
# Clinical Compendium 2025


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## Our Mission

DermaSensor's mission is to empower healthcare professionals with data-driven, breakthrough solutions that improve early skin cancer detection and save lives.

## Our solution

DermaSensor is a first-in-class, automated device that equips all physicians with the ability to non-invasively test skin lesions for cancer, providing them and their patients with an immediate, quantitative cancer risk result.

# Product Development Timeline

**2009**
Company founding

**2011**
Start of study for melanoma

**2015**
Start of study for all skin cancer types

**2018**
Completion of 4th generation device, start of studies for CE Mark

**2020**
CE Mark after completion of CE Mark studies, FDA Pivotal study start

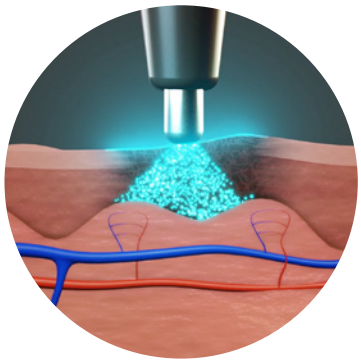
**2022**
FDA Pivotal study and supplemental studies complete

**Jan 2024**
FDA Clearance and US Launch in May

**2nd**
Generation 2016

**4th**
Generation 2018

# DermaSensor's AI-Powered Spectroscopy Technology



## Five Spectral Recordings

Xenon lamp pulses light to take five ~1mm optical tissue samples of cellular features.


## Algorithmic Analysis

The device receives and the algorithm analyzes spectral data across 47 different wavelengths, comparing each lesion's pattern of reflectance to patterns previously shown to indicate malignancy. Spectral signatures consistent with malignancy correspond to histopathology features, such as nucleus size, the presence of condensed chromatin, and melanocyte density.


## Objective, Quantitative Output

DermaSensor's algorithm analyzes spectral data and delivers assessment results within seconds. The output reports a spectral score, with higher scores corresponding to greater risks of malignancy. The AI algorithm was developed and validated on over 20,000 scans of over 4,000 benign and malignant lesions.

# Highlights of DermaSensor Study Results and Company "Firsts" For FDA Clearance

## Major Findings From Six Clinical Studies For Regulators

- 96% sensitivity for detecting all skin cancers[1]
- PCP unaided melanoma sensitivity of 69-70%, device melanoma sensitivity of 90-96%[2,3,5]
- Melanoma sensitivity and accuracy as high as expert dermatologists' in-person dermoscopic diagnosis; melanoma sensitivity comparable to or higher than that of dermatopathologists based upon study findings and from discordance rates In literature[3]
- Skin cancer sensitivity and accuracy higher than PCPs' assessments[5,6]
- Decreased PCPs' missed skin cancer referrals by 30-52%[6]
- Improved PCPs' accuracy for managing their confidence in assessing skin cancer[6]
- Ruled out 21-33% of benign lesions biopsied by physicians as being suspicious for skin cancer[3,5] and ruled out 61-77% of benign lesions that were suggestive of skin cancer to patients*[8]

## Major Product "Firsts" Achieved Upon FDA Clearance

- First FDA Breakthrough device for skin cancer
- First FDA De Novo skin cancer device
- First skin cancer device available to PCPs that provides any kind of automated risk assessment
- First automated skin cancer device indicated for use with all common skin cancers
- First/only currently available automated skin cancer device that uses light (i.e. optical or image-based device)**
- First medical device of any kind that uses ESS
- First automated skin cancer device that is simple to use (i.e. "point & click easy")

*This clinical study, called PATIENT-SELECT, Is considered an early effectiveness study by the FDA, not principal effectiveness evidence. PATIENT-SELECT was a screening-like study design of patient-selected lesions (i.e. not solely physician-selected lesions, per the indicated use). The overall device specificity was 61%, the specificity for pigmented lesions was 77%.

** MelaFind was approved (not cleared) by the FDA in 2011, and it is no longer available in the US.

# Experienced DermaSensor Leadership Team

**Maurice Ferre, MD**
**Chairman & Co-Founder**
Dr. Ferre is the current CEO of INSIGHTEC, the former CEO of MAKO Surgical (acquired by Stryker), and the former CEO of Visualization Technology (acquired by GE Healthcare). He has led the development and commercialization of several novel medical devices that have made a major impact on patient care around the world.

**Cody Simmons**
**CEO & Co-Founder**
Cody is a bioengineer and entrepreneur that has spent all of his career bringing new health technologies to physicians and patients. Prior to joining Maurice to build DermaSensor, Cody led commercial efforts for a Silicon Valley medical device screening startup and held BD and commercial strategy roles at Genentech.

**Carolyn Walsh**
**Chief Commercial Officer**
Carolyn is a healthcare executive with 25+ years experience across Fitbit Health Solutions, Qualcomm Life, Johnson & Johnson, and Coca-Cola, specializes in digital health innovation and commercial growth. She holds a BS from Northern Illinois University, MBA from Loyola University Chicago, and was named among 2023's Top 50 Women Leaders in Wellness and Fitness.

**Ryan Freiden**
**Chief Operating Officer**
Ryan has over 16 years experience founding and scaling companies in consumer goods, healthcare, and enterprise technologies. Recently, Ryan led the growth for a healthcare supply chain technology and previously.

**Justin Frazier**
**Vice President of Clinical Affairs**
Justin has been leading DermaSensor's clinical group since 2017, responsible for executing the company's pipeline of clinical studies. In his 17 years in Clinical Operations, Justin has worked with several medical device companies and CROs planning, implementing, and managing pre- and post-market medical device clinical studies. His previous employers include ReWalk Robotics, Smith & Nephew, Covidien/ Medtronic, Massachusetts General Hospital, and PAREXEL.

# DermaSensor Product and Clinical Highlights

**DermaSensor Inc.** is a health technology company designing non-invasive tools to better equip primary care physicians for skin cancer detection. The DermaSensor device is an affordable, handheld device that uses spectroscopy and algorithms to evaluate skin lesions for potential cancer in a matter of seconds.

