



Request for New ICD-10-PCS Procedure Code

Visualization Guidance for Pressure Offloading during Patient Repositioning

ICD-10 Coordination & Maintenance Committee | Requested Implementation: October 1, 2027

Submitted by: Wellsense Vū | Ron Ferber, President & CTO | ron@wellsensevu.com

FDA Registration: Class I, 510(k) Exempt | UDI Compliant | First of its kind - no predicate exists

Pressure Injuries: The Largest Preventable Hospital Harm

34.2%^[1]

of all adverse events

43.5%^[2]

of all HAC-related deaths

60,000^[3]

Americans die from
pressure injuries each year

Pressure injuries are the **ONLY** adverse event category whose share has risen (+14%) while all others have declined. ^[1]

They are also the **#1** most frequent hospital-acquired condition and appear on every CMS framework of preventable harm ^{[4] [5] [6]}

Hospital-Acquired Conditions - Ranked by Frequency

Hospital-Acquired Condition	Rate per 1,000 discharges
Pressure Ulcers / Pressure Injuries	36.3
Adverse Drug Events	35.1
Other HACs (catch-all category)	23.0
Catheter-Associated UTI (CAUTI)	8.2
Falls	6.7
Contrast Nephropathy	6.7
C. difficile	3.1
Surgical Site Infections	2.5
Obstetric Adverse Events	2.3
Ventilator-Associated Pneumonia	0.89
Postoperative VTE	0.20
Central-Line Infection (CLABSI)	0.05
TOTAL - all HACs	115

Pressure injuries are #1.

More frequent than any other single hospital-acquired condition - and the only category that is still rising.

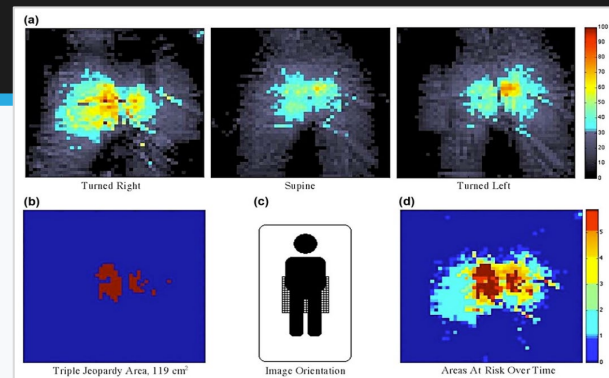
Source: AHRQ National Scorecard on Hospital-Acquired Conditions [4] - interim rates per 1,000 discharges. "Other HACs" is a catch-all, not a single category.

The Failure of Current Standard of Care

The current standard of care for pressure injury prevention is manual patient turning every 2 hours - typically requiring 2 nurses, 12 times a day, throughout the entire inpatient stay.

95%

of routine turns leave some area of the perisacral region and greater trochanters above clinically established pressure thresholds [7]



Blind turning fails three ways:

- It fails: pressure is NOT reliably offloaded - and the failure is invisible to the caregiver
- It consumes scarce nurses: 16.34 person-min per turn x 12 turns/day = ~1,176 nursing hours/year for ONE patient (Pham 2016) [8] - amid a projected 10% national RN shortage
- It injures nurses: 19% report a work-related injury each year; 72% of those involve patient handling (Rainbow 2024) [9]
- No visual confirmation = no clinical certainty

What Is VGPO? A Clinician-Performed Procedure

Visually Guided Pressure Offloading (VGPO) is a clinician-performed procedure - not a device. The nurse acts. The hardware enables.

VGPO is a procedure in which a nurse uses real-time interface pressure data - shown on a color display at the foot of the bed - to actively direct and confirm the offloading of pressure from at-risk body areas. The nurse repositions in real time until all at-risk regions show pressure below established risk thresholds.

Analogous to bedside diagnostic procedures:

