# Visual and Near Infra-Red Spectroscopy Scanner for assessment of stage I pressure injury and deep tissue injury- final clinical study results

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## Background:

- Detection of Pressure Injuries (PI) relies mainly on visual and tactile clinical evaluation. However, physiological changes below the skin (e.g., inflammatory, interstitial fluid) precede surface changes (Gefen et al., 2018).
- According to Current Perspectives on PI in Persons with Dark Skin Tones from the National Pressure Injury Advisory Panel, it is especially challenging in dark skin patients to identify early skin changes. This mandate urgent implementation of new technologies to improve early detection (Black et al., 2023). Near Infra-Red (IR) spectroscopy can asses tissue bio-markers under the skin surface and is not influenced by melanin content, hence has the potential of providing the tool for PI assessment before skin breakage in dark skin tone group (Cohen et al., 2022).

### Objectives of the study:

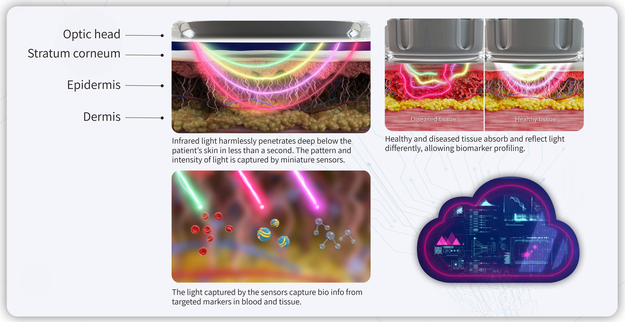
To evaluate the use of visual and Near IR-Spectroscopy Scanner (IRSS) combined with AI based algorithm for assesment of PI stage 1 / sDTI, its sensitivity, specificity and usability compared to standard of care skin assessment.

### conclusions:

Near IR spectroscopy combined with AI based algorithm is shown to be safe, efficient and valuable method for PI early assesment.

The study highlights how integrating advanced technology and structured protocols can lead to measurable improvements in patient outcomes and hospital processes.

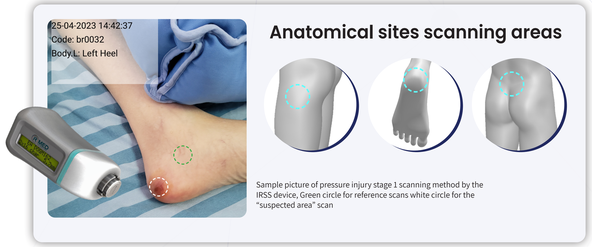
## How it works




Near Infra-Red light reflectance technology gathers information from biomarkers in different layers of the skin through optical scanning as follows:

1. Biomarker profiles are identified for a pressure injury / sDTI.
2. A handheld device that contains miniaturized electronics and passive sensors is placed on the skin, where it emits and detects visible light and infrared light.
3. Biological information is acquired by evaluating light intensity and patterns reflected from the different layers beneath the skin's surface.
4. The Bio-info is uploaded to the cloud
5. AI – based algorithm generate the results

## Methodology

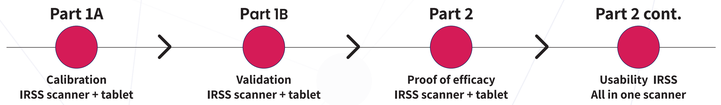



The IRSS uses harmless near IR reflectance spectroscopy to assess PI development in different skin layers by scanning:

- Multiple skin biomarkers
- skin structural changes and tissue content parameters.
- The investigetional system consists of tablet, scanner and disposable tips
- 5 anatomical sites were scanned using IRSS device for each patient
- Each body location was scanned around and in the suspected area
- The referance scan is used to adapt to the patient's skin
- A standard skin assessment was used for standards of care
- A disposable tip was changed between each patient

## Study Design

- Single arm, bi center, open label, Safety and Efficacy study up to 120 pt.
- The study design consisted of 2 parts- Calibration and validation (up to 40-patients), Proof of efficacy (80-pt. or up to 60 PI).
- Beit Rivka – A skilled nursing facility with leading innovation and research center.
- Beilinson Hospital- Leading tertiary medical center of "Clalit Health services".
- 6 Wards gradual recruitment : 2 long term ventilation Ward, 2 complex skilled nursing ward, ICU ward, acute geriatric ward.
- Study population consisted of patients with high risk of PI development (Norton >14) or stage I / deep tissue injury / PI in an eligible body locations – heels(2), trochanter(2), sacrum(1).