Key publications in support of DermaSensor are summarized in the pages that follow.

Please contact **info@dermasensor.com** for additional information on clinical data for DermaSensor.

## Rapid & Reliable Results

- Non-Invasive, point-and-click spectral recordings
- Immediate, objective results

## Easy to Learn and Use

- Just 15 minutes of minutes total training time to use the device
- Only a 30 second process per lesion

## Clinically Effective

- 96% skin cancer detection sensitivity
- 2x as many cancers missed without device use

## Cost Efficient

- No capital cost
- One subscription. No hidden fees

# Device Indications for Use, Contraindications, Warnings and Precautions

Although the DermaSensor FDA pivotal validation study (DERM-SUCCESS included 1,579 lesions biopsied by primary care physicians, and a supplemental melanoma validation study (DERM-ASSESS III) was conducted with biopsied lesions in the dermatology setting, the device indication for use is non-dermatologist physicians since the FDA's clearance was based on a benefit-risk valuation limited to physicians who are not experts in the clinical diagnosis and management of skin cancer.

## INDICATIONS FOR USE

The DermaSensor™ device is indicated for use to evaluate skin lesions suggestive of melanoma, basal cell carcinoma, and/or squamous cell carcinoma in patients aged 40 and above to assist in the decision regarding referral of the patient to a dermatologist. The DermaSensor device should be used in conjunction with the totality of clinically relevant information from the clinical assessment, including visual analysis of the lesion, by physicians who are not dermatologists. The device should be used on lesions already assessed as suspicious for skin cancer and not as a screening tool. The device should not be used as the sole diagnostic criterion nor to confirm clinical diagnosis of skin cancer.

## CONTRAINDICATIONS

There are no known contraindications.

## WARNINGS

- Do not use for the direct diagnosis of skin cancer.
- Always wear gloves during use (or examination).
- Do not use under direct focused light, such as a surgical or examination light or headlamp.
- Do not point the tip of the Handheld Unit directly at the eye.
- Do not attempt to disassemble, repair, or modify the DermaSensor device in any way.
- Do not immerse the DermaSensor device in liquid.
- Do not put the DermaSensor device in an autoclave or low temperature sterilizer.
- Do not buff or use an abrasive cream cleanser that may scratch and damage the tip of the Handheld Unit.
- Do not simultaneously make contact with the patient while touching or holding the Base or power adapter.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the DermaSensor device, including cables specified by DermaSensor, Inc.; otherwise, degradation of the performance of this equipment could result.

## WARNINGS (CONTINUED)

- DermaSensor performance has not been assessed for the following types of lesions; thus, safety and effectiveness have not been established when:
  - » Lesion is not accessible to the DermaSensor device Handheld Unit and tip (e.g., inside ears, under nails).
  - » Lesion is on areas of psoriasis, eczema, acne, or similar inflammatory skin conditions that may impede appropriate DermaSensor device tip placement on the lesion.
  - » Lesion is greater than 15mm in diameter at the widest point.
  - » Lesion has a targeted area less than 2.5mm in diameter where the DermaSensor device tip cannot be placed entirely within the border of the targeted area of the lesion.
  - » Lesion has no contiguous area of at least 2.5mm due to ulceration, erosion or liquid discharge (e.g., blood).
  - » Lesion is covered by a crust or scale, and lesion surface can not be cleared of crust or scale such that there is a contiguous area of at least 2.5mm of cleared intact skin that is free of any crust, ulceration, erosion or liquid discharge (e.g., blood).
  - » Lesion is obstructed by foreign matter that can not be non-invasively removed (e.g., tattoo, splinter).
  - » Lesion is not completely cleared of (i.e., free of any remaining residue) dermoscopy oils, makeup, sunscreen, other topical solutions or powders, markings, and staining treatments (e.g., iodine).
  - » Lesion is located on acral skin (e.g., sole or palms).
  - » Lesion is located within 10mm of the eye.
  - » Lesion is on or adjacent to scars, areas previously biopsied, or areas subjected to any past surgical intervention.
  - » Lesion is located on mucosal surfaces (e.g. genitals, lips).
  - » Lesion is located in an area with acute sunburn.

## PRECAUTIONS

- Caution: United States Federal law restricts this device to sale to a or on the order of a physician.
- A complete assessment, including
  - » the visual evaluation of the lesion,
  - » clinical considerations such as the patient's ultraviolet light exposure history, and
  - » the patient and patient's family's skin cancer history should be considered, per standards of clinical care, in conjunction with DermaSensor results when making a formal clinical determination about a lesion.
- The performance of the device has not been specifically evaluated in patients with increased risk for skin cancer, e.g., inherited or drug-induced photo-sensitivity; genetic predisposition to melanoma or BCC; immune compromise; or other medical conditions that increase the risk of skin cancer or its metastasis.
- The device is intended to assist in clinical decisions related only to the skin malignancies melanoma (including severely atypical nevi), SCC, and BCC. It has been tested on each of these three common skin cancer types but has not been tested on rare skin cancer types; thus, it should not be used for lesions that are suggestive of malignancies other than melanoma, BCC and/or SCC.
- The device is intended for use on primary lesions only and has not been tested on lesions that are previously biopsied, recurrent, or metastatic; on scars, tattoos, sunburned skin, or within a hairy area (i.e., dense hair on the scalp); or which are located on palms, soles, mucosal surfaces, genitals, ears, within 1 cm of the eye, or under nails.
- Consistent with the lower prevalence of skin cancer in Fitzpatrick skin phototypes IV-VI, less data is available for sensitivity of the DermaSensor device for melanoma in these patients. The decision to refer patients with suspicious pigmented lesions in this group should be primarily based on clinical concern.
- Protect the tip of the Handheld Unit by storing the Handheld Unit in the Base when not in use.
- To maintain optimal device integrity, follow the cleaning and disinfection instructions before and after use.
- Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Use of this equipment adjacent to or stacked with other equipment should be avoided as it may result in improper operation. If such use is necessary, this equipment, and the other equipment, should be observed to verify that they are operating normally.
- Only use the included components and accessories provided as part of the DermaSensor medical equipment system.
- Connection to IT networks including other equipment could result in previously unidentified risks to patients, operators, or third parties. The user should identify, analyze, evaluate, and control these risks.
- Changes to the IT network (e.g., changes in network configuration, connection of additional items, disconnection of items, update of equipment, upgrade of equipment) could introduce new risks that require additional analysis.
- To avoid EMC disturbances, floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

