Advancing Chronic Wound Care Using Near Infrared Spectroscopy: Survey of FDA-cleared Class II Devices for Oxygenation Assessment

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Introduction

High-quality research and clinical practice in wound care necessitate the use of validated tools for data collection, assessment, and documentation. This study aimed to identify near-infrared (NIR) imaging devices that measure tissue oxygen saturation (StO_2) and clarify their technical capabilities through manufacturer surveys. There is no current consolidated comparison of FDA-cleared NIR devices for wound care. This study addresses that knowledge gap.

Methods

Devices measuring tissue oxygen saturation for wound assessment were identified through publicly available databases. Inclusion/Exclusion criteria were based on FDA classification as non-invasive tissue-saturation oximeters (Product Code MUD), the generation of visual oxygenation maps, and non-contact data acquisition. Searches of the FDA Device Registration and Listing database were cross-referenced with the Global Unique Device Identification Database (GUDID) on May 16, 2025. A questionnaire was developed and sent to manufacturers of the devices identified during Q2–Q3 2025, requesting information on product specifications, ergonomics, training, and performance characteristics. The overall methodological process is illustrated in Figure 1.

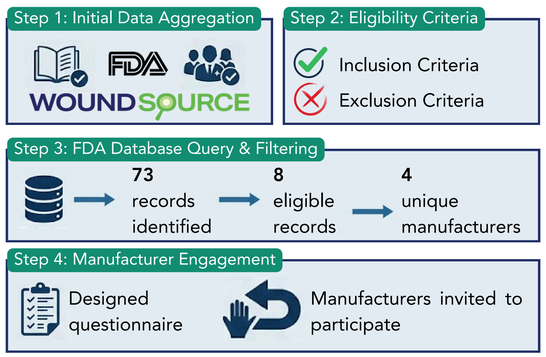


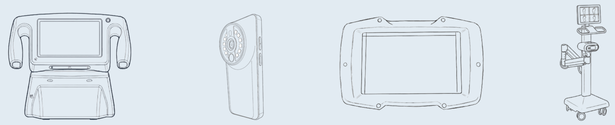
Figure 1. Methodological Process for Identification, Characterization, and Selection of the Final StO_2 Imaging Device Cohort

FDA (FDA Device Registration and Listing database); StO_2 (tissue oxygen saturation)

Results

100% of the four identified FDA-cleared NIR tissue oxygen saturation imaging device manufacturers meeting the inclusion criteria responded to the survey. All devices utilize Multispectral Imaging (MSI), with one also employing Spatial Frequency Domain Imaging (SFDI). While ergonomics and artifact mitigation strategies varied, three devices (A, B, C) measured wound size, two (A, B) calculated Percent Area Reduction (PAR), and one (B) calculated Percent Volume Reduction (PVR).

Device Cohort Overview



	A	B	C	D
510(k) Number	K161237	K190334	K240601	K181623
Form factor	Handheld (2-hand)	Handheld (1-hand)	Handheld (2-hand)	Cart-based

Table 1. Device Cohort Overview and Regulatory Identification

Device Key: A = HyperView; B = MIMOSA Pro; C = SnapshotNIR; D = Clarifi

End-to-End Clinical Workflow

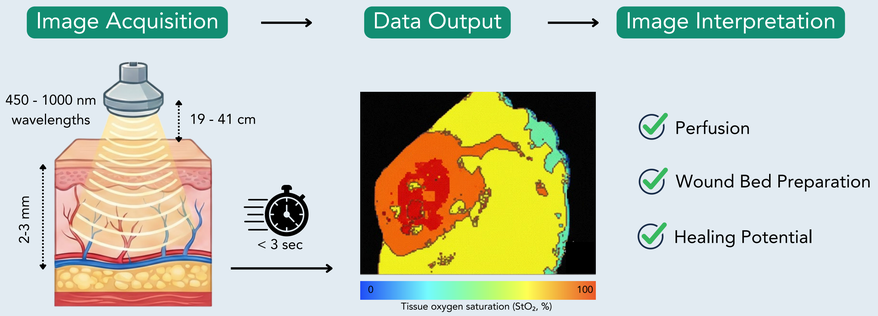


Figure 2. Tissue Assessment. This figure illustrates the standardized pipeline for tissue assessment across all cohort systems, highlighting a unified end-to-end clinical workflow. All devices capture data within a 19–41 cm distance range in under 3 seconds, generating tissue oxygen saturation maps.

