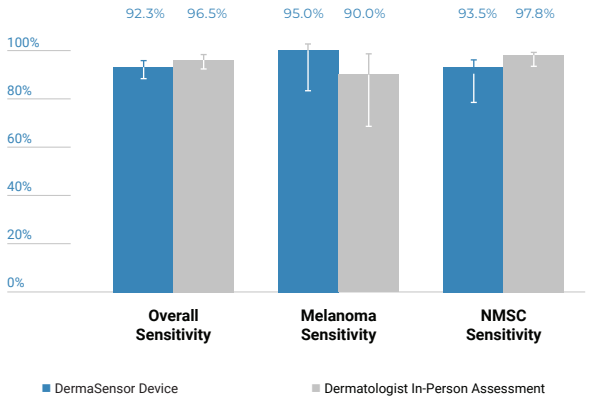
DermaSensor Optical Spectroscopy Technology

Safety and Effectiveness Results for DERM-ASSESS II Prospective, Multi-Centre Study[1,2]

Overall study performance summary:
Study reported no adverse events as well as no significant difference between DermaSensor's and dermatologists' sensitivity and specificity.



DermaSensor's sensitivity for melanoma was 95% while the study dermatologists' was 90%. For non-melanoma skin cancer (NMSC), i.e. BCC and SCC, DermaSensor's performance was 94% and the dermatologists' was 98%.[2]

- There were no adverse events, confirming the safety of this light-based, non-invasive device.[1,2]
- There was no statistical difference between the sensitivity of DermaSensor (92%) and dermatologists' (96%) nor between their specificity (32% and 37%, respectively) for lesions biopsied by the dermatologists per their standard of care.[2,3]
- DermaSensor's specificity was 45% for benign lesions assessed by the study dermatologists as being suggestive of skin cancer to non-specialist healthcare professionals.[2,4]
- As reported in Nature in 2019, "... most skin lesions are diagnosed by primary care doctors, and problems with inaccuracy have been underscored; if AI can be reliably shown to simulate experienced dermatologists, that would represent a significant advance."[5]
- DermaSensor's sensitivity results for melanoma, SCC and BCC were 95%, 93%, and 94%, respectively. Dermatologists' sensitivity results were 90%, 96% and 100%, respectively.[2,3]
- In a randomized, prospective study of DermaSensor utility with 57 GPs, these physicians made over 5,000 assessments of skin lesions. The study results showed that physicians' correctly referred or biopsied cancerous lesions 13 percent more when the DermaSensor output was available to them, compared to their evaluation with no device output.[6]
- DermaSensor increased physicians' cancer detection sensitivity from 81% to 94%, and this improvement was statistically significant (p = .0009).[6] There was no statistically significant change in the GP's specificity, or false positive rate, for benign lesions (p = .3558).[6]

DermaSensor Sensitivity Summary Table

Pathology	Study 002[7]	DERM-ASSESS II[2]	NZ IIS[9]
All skin cancers	**94%**	**92%**	**98%**
Melanoma	100%	95%	N/A[8]
SCC	93%	93%	100%
BCC	94%	94%	100%

DermaSensor Specificity Summary Table

Pathology	Skin specialist biopsied lesions of concerns (DA-II)[2]	GP lesions of concern		Patient lesions of concern[2]
		DA-II[2,4]	NZ IIS[9]	
All benign lesion	**32%**	**45%**	**47%**	**48%**
Benign nevi	50%	75%	60%	43%
Seborrheic Keratosis	38%	20%	52%	64%
AK	24%	50%	27%	43%
Benign Other	45%	61%	N/A[8]	33%

94%

Skin cancer detection results improved from 81% to 94% with use of the DermaSensor device.[6]

95-100%

DermaSensor's spectroscopy technology showed a 95-100% sensitivity for melanoma in two multi-year, multi-site prospective studies.[1,2,7]

[1]Benvenuto-Andrade C, Manolakos D, Cognetta AB. Safety and Effectiveness of Elastic Scattering Spectroscopy and Machine Learning in the Evaluation of Skin Lesions. Poster Presentation, World Congress of Teledermatology, Nov 2020. [2]Data on file, DermaSensor Inc. [3]For lesions biopsied in DERM-ASSESS II, dermatologist performance (i.e. dermatologist sensitivity and specificity) is based on the study dermatologists' in-person binary assessment of biopsied lesions as being malignant or benign, prior to receiving pathology results. [4]For unbiopsied lesions the dermatologists' clinical determination of the lesion as benign was used as the reference standard; however, for the dermatologists' clinical assessment there was no reference standard since no biopsies were performed and accordingly no specificity is reported for their evaluations.[5]Topol E. High-performance medicine: the convergence of human and artificial intelligence. Nature Medicine. 2019;25:44-66. [6]Tepedino K, Tablada A, Barnes E, Da Silva, T. Clinical Utility of a Handheld Elastic Scattering Spectroscopy Tool and Machine Learning on the Diagnosis and Management of Skin Cancer by Primary Care Physicians. Poster Presentation, SDPA Fall Conference, Nov 4-7, 2021. [7]Rodriguez-Diaz E, et al. Optical Spectroscopy as a Method for Skin Cancer Risk Assessment. Photochem Photobiol. 2019;95(6):1441-1445. [8]N/A: Where the sample size was less than 10 lesions, results for sensitivity and specificity were excluded due to small sample size. [9]Salmon P and Bonning M. Use of Elastic-scattering Spectroscopy and Machine Learning When Assessing Skin Lesions Suggestive of Skin Cancer, Poster Presentation, SDPA Fall Conference, Nov 4-7, 2021.