## Clinical Benefits

The implementation of the device has demonstrated significant clinical benefits in the assessment and management of pressure injuries:

- **Enhanced Assessment and Monitoring:**
  - Improved the reporting process for Stage 1 pressure injuries, increasing the accuracy and assessment of wounds in the hospital's quality measures.
- **Reduction in Pressure Injury (PI) Incidence:*****
  - 23% Reduction: A significant decrease in PI incidence rate at the major study site, independent of study participation.
  - Incidence Rates: 2022: 191 PIs per 100K patient days (n=101) compared to 148 PIs per 100K patient days (n=90).
- **Key Drivers of Success:**
  - **Increased Awareness:** Nursing staff and support teams showed greater attention to prevention, particularly for high-risk areas.
  - **Enhanced Monitoring:** Departmental nursing leadership improved their ability to monitor and report pressure injuries in their early stages
  - **Improved Patient Care:** The device minimized reliance on user expertise, ensuring systematic scanning and documentation of all high-risk areas.
  - **Data Integrity:** Evidence- and technology-based documentation enhanced the quality of data, reducing subjectivity and improving reliability.
  - **Resource Allocation:** Insights from the study guided hospital leadership in better allocation of human and technological resources for pressure injury prevention.

*** Contributing Factors:
Study and device influence on work processes
Enhanced data management and focus on implementation.

## Results

### Part 1 - device calibration and validation

- Initial device calibration and validation versus the Standard of Care of
- skin and tissue assessment
- Training and validation of the device AI algorithm
- Scanning one time, No follow up.
- Anatomical Sites: heels (2), sacrum (1), trochanter (2)
- 37 body locations in 20 patients with of them 19 PI (stage 1 or DTI)
- In total 551 scans for Part 1.

### Part 2 - proof of efficacy

- Scanning pressure injury stage 1 /sDTI and healthy tissues.
- Scanning one time with the device on the first day.
- Up to14 days visual STA follow up by the medical team.
- Device results encrypted (blinded to the nurse).

- Efficacy set included 38 patients that participated in Part 2 of the study.
- Total of 155 anatomical sites were scanned, of them 36 PI (Stage 1 or sDTI).
- In total 924 scans for Part 2.
- sensitivity= 89%, 95%CI [75-96%] .
- specificity= 90%, 95%CI [83-94%].
- AUC score 0.89
- 64 patients' data was obtained for safety analysis (part 1 + part 2).
- Safety analysis showed no device-related adverse events.
- No safety signals were identified in 1,475 total scans.


| | | ACTUAL | |
|---|---|---|---|
| | | Positive | Negative |
| PREDICTION | Positive | 32 | 12 |
| | Negative | 4 | 107 |

- ROC curve and Confusion Matrix for Part 2 of the study "efficacy set"

## All-In-One IRSS Usability Results

- **User-Centered Design:**
  - Developed based on feedback from study nurses to align with end-user needs.
  - Reported as user-friendly and meeting requirements by study nurses.
- **Usability Testing:**
  - Scans performed on 16 body locations, totaling 80 scans.
  - Testing confirmed ease of use and scanning efficiency.
- **Safety:**
  - No safety signals identified during the study, demonstrating device safety.
- **Enhanced Integration:**
  - Significant advantages over the tablet-and-scanner setup.
  - Improved integration and convenience for end-users.
- **Follow-Up Study:**
  - A new study utilizing the IRSS all-in-one solution has been initiated in the United States.
  - Designed to further validate device performance and applicability.


## Bibliography

1. Gefen A. The future of pressure ulcer prevention is here: Detecting and targeting inflammation early. EWMA 2018; 19:7-13.
2. Black et al., Current Perspectives on Pressure Injuries in Persons with Dark Skin Tones from the National Pressure Injury Advisory Panel. Advances in Skin & Wound Care 36(9):p 470-480, September 2023.
3. Cohen, Y., Dekel, B.Z., Yuldashev, Z., Blaunstein, N. (2022). NIR-SWIR Spectroscopy and Imaging Techniques in Biomedical Applications—Experimental Results. In: Czarnowski, I., Howlett, R.J., Jain, L.C. (eds) Intelligent Decision Technologies. Smart Innovation, Systems and Technologies, vol 309. Springer, Singapore.