# Glossary of Terms

| | |
|---|---|
| AUC | Area Under Curve |
| BCC | Basal Cell Carcinoma |
| EIS | Elastic Impedance Spectroscopy |
| ESS | Elastic Scattering Spectroscopy |
| FDA | Food and Drug Administration |
| IFU | Instructions for Use |
| NPV | Negative Predictive Value |
| NMSC | Non-melanoma skin cancers |
| PCP | Primary Care Physician |
| PLA | Pigmented Lesion Assay |
| PPV | Positive Predictive Value |
| SCC | Squamous Cell Carcinoma |

# Key Information Supporting DermaSensor Effectiveness

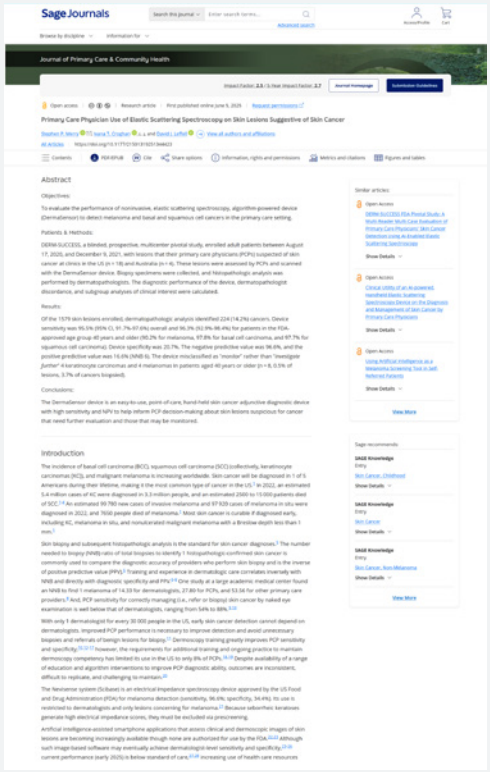
**The following studies are presented in the subsequent pages:**

- DERM-SUCCESS FDA Pivotal Study: Primary Care Physician Use of Elastic Scattering Spectroscopy on Skin Lesions Suggestive of Skin Cancer
- DERM-SUCCESS FDA Pivotal Study: A Multi-Reader Multi-Case Evaluation of Primary Care Physicians' Skin Cancer Detection Using AI-Enabled Elastic Scattering Spectroscopy
- Clinical Capabilities of a Handheld Elastic Scattering Spectroscopy - Artificial Intelligence Device as an Adjunctive Tool for Evaluating Skin Cancer in Skin of Color
- DERM-ASSESS III: Validation of a Handheld Elastic-Scattering Spectroscopy Device on Lesions Suggestive of Melanoma
- Skin Lesion Analyzers: Economic Impact of Integrating These Technologies into Dermatology Clinical Practice for Detecting Melanoma
- Summary of DermaSensor Early Clinical Effectiveness Studies

# DERM-SUCCESS FDA Pivotal Study: Primary Care Physician Use of Elastic Scattering Spectroscopy on Skin Lesions Suggestive of Skin Cancer

*Stephen P Merry[1], Ivana T Croghan[2], Kimberly A Dukes[3], Brian C McCormick[4], Gerard T Considine[5], Michelle J Duvall[1], Curtis T Thompson[6], David J Leffell[7]*

***1** Department of Family Medicine, Mayo Clinic, Rochester, MN, USA. **2** Department of Internal Medicine, Division of General Internal Medicine, Mayo Clinic, Rochester, MN, USA. **3** Department of Biostatistics, Boston University School of Public Health, Boston, MA, USA. **4** Hampton Family Practice, Hampton, VA, USA. **5** Clare Medical Centre, Clare, SA, Australia. **6** Department of Dermatology and Department of Pathology, Oregon Health & Science University, Portland, Oregon, USA; CTA Pathology: Curtis Thompson, MD & Associates, Beaverton, OR, USA. **7** Department of Dermatology, Section of Dermatologic Surgery and Cutaneous Oncology, Yale School of Medicine, New Haven, CT, USA.*




Link to Publication

## Objective

This study investigated the sensitivity and specificity of a noninvasive, hand-held DermaSensor in evaluating skin lesions compared to the in-person clinical evaluation by primary care physicians (PCPs).

## Trial Design

This blinded, prospective, multi-center study was conducted at 22 primary care study sites across the United States (18 sites) and Australia (4 sites). Patients with lesions suggestive of skin cancer were clinically assessed by PCPs and then evaluated by the DermaSensor. Patients and PCPs were blinded to device output. All lesions enrolled were biopsied per physician assessments and standard of care. Each lesion's diagnosis involved 2-5 dermatopathologists, dependent on pathology and discordance. Statistical analyses after study unblinding included standard diagnostic test parameters of the device for detecting skin cancer as well as the influence of lesion and patient factors on device performance.

## Enrollment

During study enrollment, five lesions (0.3%) were excluded due to device data capture issues and five lesions (0.3%) due to lack of dermatopathology consensus. A total of 1,005 patients with 1,579 lesions suggestive of skin cancer were enrolled. Among the patients enrolled, 51.4% were female with a mean age of 59 years, and 72.5% of patients were Fitzpatrick Skin Type I-III.

## Results and Conclusions

The DermaSensor device is an easy-to-use, point-of-care, hand-held skin cancer adjunctive diagnostic device with high sensitivity and NPV to help inform PCP decision-making about skin lesions suspicious for cancer that need further evaluation and those that may be monitored. Coupled with clinical exam findings, this device may aid PCPs to improve clinical decisions about suspicious skin lesions (i.e., to refer, or monitor), with this study suggesting device use could rule out 20.7% of suspicious lesions from needing further evaluation. With the device PPV reaching as high as 61%, the device can also help inform which lesions merit urgent evaluation by dermatologists.

