

Biophysical detection of skin changes to cue pressure injury prevention in nursing homes

NCT06127524

February 20, 2026

Information for Residents & Families about the SCAN Study (Skin Change Action by Nursing)

[name of center] is pleased to announce that we will soon begin using a new device for all residents as part of the routine skin care this center already provides. The use of this device (SEM Scanner) will enhance the nursing staff's ability to observe skin changes below the skin surface that cannot be seen by the naked eye. This center already has skin health and pressure injury (also called "pressure ulcer or bedsore") prevention care in place, which is why we were chosen to participate in a study with the University of California, Los Angeles (UCLA) School of Nursing and Duke University School of Nursing. The study is funded by the National Institute of Health and National Institute of Nursing Research and does not involve experimental drugs or devices and has UCLA Office of Human Research Protection Program approval. We believe participation in the 8-month-long study has the potential to assist us in our nursing skin health and pressure injury prevention efforts.

The SEM Scanner is a handheld medical device that nursing staff will use to lightly touch the skin over the sacrum (buttocks) and heels to identify edema (moisture) changes below the skin surface. These changes may be an early sign of a possible developing pressure injury. Each resident at this center will be examined with the SEM Scanner during routine weekly nursing skin care. Our goal is to enhance skin health and prevention of pressure injury. However, as with any routine care provided, residents will retain their right to refuse the use of the SEM Scanner.

Study researchers will monitor the resident's electronic health record (EHR) information that will be provided using a unique study identifier that protects the resident's identity. Federal Privacy Regulation safeguards about privacy, security, and access will be followed. If you would like more information about this study, contact the co-principal investigators: Barbara Bates-Jensen, PhD, RN, WOCN, FAAN ((626) 437-8543 or batesjen@sonnet.ucla.edu), or Tracey Yap, PhD, RN, WCC, FGSA, FAAN ((502) 686-0016 or tracey.yap@duke.edu).

Protocol ID:IRB#22-001256 UCLA IRB Approved Approval Date: 7/20/2023 Through: 7/19/2024

Committee: Medical IRB 3

TO: Administrators, Directors of Nursing (DON), and Medical Directors
SUBJECT: Implementation of the SCAN Study (Skin Change Action by Nursing Study)

BACKGROUND: The SCAN (Skin Change Action by Nursing) Study uses subepidermal moisture (SEM) measures as an adjunct to visual skin assessment to detect early pressure injuries among nursing home residents. The SEM measures for the sacrum and heels will be obtained using the Provizio SEM Scanner, an advanced technology for monitoring skin health, including pressure injury detection. Your center will use the SEM Scanner center-wide for all residents as part of an 8-month study conducted by the University of California, Los Angeles (UCLA) School of Nursing and Duke University School of Nursing SCAN study. The study is funded by the National Institute of Nursing Research, does not involve experimental drugs or devices, and has UCLA Office of Human Research Protection Program approval. The overall goal of the project is to enhance skin health and prevention of pressure injury.

Your nursing staff will use the SEM Scanner to augment the visual skin assessments they are already doing for all residents by detecting changes below the skin surface, such as edema or inflammation in the dermis, that are often associated with a possible developing pressure injury. A single-use disposable sensor will be placed on each handheld scanner device to lightly touch the skin. The device is FDA-approved for detecting sacral and heel pressure injuries. Each resident at this center will have his/her sacrum and heels assessed with the SEM Scanner during routine weekly nursing skin assessments. As with any routine care provided, residents will retain their right to refuse the use of the SEM Scanner.

The study will be conducted with 6 centers. Each participating center will be able to keep the Provizio SEM Scanners after the study and will receive \$3,000 for support of the center's implementation of the project.

This informational bulletin provides details and instructions for that implementation.

GENERAL INFORMATION:

- Your center has been selected to participate in the SCAN study and will use the Provizio SEM Scanners as part of the skin assessment for all residents.
- Your center will receive **6** Provizio SEM Scanners, charging cradles, a medical-grade electrical outlet extender, and a container drawer for storing the SEM Scanner sensors.
- A one to two-month supply of SEM Scanner sensors will be provided during the implementation launch of the study. As the study continues, SEM Scanner sensor resupply should be requested from Michelle Simplina at (310) 206-5739 or scanstudy@mednet.ucla.edu.



Figure 1: Provizio SEM Scanner

- Each resident at your center will be assigned a SCAN study ID by [name of healthcare agency]. The SCAN Study ID will be used to create an individual barcode for each resident which will be taped to the foot of the resident's bed (Figure 2).
 - The first step in using the Provizio SEM Scanner is to scan the barcode of the resident. Then, take the SEM Scanner measures for the sacrum and heels.
 - Place the Provizio SEM Scanner back in the charging stand when all the measures are completed that day for the residents. All data collected using the SEM Scanner device will be automatically saved once returned to the charging stand.



Figure 2: SCAN Study ID Barcode example

NOTE: Please refer to the barcode procedure for information on obtaining barcodes for new admissions or updates based on resident bed/room changes.