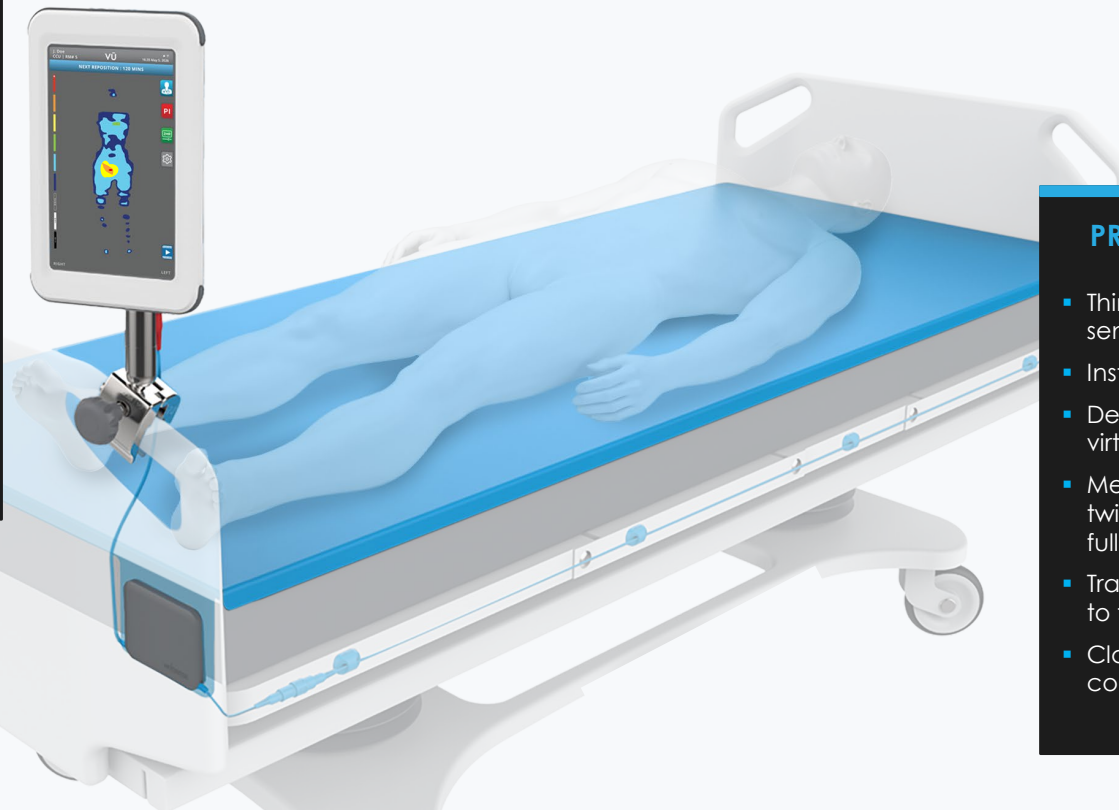
Fluoroscopy-Guided Procedure: Clinician uses real-time visual imaging to guide an intervention and confirm a clinical endpoint before leaving the patient. Acting on what they see.

Visually-Guided Pressure Offloading: Nurse uses real-time pressure data on a display to assess and confirm successful pressure offloading. Acting on what they see.

The Hardware Components That Enable the Procedure

INTERACTIVE DISPLAY

- Color display affixed to universal armature at foot of bed
- Faces inward toward patient during procedure - direct nurse line of sight
- Rotates outward when unattended - any passing clinician can assess patient pressure status
- Renders pressure (mmHg) as intuitive real-time color map
- Class I FDA-registered | UDI compliant | 510(k) exempt



PRESSURE SENSING MAT

- Thin, flexible, proprietary multi-sensor pressure mat
- Installed beneath the patient
- Designed to operate with virtually any bed brand/model
- Measures interface pressure twice per second across the full patient contact surface
- Transmits readings continuously to the foot-of-bed display
- Class I FDA-registered | UDI compliant | 510(k) exempt

Confirmation Is What Separates a Monitor from a Procedure

Monitors Deliver Data



Data is not an outcome

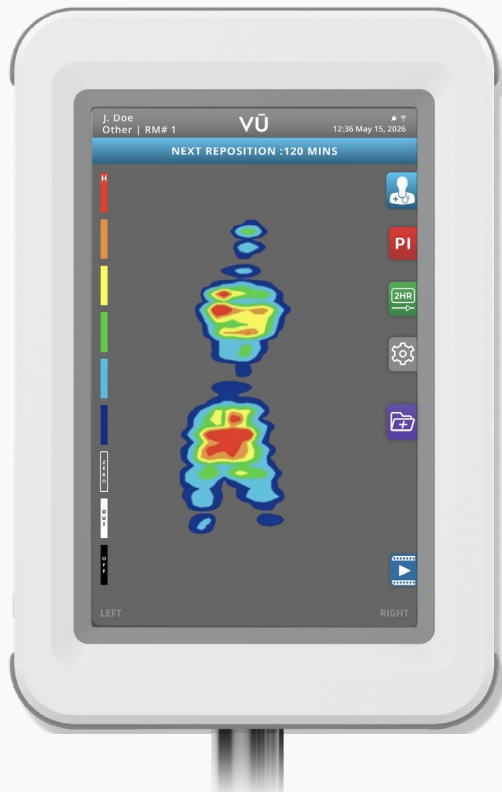
Pressure offloading never has. **Until now.**

Procedures Deliver Outcomes



A procedure ends when
the outcome is confirmed

How VGPO Is Performed: Procedural Steps



The live display the nurse acts on

1

Patient Registration

Registered with name, MRN, weight, existing PI locations, and repositioning interval as clinically indicated.



2

Live Pressure Assessment

Nurse enters the room and views the live color display for instant assessment of current pressure distribution.



3

Existing Injury Review

Nurse reviews the injury record on the display to keep pressure away from wounds already present.



4

History Replay (if needed)

Nurse accesses the 2-hour pressure history to see how the patient reached the current pressure state.



5

Guided Repositioning

Nurse repositions in real time, guided by the live pressure image, until offloading is confirmed.



6

Confirmation & Documentation

Nurse leaves with visual confirmation that all at-risk areas are below threshold, and records the outcome in the EMR.