## Key Findings

- DermaSensor demonstrated high sensitivity of 95.5% in detecting all skin cancer types when compared to the gold standard of histopathologic examination, with similar sensitivity and specificity across all Fitzpatrick skin type subgroups.
- NPV of the device was 96.6%, meaning a negative "monitor" device result had only a 3.4% chance of being a false negative, i.e. any of the three cancer types.
- The overall positive predictive value (PPV) for an "investigate further" result was 16.6% (NNB of 6:1).
- The device sensitivity and overall accuracy (i.e. AUC) were both found to be superior to those of the PCPs
- By pairing high sensitivity with clinical exam findings, the device may rule out 20.7% of lesions from needing further evaluation, reducing patient anxiety and optimizing healthcare resource allocation
- Likelihood of malignancy increased significantly with increasing spectral scores. For scores of 1-3, PPV was 6%, which increased to 18% for scores of 4-7 and 40% for scores of 8-10.

# DERM-SUCCESS FDA Pivotal Study: A Multi-Reader Multi-Case Evaluation of Primary Care Physicians' Skin Cancer Detection Using AI-Enabled Elastic Scattering Spectroscopy

*Laura K Ferris[1], Erik Jaklitsch[2], Elizabeth V Seiverling[2,3], Thomas Agresta[4], Peggy Cyr[5], Laurie Caines[6], Na Wang[7], Daniel M Siegel[8]*

***1*** *Department of Dermatology, University of North Carolina, Chapel Hill, USA.* ***2*** *University of Pittsburgh School of Medicine, PA, USA.* ***3*** *Tufts University School of Medicine, Boston, MA, USA.* ***4*** *University of Connecticut School of Medicine, Farmington, USA.* ***5*** *Department of Family Medicine, Maine Medical Center, Portland, USA.* ***6*** *UConn Health, Farmington, CT, USA.* ***7*** *Biostatistics and Epidemiology Data Analytics Center, Boston University, MA, USA.* ***8*** *SUNY Downstate Health Sciences University, Brooklyn, USA.*

Original Research

DERM-SUCCESS FDA Pivotal Study: A Multi-Reader Multi-Case Evaluation of Primary Care Physicians' Skin Cancer Detection Using AI-Enabled Elastic Scattering Spectroscopy

Laura K. Ferris[1], Erik Jaklitsch[2], Elizabeth V. Seiverling[2,3], Thomas Agresta[4], Peggy Cyr[5], Laurie Caines[6], Na Wang[7], and Daniel M. Siegel[8]

Abstract

**Background:** Elastic Scattering Spectroscopy (ESS), an optical tissue sampling technique, distinguishes between benign and malignant tissue in vivo without the need to perform a surgical biopsy. A handheld device that employs ESS enabled with an artificial intelligence algorithm was developed as an objective tool to aid primary care physicians (PCPs) in their management of lesions suspicious for skin cancer. The aim of this study was to assess and compare the diagnostic and management performance of PCPs with and without the use of the ESS device in detecting skin cancer.

**Methods:** In this clinical utility study, 108 PCPs evaluated 100 skin lesion cases (50 aided with the device output and 50 unaided by the device). For each case, PCPs provided a diagnosis, management decision, and level of confidence in that decision initially without, and then subsequently with, device output. Sensitivity, specificity, AUC, and confidence in their assessment prior to, and then with, device output were compared.

**Results:** With visual assessment assisted by device output, diagnostic sensitivity increased significantly from 71.1% to 81.7% (P= .0085) and referral sensitivity increased significantly from 82.0% to 91.4% (P= .0027) compared to visual assessment only. Device-aided diagnostic specificity decreased from 60.9% to 54.7% (P= .1896), and referral specificity decreased from 44.2% to 32.4% (P= .0256). Overall management performance (ie, AUC) also increased from 0.708 to 0.762, and increased from 0.567 to 0.682 for lesions which physicians reported low confidence in their unassisted management decision. Physicians reporting high confidence in their management assessment increased from 36.8% to 53.4%.

**Conclusion:** Use of the ESS device output by PCPs significantly improved their diagnostic and management sensitivities as well as their overall management performance. The findings suggest the ESS device can improve PCP skin cancer detection and confidence in their skin lesion evaluation and management.

Keywords

melanoma, squamous cell carcinoma, basal cell carcinoma, artificial intelligence, machine learning, skin cancer, technology, diagnostic tools, elastic scattering spectroscopy

Introduction

Skin cancer is the most common malignancy in the U.S.[1] The most common skin cancers are basal cell carcinomas (BCC) and squamous cell carcinomas (SCC), which arise from keratinocytes in the epidermis and are collectively referred to as keratinocyte carcinomas (KCs); approximately 5.4 million are diagnosed in the U.S. each year.[2,3] Melanoma, the next most common type of skin cancer, has lower incidence but higher risk of mortality than KCs; in 2023, an estimated 186 680 new cases are expected to be diagnosed in the U.S.[1,2] In the U.S., approximately 7990 people die from melanoma and 8000 die from KCs each year.[3,4,5] Most skin

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Link to Publication

## Objective

The aim of this study was to assess and compare the diagnosis and management performance of primary care physicians (PCPs) with and without the use of the handheld DermaSensor in detecting skin cancer.

## Trial Design

In this clinical utility study, 108 PCPs evaluated 50 skin lesions (25 malignant, 25 benign), with and without ESS device output. For each case, high-resolution digital clinical images, the patient's clinical information, including prior skin cancer history, risk factors, and physical examination results were provided. The PCPs completed a questionnaire about their diagnosis of the lesion, their recommended management decision, and their confidence level in their management decision for each case.

Sensitivity and specificity of PCP diagnostic and management with and without the device output were calculated.