- **On-site In-service:** Your center has been scheduled for mandatory on-site education/training of all nursing staff (RNs, LPNs, CNAs) on the use of the SEM Scanner during December 4-8, 2023. The 8-month period of the SCAN study at your center is to occur December 4, 2023, through August 9, 2024.
 - The training will include conducting SEM Scanner measures on residents during the training dates.
 - The SCAN Study team members will arrive at your center on Monday, December 4 to meet center leadership.
 - In-service education materials will be provided by the SCAN study team. Training materials include:
 - Video
 - User Quick Guide to Scanning
 - Badge Buddy
 - Competency checklist
- For issues related to the SCAN Study, contact:

Barbara Bates-Jensen batesjen@sonnet.ucla.edu Co-Principal Investigator	Tracey Yap tracey.yap@duke.edu Co-Principal Investigator
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- **Attention Medical Directors:** Attached is a template letter of introduction prepared for the center's distribution to attending provider staff. The use of this technology is supported and endorsed by our Senior Vice Presidents of Medical Affairs (VPMA); however, it is important for attending resident providers to be informed of the implementation. The Administrator and/or DON will contact you for assistance in disseminating the information to all attending providers. If you have any questions, please contact your center's VPMA.

TO DO:

Administrator and/or DON:

1. Review the accompanying preliminary checklist and document as action items are completed.

2. Expect contact from the SCAN Study research team to discuss preparations for the implementation.
3. Contact your Manager of Clinical Operations to inform them of the in-service and implementation schedule.
4. Distribute this Update to your Medical Director, Medical Supply Coordinator, and staff.
 - a. Ask the Medical Director to send the introduction letter to attending physicians (*template attached*).
5. Distribute the “Letter to Resident/Family” to each resident and primary family member or guardian at least 1 week before December 4, 2023 (the week of November 27, 2023).
6. The SCAN study team will arrive at your center on December 4, 2023.
7. On the scheduled training days (Tuesday, December 5, Wednesday, December 6, and Thursday, December 7), the SCAN Study team will conduct the mandatory in-service training sessions. Participation should include all nursing staff (RNs/LPNs/CNAs). A SCAN research team member will contact the center to determine a process for staff sign-ups for training sessions (up to 6 offerings/day, approximately 15 staff per session) and send the nurse staff sign-up sheets.
8. For follow-up questions, contact the SCAN Study team.
9. The SCAN Study team and the Skin Health Team Lead will coordinate ongoing in-service.
10. **ALL NURSE STAFF TRAINING WILL BE COMPLETED DURING THE SCAN STUDY TEAM’S ON-SITE IN-SERVICE TRAINING DAYS BEFORE INITIATING IMPLEMENTATION.**
11. Send the completed checklist to the SCAN Study team at scanstudy@mednet.ucla.edu

[Date]

To be placed on Center's Letterhead

Dear Provider,

[name of center] is pleased to announce that as of December 4, 2023, we will begin using the SEM Scanner nursing home-wide for all residents as part of an 8-month University of California, Los Angeles (UCLA) School of Nursing and Duke University School of Nursing Skin Change Action by Nursing (SCAN) study. The study is funded by the National Institute of Nursing Research and does not involve experimental drugs or devices and has UCLA Office of Human Research Protection Program approval.

The SEM Scanner is an advanced technology for monitoring skin health, including pressure injury detection, by measuring subepidermal moisture (SEM). Our nursing staff will use the SEM Scanner to augment the visual skin checks they are already doing by detecting changes below the skin surface, such as edema or inflammation in the dermis, that are often associated with a possible developing pressure injury. This handheld device uses a single-use disposable scanner head to lightly touch the skin and it is already FDA-approved for detecting sacral and heel pressure injury. Each resident at this center will have his/her sacrum and heels assessed with the SEM Scanner during routine weekly nursing skin checks. As with any routine care provided, residents will retain their right to refuse the use of the SEM Scanner. Our goal is to enhance skin health and prevention of pressure injury.

Please note, as per VPMAs, an order containing the components listed below will be activated in the center's EMR for each of the center's residents:

- SEM Scanner will be used weekly by either a CNA or licensed nurse to examine each resident's skin on the sacrum and heels.
- Detection of an orange/red SEM value (≥ 0.6) that indicates an increased risk; early-stage pressure injury will be immediately reported to the licensed nurse and a repeat SEM scan obtained to verify the result.
- If an orange/red SEM value (≥ 0.6) is confirmed by the licensed nurse, the Genesis Skin and Wound Protocol will be implemented.

Study researchers will monitor the resident's electronic health record (EHR) information that will be provided using a unique study identifier that protects the resident's identity. Federal Privacy Regulation safeguards about privacy, security, and access will be followed. If you would like more information about this study, contact the co-principal investigators: Barbara Bates-Jensen, PhD, RN, WOCN, FAAN (batesjen@sonnet.ucla.edu), or Tracey Yap, PhD, RN, WCC, FGSA, FAAN (tracey.yap@duke.edu).

We believe participation in the SCAN study will facilitate nursing care skin health processes and has the potential to assist us in our pressure injury prevention efforts. As always, we welcome your comments and questions. Please feel free to contact us at any time, and thank you in advance for your cooperation.