Two New Studies Show DermaSensor™ Devices' Consistent Performance and Improvements to Physicians' Melanoma Detection

MIAMI, FL, UNITED STATES, November 5, 2025 /EINPresswire.com/ -- Newly published studies by the American Academy of Dermatology and the Journal of Clinical and Aesthetic Dermatology (JCAD) highlight the consistent performance and clinical benefits of the DermaSensor device, an FDA cleared, AI-powered solution that benefits physicians in evaluating suspicious skin lesions [1,2].

Addressing a Growing Public Health Issue

Skin cancer remains the most common cancer in the U.S., affecting millions of Americans each year, with melanoma carrying the highest risk of mortality. Limited access to dermatologists increases PCPs' responsibility to evaluate lesions suggestive of skin cancer [2,3].

"Primary care physicians are often the first to encounter suspicious skin lesions, yet many lack significant training and confidence in dermatologic assessment," said Dr. Dan Siegel, Clinical Professor of Dermatology at SUNY Downstate and former President of the American Academy of Dermatology. "This study demonstrates how the non-invasive DermaSensor technology can significantly enhance diagnostic accuracy and empower clinicians to make more informed, confident decisions for their patients" [1,4].

Overview and Results of the Clinical Studies

The JAAD International study was conducted at UPMC and was the first investigator-initiated study ever conducted with DermaSensor in the United States. This independent, prospective study evaluated patients' lesions of concern among 150 dermatology patients and found [8]:

Sensitivity and specificity of the device were 100% and 9.4%, respectively, using Investigate Further vs Monitor as the cutpoint for positive vs negative. The publication also reported that sensitivity was 86.4% and specificity was 67.2% when considering 7-10 results as positive and 0-6 results as negative.

59.5% of the Investigate Further false positive results were still considered high risk lesions in that they were actively managed or treated by the study dermatologists.

Overall diagnostic accuracy, i.e., Area Under the Curve (AUC), was 0.79, which was identical to the AUC in the FDA pivotal study with over 1,000 patients and 22 primary care study centers [8].

"These results further confirm that the DermaSensor device maintains consistent performance, in this case at a new health system and in the dermatology setting with patients' suspicious lesions rather than primary care provider selected lesions," said Dr. Laura K. Ferris, MD, PhD, who was the study's Principal Investigator and is currently the Chair of Dermatology at UNC Chapel Hill. "This supports the device's role as an important adjunctive tool for triage and clinical decision-making, helping non-dermatologists identify high-risk lesions with improved performance and confidence."

The DERM-ASSESS III melanoma clinical utility study, published in JCAD, comprised of 118 PCPs that completed assessments of over 10,000 lesion cases. This study found that:

Physician AUC improved significantly with the use of DermaSensor, from 0.630 to 0.671 ($p = 0.036$) [1].

Melanoma detection increased from 70.2% to 79.1%, decreasing missed melanoma from 29.8% to 20.9% [1,5].

91.5% of the study physicians agreed the device added value to their clinical care [1].

75% agreed it would help detect more skin cancers [1,5].

71% reported increased confidence in evaluating skin lesions [1,8].

Clinical Significance

The DermaSensor solution offers rapid, objective assessment of skin lesions at the point of care, providing a 0-10 risk scale with “Investigate Further” or “Monitor” guidance within seconds for suspicious lesions [6,8]. Bridging gaps in dermatology access helps ensure timely evaluation of high-risk lesions while optimizing triage and resource allocation [1,3,5,8].

“By giving PCPs access to an AI-powered tool that objectively analyzes skin lesions in real time, we can help bridge the gap in dermatology access and ensure more patients receive timely, appropriate care,” said Dr. Falk, co-author and family medicine physician at Florida State University College of Medicine [1].

A Transformative Tool for the Future of Skin Cancer Detection

With rising skin cancer incidence nationwide, DermaSensor’s AI-powered, handheld device offers a scalable solution for improving detection, reducing unnecessary referrals, and enabling earlier intervention [2,5,8].

“This independent prospective UPMC study further reinforces that DermaSensor has strong and highly generalizable performance across different health systems and across the primary care and dermatology settings. Many published studies have shown that performance issues with generalizability and with skin of color are major shortcomings for image-based tools,” said Cody Simmons, CEO of DermaSensor. “Our spectroscopy-based system has already been used to test tens of thousands of lesions by several hundred doctors in the US, even though we just received FDA clearance last year. In the years to come, we look forward to our device helping tens of thousands of doctors to improve care for millions of patients.” [6,8]

About DermaSensor Inc.

DermaSensor Inc. is a Miami-based medical device company that enables healthcare professionals to effectively check for skin cancer by leveraging cutting-edge technologies. The DermaSensor™ device is a cost-effective handheld tool that uses artificial intelligence and spectroscopy to non-invasively test skin lesions for skin cancer risk in seconds. By enabling quick and effective skin cancer checks, DermaSensor ultimately hopes to improve skin cancer detection and save lives. DermaSensor is currently FDA Cleared, CE Marked, and is available for sale in the U.S.

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