## Enrollment

PCP participants included U.S. board-certified internal and family medicine physicians with an even distribution of years in practice (range:1-21+ years). PCPs were recruited from across the U.S., including urban and rural areas.

## Results and Conclusions

Management sensitivity increased significantly from 82.0% to 91.4% (p=0.003) with device output. Thus, PCPs' false negative referrals decreased from 18.0% to 8.6%, a relative decrease in false negatives of 52%. Diagnostic sensitivity increased significantly from 71.1% to 81.7% with device output (p=0.008). Specificity was found to decrease non-significantly from 60.9% to 54.7% (p=0.190) for diagnosis and 44.2% to 32.4% (p=0.026) for referrals. Additionally, the effectiveness analyses observed an increase in PCPs' overall diagnostic performance (i.e. AUC) and confidence level in their management decisions with the use of the handheld DermaSensor. This technology improves sensitivity and inherent validity of skin cancer diagnosis and management. The use of the ESS device in a primary care setting is further supported by a reduction in the subjectivity of the PCPs regarding their evaluations and the limited training required for its use, as well as the increased diagnostic and management performance.

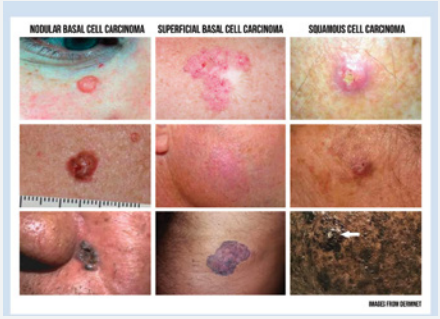
## Key Findings

- Improvement in Sensitivity: Management sensitivity increased significantly from 82.0% to 91.4% (p=0.003) with device output. Diagnostic sensitivity increased significantly from 71.1% to 81.7% with device output (p=0.008). Specificity decreased non-significantly to 60.9% to 54.7% (p=0.190) for diagnosis and 44.2% to 32.4% (p=0.026) for referrals.
- 52% False Negative Reduction: Skin cancer referrals decreased from 18.0% to 8.6% with device use, a relative decrease of 52%.
- Improvement in Physician Confidence: Physicians reporting high confidence in their management assessment increased from 36.8% to 53.4%.
- Improvement in Area-Under-the-Curve: Overall management performance (i.e., AUC) increased from 0.708 to 0.762, and it increased from 0.567 to 0.682 for lesions which physicians reported low confidence in their unassisted management decision.

# Clinical Capabilities of a Handheld Elastic Scattering Spectroscopy - Artificial Intelligence Device as an Adjunctive Tool for Evaluating Skin Cancer in Skin of Color

*Genevieve Patrick[1], David Leffell, MD[2], Stephen P Merry, MD[3], Ivana Croghan, PhD[3], Harold Rabinovitz, MD[4], Armand Cognetta, MD[5]*

***1** Florida State University College of Medicine, **2** Yale University School of Medicine, **3** Mayo Clinic, **4** Medical College of Georgia, **5** Florida State University Department of Micrographic Surgery and Dermatology Oncology*




Consistent with the lower prevalence of skin cancer in Fitzpatrick skin phototypes IV-VI, less data is available for sensitivity of the DermaSensor device for melanoma in these patients.

**Link to Publication**

## Objective

To evaluate DermaSensor's performance in patients with skin of color, this sub-analysis of the DERM-SUCCESS study compared device sensitivity and specificity in patients of Fitzpatrick skin type I-III and IV-VI subgroups.

## Trial Design

In total, 1,579 lesions from 1005 patients were enrolled in the study. All Fitzpatrick skin types were represented with 72.5% of individuals characterized as Fitzpatrick skin types I-III and IV-VI.

Lesions suggestive of skin cancer were clinically assessed by primary care physicians (PCPs) and scanned by the DermaSensor device.

Limitations of this study involve the unknown impact of the device on the clinical decision to biopsy lesions in skin of color as the study was designed to be double-blinded. Additionally, the sample size for various malignant pathologies across all skin types as well as the racial and ethnic diversity of the study population were limited.

## Enrollment

Double-blinded, prospective, multi-center study; 22 primary care study sites across the, U.S. (18 sites) and Australia (4 sites)

## Results and Conclusions

The DermaSensor demonstrated a high sensitivity of 95.5% in detecting all skin cancer types when compared to histopathologic examination. Additionally, the device correctly classified 20.7% of biopsied benign lesions.

Overall sensitivity was similar between Fitzpatrick skin types I-III and IV-VI, with 96.5% (95% CI: 92.1-98.5%) and 92.2% (95% CI: 82.1-96.8%), respectively. Sensitivity was consistent across Fitzpatrick skin types.

There was little variation in device sensitivity or specificity when comparing patients based on Fitzpatrick skin type subgroups. This is in line with ESS functionality being unaffected by the underlying melanin content of the skin.

Unlike image-based tools which are subject to skin-type bias, the DermaSensor has the potential to augment PCPs exams and improve skin cancer detection capabilities across skin types.

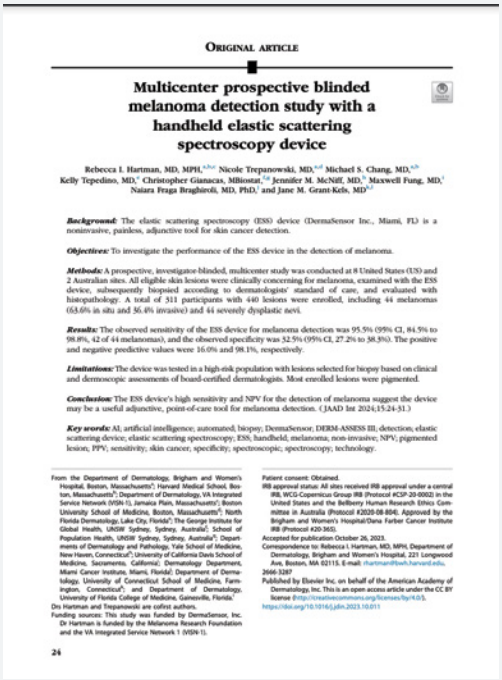
## Key Findings

- Unlike tools that use clinical and/or dermoscopic images, which many publications have shown are subject to skin type bias, skin color has not been found to impact DermaSensor results which has the potential to augment PCPs exams and improve skin cancer detection capabilities across skin types.
- Overall sensitivity was similar between Fitzpatrick skin types I-III and IV -VI, with 96.5% (95% CI: 92.1-98.5%) and 92.2% (95% CI: 82.1-96.8%), respectively. Sensitivity was consistent across Fitzpatrick skin types.
- The specificity of the DermaSensor for Fitzpatrick skin types I-III was 18.7% (95% CI: 16.2-21.5%) and 25.1% (95% CI 20.9-29.7%) for types IV-VI. The device has the potential to avoid 18.7% to 25.1% of unnecessary care that was provided for suspicious yet benign lesions.

