitoring of chronic, preventable conditions in collaboration with clinicians. Bruin Biometrics work on SEM Assessment Technology has been recognized with multiple global healthcare innovation

awards and is implemented in healthcare facilities across a variety of care settings. Bruin Biometrics HQ is based in Los Angeles, USA.

References

¹ K231830, September 2023: "The Provizio SEM Scanner S measures the electrical capacitance of tissue ("Biocapacitance"), below the electrode when placed on the patient's skin. Biocapacitance is a biophysical measure of changes in sub-epidermal moisture ("SEM") a physiological process associated with pressure-induced tissue damage, The Provizio SEM Scanner S is designed to measure changes in SEM which is equally known in literature as persistent focal edema, or localized edema.

* A pressure injury can also be known as a pressure ulcer, pressure sore, decubitus ulcer and bed sore.