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DermaSensor NPV/PPV Performance Across Spectral Score Ranges 1-10

DermaSensor NPV/PPV Performance

Performance Metric	NZ IIS[9]	Patient-Select[2]
NPV	**99.5%**	**98.6%**
PPV	**18.2%**	**10.6%**
1-4 PPV	7.1%	8.6%
5-7 PPV	27.9%	12.5%
8-10 PPV	58.6%	66.7%

Indications for Use

The DermaSensor™ device is indicated for use as an objective tool to assist qualified healthcare professionals in evaluating skin lesions suggestive of melanoma, basal cell carcinoma, and/or squamous cell carcinoma. The DermaSensor device is intended to assist the user in deciding whether skin lesions require further clinical care and is not intended to be used for direct diagnosis of skin cancer. DermaSensor is only for use by qualified healthcare professionals appropriately trained in the assessment of skin lesions for cancer.

Risks

False-positive and false-negative results may lead to unnecessary care or to a malignant skin lesion not being optimally managed, respectively. However, it is important to note that biopsy is used to confirm pathology and that elastic scattering spectroscopy is to be used as an adjunctive tool to visual inspection and history-taking.

Device Sensitivity and Specificity for Detecting Malignant Lesions[9]

Performance Metric	Result	Exact 95% CI
Specificity	46.5% (211/454)	41.8% to 51.2%
Specificity Excluding AKs	52.6% (181/344)	47.2% to 58.0%
Sensitivity	98.2% (54/55)	90.3% to 100.0%

Device NPV and PPV with and without AKs for Detecting Malignant Lesions[9]

Performance Metric	Result	Exact 95% CI
NPV	99.5% (211/212)	97.4% to 100.0%
NPV Excluding AKs	99.5% (181/182)	97.0% to 100.0%
PPV	18.2% (54/297)	14.0% to 23.0%
PPV Excluding AKs	24.9% (54/217)	19.3% to 31.2%

Spectral Score Groupings 1-5 and 6-10[9]

Spectral Scores Groupings	PPV	Frequency of 'Investigate Further' Lesions
1-5	8.5%	76.8%
6-10	42.4%	23.2%

Spectral Score Groupings 1-4, 5-7 and 8-10[9]

Spectral Scores Groupings	PPV	Frequency of 'Investigate Further' Lesions
1-4	7.1%	64.2%
5-7	27.9%	28.7%
8-10	58.6%	7.1%

Publications

Clinical Utility of a Handheld Elastic Scattering Spectroscopy Tool and Machine Learning on the Diagnosis and Management of Skin Cancer by Primary Care Physicians
Tepedino K, Tablada A, Barnes E, Da Silva, T. (2021)

Use of Elastic-scattering Spectroscopy and Machine Learning When Assessing Skin Lesions Suggestive of Skin Cancer
Salmon P and Bonning M. (2021)

Safety and Effectiveness of Elastic Scattering Spectroscopy and Machine Learning in the Evaluation of Skin Lesions for Cancer
Benvenuto-Andrade, C., Manolakos, D., Cognetta, A.B. (2020)

Optical Spectroscopy as a Method for Skin Cancer Risk Assessment
Eladio Rodriguez-Diaz, Danielle Manolakos, Holly Christman, Michael A Bonning, John K Geisse, Ousama M A'Amar, David J Leffell, Irving J Bigio (2019)

Elastic Scattering Spectroscopy in Assessing Skin Lesions: An "In Vivo" Study
Tahwinder Upile, Waseem Jerjes, Hani Radhi, Jaspal Mahil, Anuja Rao, Colin Hopper (2011)

A New Tool to Inform Intra-Operative Decision Making in Skin Cancer Treatment: The Non-Invasive Assessment of Basal Cell Carcinoma of the Skin Using Elastic Scattering Spectroscopy
T Upile, Waseem Jerjes, O Johal, Simione Lew-Gor, J Mahil, Holger H Sudhoff (2012)

Elastic Scattering Spectroscopy in the Diagnosis of Pigmented Lesions: Comparison with Clinical and Histopathological Diagnosis
J. J. Scarisbrick, C. D. O. Pickard, Andrew C. Lee, Gavin M. Briggs, Kristie Johnson, Stephen G. Bown, Marco Novelli, M. R. S. Keshtgar, Irving J. Bigio, R. Yu (2003)

Comparison Between Ultraviolet-Visible and Near-Infrared Elastic Scattering Spectroscopy of Chemically Induced Melanomas in an Animal Model
Ousama M. A'amar, Ronald D. Ley, Irving J. Bigio (2004)

Spectroscopic Sensing of Cancer and Cancer Therapy: Current Status of Translational Research
Irving J Bigio, Stephen G Bown (2004)

Real-Time Pathology to Guide Breast Surgery: Seeing Alone is Not Believing
Irving J Bigio (2012)

The Color of Cancer: Margin Guidance for Oral Cancer Resection Using Elastic Scattering Spectroscopy
Gregory A Grillone, Zimmern Wang, Gintas P Krisciunas, Angela C Tsai, Vishnu R Kannabiran, obert W Pistey, Qing Zhao, Eladio RodriguezDiaz, Ousama M A'Amar, Irving J Bigio (2017)

Preoperative Discrimination of Benign From Malignant Disease in Thyroid Nodules With Indeterminate Cytology Using Elastic LightScattering Spectroscopy
Jennifer E Rosen, Hyunsuk Suh, Nicholas J Giordano, Ousama M Aamar, Eladio Rodriguez-Diaz, Irving I Bigio, Stephanie L Lee (2014)

Endoscopic Histological Assessment of Colonic Polyps by Using Elastic Scattering Spectroscopy
Eladio Rodriguez-Diaz, Qin Huang, Sandra R Cerda, Michael J O'Brien, Irving J Bigio, Satish K Singh (2014)

Skin Cancer: Precancers
Paul Bruner, Benjamin Bashline (2019)

DermaSensor™