# DERM-ASSESS III: Validation of a Handheld Elastic-Scattering Spectroscopy Device on Lesions Suggestive of Melanoma

*Rebecca I. Hartman, MD MPH[1]; Nicole Trepanowski, MD[2]; Michael S. Chang, MD[3]; Kelly Tepedino, MD[4]; Christoper Gianacas, MBiostat[5]; Jennifer M. McNiff, MD[6]; Maxwell Fung, MD[7]; Naiara Fraga Braghiroli, MD, PhD[8]; Jane M. Grant-Kels, MD[9]*

***1*** *Brigham and Women's Hospital, USA* ***2*** *Harvard Medical School, USA* ***3*** *VA Integrated Service Network (VISN-1), USA* ***4*** *Boston University School of Medicine, USA* ***5*** *North Florida Dermatology, USA* ***6*** *The George Institute for Global Health, Australia* ***7*** *School of Population Health, Australia* ***8*** *Yale School of Medicine, USA* ***9*** *UC Davis, USA* ***10*** *Miami Cancer Institute, USA* ***11*** *University of Connecticut, USA* ***12*** *UF College of Medicine, USA*



ORIGINAL ARTICLE

**Multicenter prospective blinded melanoma detection study with a handheld elastic scattering spectroscopy device**

Rebecca I. Hartman, MD, MPH,[a,b,c] Nicole Trepanowski, MD,[a,c,d] Michael S. Chang, MD,[e,b] Kelly Tepedino, MD,[f] Christopher Gianacas, MBiostat,[f,g] Jennifer M. McNiff, MD,[h] Maxwell Fung, MD,[i] Naiara Fraga Braghiroli, MD, PhD,[j] and Jane M. Grant-Kels, MD[k,l]

**Background:** The elastic scattering spectroscopy (ESS) device (DermaSensor Inc., Miami, FL) is a noninvasive, painless, adjunctive tool for skin cancer detection.

**Objectives:** To investigate the performance of the ESS device in the detection of melanoma.

**Methods:** A prospective, investigator-blinded, multicenter study was conducted at 8 United States (US) and 2 Australian sites. All eligible skin lesions were clinically concerning for melanoma, examined with the ESS device, subsequently biopsied according to dermatologists' standard of care, and evaluated with histopathology. A total of 311 participants with 440 lesions were enrolled, including 44 melanomas (63.6% in situ and 36.4% invasive) and 44 severely dysplastic nevi.

**Results:** The observed sensitivity of the ESS device for melanoma detection was 95.5% (95% CI, 84.5% to 98.8%, 42 of 44 melanomas), and the observed specificity was 52.5% (95% CI, 27.2% to 58.3%). The positive and negative predictive values were 16.0% and 98.1%, respectively.

**Limitations:** The device was tested in a high-risk population with lesions selected for biopsy based on clinical and dermoscopic assessments of board-certified dermatologists. Most enrolled lesions were pigmented.

**Conclusion:** The ESS device's high sensitivity and NPV for the detection of melanoma suggest the device may be a useful adjunctive, point-of-care tool for melanoma detection. (JAAD Int 2024;15:24-31.)

**Key words:** AI; artificial intelligence; automated; biopsy; DermaSensor; DERM-ASSESS III; detection; elastic scattering device; elastic scattering spectroscopy; ESS; handheld; melanoma; non-invasive; NPV; pigmented lesion; PPV; sensitivity; skin cancer; specificity; spectroscopic; spectroscopy; technology.

From the Department of Dermatology, Brigham and Women's Hospital, Boston, Massachusetts[a]; Harvard Medical School, Boston, Massachusetts[b]; Department of Dermatology, VA Integrated Service Network (VISN-1), Jamaica Plain, Massachusetts[c]; Boston University School of Medicine, Boston, Massachusetts[d]; North Florida Dermatology, Lake City, Florida[e]; The George Institute for Global Health, UNSW Sydney, Sydney, Australia[f]; School of Population Health, UNSW Sydney, Sydney, Australia[g]; Departments of Dermatology and Pathology, Yale School of Medicine, New Haven, Connecticut[h]; University of California Davis School of Medicine, Sacramento, California[i]; Dermatology Department, Miami Cancer Institute, Miami, Florida[j]; Department of Dermatology, University of Connecticut School of Medicine, Farmington, Connecticut[k]; and Department of Dermatology, University of Florida College of Medicine, Gainesville, Florida.[l]

Drs Hartman and Trepanowski are cofirst authors.

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Correspondence to: Rebecca I. Hartman, MD, MPH, Department of Dermatology, Brigham and Women's Hospital, 221 Longwood Ave, Boston, MA 02115. E-mail: rhartman@bwh.harvard.edu.

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Link to Publication

## Objective

This study aimed to validate whether the use of an ESS point-of-care test can detect melanoma when dermatologists are evaluating lesions that were concerning for melanoma.