Feature Comparison

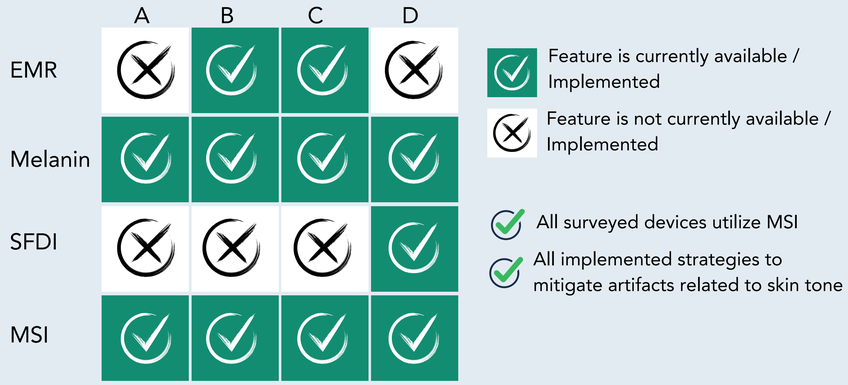


Figure 3. Feature Comparison. Heat map illustrating EMR (Electronic Medical Records) integration, melanin compensation, and imaging modalities used - SFDI (Spatial Frequency Domain Imaging) and MSI (Multispectral Imaging).

Wound Measurements

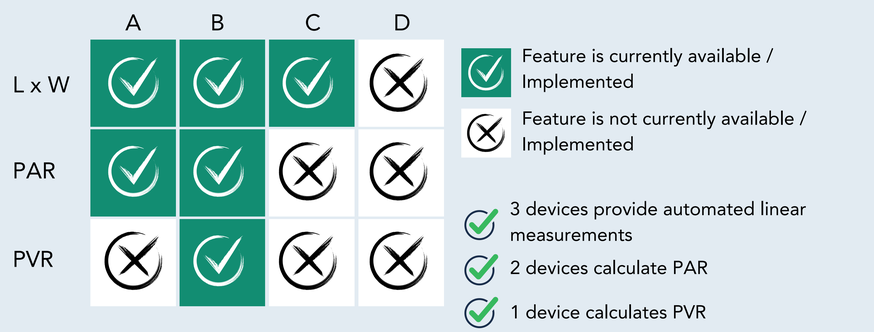


Figure 4. Wound Measurement Capabilities. Heat map illustrating integration of linear measurements (L × W: Length × Width), PAR (Percent Area Reduction), and PVR (Percent Volume Reduction) across the four surveyed manufacturers.

Discussion & Conclusion

FDA-cleared NIR tissue oxygen saturation imaging devices, used in the non-invasive assessment of tissue perfusion and oxygenation, differ in technical specifications, ergonomics, and integration with wound measurement parameters such as Percent Area Reduction (PAR) and Percent Volume Reduction (PVR). This study highlights key device specifications and features of these increasingly important devices for evaluating adequate blood flow and supporting evidence-based wound care. The study provides information that clinicians and researchers might consider when selecting and implementing imaging devices that measure StO_2 and applicable wound care endpoints. A manuscript is currently in development for future publication, incorporating extensive additional data collected through the investigations.

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A sincere thank you to our participating manufacturers for their valuable contributions and commitment to advancing clinical insights through this survey.