Clinical Validation: 50+ Independent Publications

50+

Independent
publications

20M+

Recorded clinical
hours and growing

20+

Leading US hospitals
deployed

Deployed across all ICU environments - Cardiovascular, Neuro, Burn, SCI, ECMO, Surgical, and Medical - as well as MedSurg and Long-Term Acute Care settings, delivering significant, documented HAPI reductions across every deployment.

**ADVERSE
EVENTS:**

None. VGPO is non-invasive. Nothing is inserted, implanted, or physically attached to the patient. Zero known adverse events across all documented clinical use.

Clinical Outcomes: Documented HAPI Reductions

- Consistent, measurable HAPI reductions across diverse ICU environments
- Outcomes achieved in real-world clinical settings - not controlled trials
- Performance validated across multiple hospital types and unit specialties
- Demonstrates repeatable impact across independent institutions

Independent hospital deployments have demonstrated an average HAPI reduction of approximately 78% across documented clinical sites.

Hospital	Unit	HAPI Reduction
Johns Hopkins Bayview	BICU	56%
University of North Carolina	CVTICU	61%
University of North Carolina	MICU	70%
University of New Mexico	MICU	70%
Baptist Hospital of Miami	ICU	71%
University of North Carolina	SICU	74%
The Ohio State University	CVICU	90%
ChristianaCare	MICU	91%
University of California - Irvine	SICU & CVICU	100%
BHSF Doctors Hospital	ICU	100%

Documentation and Terminology in the Medical Record

The clinician documents the VGPO intervention in the hospital's EMR nursing documentation, where repositioning care is charted today. Charting fields vary by hospital and EMR (turn direction, turn angle, head-of-bed changes, and other customized fields).

The VŪ system independently creates a permanent, timestamped record of each procedure: initiation, the offloading intervention, and clinician confirmation that the measured offloading endpoint was achieved.

For medical coders, the procedure is identifiable by its name - Visually Guided Pressure Offloading (VGPO) - together with the confirmation entry.

A direct EMR interface has been developed and is available at each hospital's election, enabling the VGPO procedure record to flow automatically into the patient's permanent medical record.

Historical technology names - advanced pressure visualization system (APVS), continuous bedside pressure mapping (CBPM), pressure mapping - describe the measurement technology, not the procedure. The procedure is documented as VGPO.

Summary & Request

- Pressure injuries are the #1 adverse event category - 34.2% of all adverse events among Medicare hospitalizations [1], 43.5% of adverse-event-related deaths [2], and 60,000 Americans deaths annually [3]
- The current standard of care - manual turning - has no mechanism to confirm that pressure is actually offloaded. Studies show that 95% of turns leave high pressure in the perisacral region [7]
- VGPO is a distinct clinician-performed procedure: the nurse uses real-time pressure data to guide repositioning and confirm offloading before leaving the bedside
- This single FDA Class I registered system enables the procedure and remains installed at the bedside. No predicate exists. No existing ICD-10-PCS code captures this combination of measurement, visualization, and clinician-confirmed intervention.
- Validated by 50+ independent published studies [10], 20M+ clinical hours, and deployed across 20+ leading US hospitals - with an average documented HAPI reduction of approximately 78%
- **Wellsense VŪ respectfully requests the creation of a new ICD-10-PCS code for Visually Guided Pressure Offloading - with a requested implementation date of October 1, 2027**

References

[1] Agency for Healthcare Research and Quality (AHRQ). Adverse Events Among Medicare Hospitalizations in 2021-2023. September 2025. data.ahrq.gov

[2] Agency for Healthcare Research and Quality (AHRQ). Hospital-Acquired Conditions data. November 2017.

[3] Duchesne GA, Waller JL, Baer SL, Young L, Bollag WB. Pressure Ulcer Diagnosis Is Associated with Increased Mortality in Patients with End-Stage Renal Disease. *Life (Basel)*. 2023;13(8):1713. PMID: 37629570.

[4] Agency for Healthcare Research and Quality (AHRQ). National Scorecard on Rates of Hospital-Acquired Conditions 2010 to 2015: Interim Data. ahrq.gov/hai/pfp/2015-interim.html

[5] Centers for Medicare & Medicaid Services (CMS). Hospital-Acquired Conditions (Deficit Reduction Act), 14 categories.

[6] Agency for Healthcare Research and Quality (AHRQ). Patient Safety Indicators (PSI-90) Composite, including PSI-03 Pressure Ulcer Rate.

[7] Peterson MJ, et al. Patient repositioning and pressure ulcer risk - Monitoring interface pressures of at-risk patients. *J Rehabil Res Dev*. 2013;50(4):477-88.

[8] Pham B, et al. Evaluating the Impact of a Turn-and-Position Device on the Incidence of Hospital-Acquired Sacral Pressure Ulcers and Nursing Staff Time Needed for Repositioning Patients. *Wound Repair Regen*. 2016. PMID: 27861136.

[9] Rainbow JG, et al. Work-Related Health Conditions Among American Nurses: A Scoping Review. *SAGE Open Nurs*. 2024;10:23779608241257026. PMCID: PMC11113033.

[10] Wellsense VU. Independent Clinical Publications Library. resources.wellsensevu.com

Thank You

Ron Ferber

President & CTO, Wellsense Vū

ron@wellsensevu.com

248-761-0000