## Trial Design

Ten dermatology study centers, across the US and Australia, scanned lesions that they found concerning for melanoma. All dermatologists were blinded to the device results. Gold standard comparison for performance of the device and dermatologists was the biopsy result with multiple dermatopathologist review when consensus was not reached during the primary review process. High resolution digital images and the patient's clinical information, including prior skin cancer history, risk factors and physical exam results, were recorded for each case. After clinical evaluation, dermatologists reported their diagnosis and confidence level, which provided the physician comparison data. The results evaluated were sensitivity, specificity, Negative Predictive Value for melanoma, melanoma + severely atypical nevi, and all high-risk lesions. Area Under the Curve (AUC) was also calculated and modeled and compared between the study dermatologists and the device performance.

## Enrollment

A total of 311 patients with 440 biopsied lesions were evaluated by the study dermatologists, device and dermatopathology results.

## Results and Conclusions

The use of the handheld DermaSensor by physicians, in addition to clinical evaluation, may improve melanoma detection. The device was able to identify 96% of melanomas when compared to dermatopathology results.

While this study was conducted by melanoma specialists, given the device's similar overall performance to these specialists and its simple, non-invasive use, there is potential for the device to be used to help rule in or out lesion referrals for primary care physicians.

## Key Findings

- The 10 dermatology study centers biopsied all lesions that were suspicious of melanoma based on their standard of care clinical and dermoscopic assessment and decision making.
- DermaSensor was able to identify 96% of melanomas when compared to dermatopathology consensus results (at least two dermatopathologists reviewed each high-risk melanocytic lesion case); for both melanomas and several atypical nevi, the device sensitivity was 91%.
- Overall device specificity was 33%, thus DermaSensor could have effectively ruled out 33% of benign biopsied lesions as benign while detecting 96% of melanomas.
- The overall negative predictive value (NPV) for a "monitor" result was 98% for melanoma, i.e. a negative result had less than a 2% chance of being melanoma. The positive predictive value (PPV), i.e. the likelihood a lesion was melanoma for a positive "investigate further" result, was 10% for low 1-3 scores (NNB of 10:1), 21% for mid 4-7 scores (NNB of 5:1), and 47% for high 8-10 scores (NNB of 2.1:1).
- The overall device accuracy (i.e. Area Under the Curve or AUC) of 0.76 was comparable to that of 0.75 for the Dermatologists.

# Enhancing Diagnostic Precision in Primary Care: A Multireader Multicase (MRMC) Study of an AI-Powered Handheld Elastic Scattering Spectroscopy Device for Informed Referral Decisions in Melanoma Evaluation

*Elizabeth V. Seiverling, MD[1]; Asghar Shah, BA[2]; Martin A. Weinstock, MD, PhD[3]; Jane M. Grant-Kels, MD[4]; Nathan P. Falk, MD, MBA[5]; And Daniel M. Siegel, MD[6]*

***1** University of Pittsburgh in Pittsburgh, Pennsylvania **2** Warren Alpert Medical School of Brown University in Providence, Rhode Island. **3** Brown University and the Providence VA Medical Center in Providence, Rhode Island. **4** Department of Dermatology at the University of Connecticut School of Medicine in Farmington, Connecticut and the Department of Dermatology at the University of Florida College of Medicine in Gainesville, Florida. **5** Department of Family Medicine and Rural Health at Florida State University College of Medicine in Tallahassee, Florida. **6** SUNY Downstate Health Sciences University in Brooklyn, New York.*

ORIGINAL RESEARCH

**Enhancing Diagnostic Precision in Primary Care:** A Multireader Multicase (MRMC) Study of an AI-Powered Handheld Elastic Scattering Spectroscopy Device for Informed Referral Decisions in Melanoma Evaluation

by ELIZABETH V. SEIVERLING, MD; ASGHAR SHAH, BA; MARTIN A. WEINSTOCK, MD, PhD; JANE M. GRANT-KELS, MD; NATHAN P. FALK, MD, MBA; and DANIEL M. SIEGEL, MD

**BACKGROUND:** Skin cancer is the most common cancer faced by adults in the United States. Melanoma, while a less common subtype of skin cancer compared to basal cell and squamous cell carcinomas, is associated with greater rates of metastases, mortality, and morbidity, and its rate of incidence is projected to increase. Primary care physicians (PCPs) can play an important role in skin cancer detection and in the decision to refer a patient to a dermatologist. Technologies such as the elastic scattering spectroscopy (ESS) device (DermaSensor, Inc.), a handheld, noninvasive assistive tool, may help in the evaluation of a skin growth and improve appropriate referral decision making. **METHODS:** A total of 50 malignant and 50 benign lesions were assessed by each of the 118 physicians (board-certified internal and family medicine physicians), yielding 5,900 malignant and benign lesion assessments without the device and 5,900 with the ESS device. Physicians were also surveyed regarding their confidence in their management decision. **RESULTS:** The study met the primary endpoint; the area under the receiver operating characteristic (AUROC) of the PCPs aided with the device was 0.671 (95% confidence interval [CI]: 0.611-0.732) compared with the AUROC unaided by the device of 0.630 (95% CI: 0.582-0.678), a significant increase (p=0.036). When asked whether the device would provide value to their decision making, 91.5% of respondents either agreed or strongly agreed. **CONCLUSION:** The ESS device improved PCP accuracy in managing lesions suggestive of melanoma and increased their sensitivity for all skin cancers and melanoma. Participating internal medicine and family medicine physicians reported increased confidence in their assessments with the device. The ESS device can improve PCP decision making when managing lesions suggestive of melanoma. **KEYWORDS:** Primary care, elastic scattering spectroscopy, melanoma, skin cancer detection

Skin cancer is the most common type of cancer in the United States (US), and, compared to basal cell and squamous cell cancers, melanoma has the highest mortality rate.[1] Melanoma is projected to become the second most common cancer in the US by 2040 with 219,000 cases.[2] Early detection reduces the likelihood of disease-specific morbidity and mortality.[3] However, there are drastic shortages of dermatologists,[4] and patients often seek care for dermatologic conditions in the primary care setting.

While the American Academy of Family Physicians includes some skin cancer detection training as an important part of all family medicine resident training, access to training can be limited and many primary care physicians (PCPs) feel ill-equipped to evaluate skin growths.[5]

Recent advances have been made in artificial intelligence (AI) technology to improve melanoma detection and have the potential to aid PCPs in the evaluation of skin growths.[6-8] Efforts to implement AI algorithms for melanoma detection have also been applied in primary cancer screening.[9] One such AI-based tool that has been investigated and cleared by the US Food and Drug Administration (FDA) is the elastic scattering spectroscopy (ESS) device (DermaSensor, Inc.), a handheld, noninvasive, and painless assistive tool for skin cancer detection. In a prospective multicenter study, the ESS device exhibited a sensitivity of 97.04% in detecting skin cancer lesions, including a sensitivity of 96.67% for melanoma, with sensitivity and accuracy (ie, area under the curve) found to be comparable to dermatologists' in-person performance, which holds promise for improving PCPs' ability to assess suspicious lesions and appropriately refer suspicious lesions to dermatologists.[10] Results of the DermaSensor Use in the Assessment of Skin Lesions Suggestive of Melanoma III (DERM-ASSESS III) study, a prospective blinded melanoma validation study, demonstrated similar findings for device sensitivity and accuracy compared to dermatologists, reporting that the ESS device had a

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CORRESPONDENCE: Asghar Shah, BA; Email: asghar_shah@brown.edu

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Link to Publication

## Objective

Given the importance of PCP decision making regarding lesions suspicious of skin cancer, particularly melanoma, it is postulated that use of the ESS device may assist PCPs in referral decision making and enhance provider confidence in managing these cases. Here, we describe the findings of a multireader multicase (MRMC) study to assess the referral performance of PCPs when evaluating lesions suggestive of melanoma with and without the aid of the ESS device.

## Trial Design

This melanoma-focused reader study was a web-based, MRMC investigation using clinical information, digital images, and ESS device result data. PCPs were asked to perform 200 reads for 100 skin lesion cases, each presented without and then with ESS device output. The study examined two aspects of PCP decisions concerning skin evaluation using the device: (1) the impact of the device result on the PCPs' management decision on whether the lesion should be referred for further evaluation by a dermatologist, and (2) the device's impact on the PCP's diagnostic assessment of whether the lesion was malignant or benign.

## Enrollment

A total of 118 PCP readers, none of whom participated in prior studies pertaining to the device, completed the study and were eligible for the effectiveness analysis.

## Results and Conclusions

The study met the primary endpoint; the area under the receiver operating characteristic (AUROC) of the PCPs aided with the device was 0.671 compared with the AUROC unaided by the device of 0.630, a significant increase (p=0.036).

The device significantly improved physicians' accuracy in managing lesions suggestive of melanoma, as well as significant increases in sensitivity for all skin cancers and melanoma, while not significantly raising the rate of unnecessary referrals. Moreover, the physicians reported increased confidence in their assessments with the availability of the device result. As such, the device can improve PCP decision making and confidence when managing lesions suggestive of melanoma.

By enhancing PCP management accuracy and confidence, this FDA-approved device has the potential to optimize resource utilization by minimizing unnecessary referrals and biopsies, saving healthcare dollars, and reducing patient morbidity and concern, while helping to prioritize access for patients with high-risk lesions. Given the rising rates of skin cancer in the US and limited access to dermatologic care, this device has the potential to make a significant impact in skin cancer detection in the primary care setting.

## Key Findings

- The study met the primary endpoint, and a statistical test for superiority found that physicians device-aided accuracy (i.e. AUROC) was significantly higher than the unaided accuracy.
- Aided PCP AUROC increased 4.1% for all skin cancers, achieving non-inferiority ($p<0.001$) and superiority ($p=0.036$)
- Aided PCP sensitivity for all skin cancers increased 8.1%, achieving non-inferiority ($p<0.001$) and superiority ($p<0.001$)
- Aided PCP sensitivity for melanoma increased 8.8%, achieving non-inferiority ($p<0.001$) and superiority ($p<0.001$)
- Aided PCP specificity decreased by 5.6%, achieving its non-inferiority margin ($p<0.001$)

# Prospective Evaluation of an AI-enabled Elastic Scattering Spectroscopy Device for Triage of Patient-identified Skin Lesions in Dermatology Clinics

*Erik Jaklitsch MD[1], Selina Chang BS[1], Sabrina Bruno BS[1], Nicholas D'Angelo BS[1], Joe K. Tung MD[1,2], Laura K. Ferris MD, PhD[2,3]*

***1*** *University of Pittsburgh School of Medicine, Pittsburgh, Pennsylvania* ***2*** *Department of Dermatology, University of Pittsburgh, Pittsburgh, Pennsylvania* ***3*** *Department of Dermatology, University of North Carolina, Chapel Hill, North Carolina*

RESEARCH LETTER

**Prospective evaluation of an AI-enabled elastic scattering spectroscopy device for triage of patient-identified skin lesions in dermatology clinics**

*To the Editor.* Early detection of skin cancer holds promise for reducing mortality and surgical morbidity.[1] However, wait time for suspicious lesions can be long, and although many patient-identified lesions are benign, initial skin cancer presentations are often first noticed by patients.[2,3] A highly sensitive Elastic Scattering Spectroscopy (ESS) device integrated with artificial intelligence (AI) utilizing spectral scans was cleared for adjunct usage in primary care and is the only FDA-cleared tool for evaluating all 3 common types of skin cancer (melanoma, basal cell carcinoma [BCC], and squamous cell carcinoma [SCC]).

This investigator-initiated, matched comparison study aims to evaluate device performance on patient-identified lesions in a dermatology setting to assess its utility for screening lesions appropriate for referral across clinical contexts. We prospectively evaluated 150 patients presenting with self-identified lesions of concern to 3 outpatient dermatology offices. Diagnostic accuracy of device readout (classifying lesions as either "Monitor," alone, or "Investigate Further," alongside a score of 1 to 10, indicating spectral similarity to malignant tissue) was compared to blinded dermatologist management decisions and histopathology.

The study included 150 lesions in 72 males and 78 females, with a mean age of 59.6 years. Malignant lesions were identified in 14.7% of cases (22/150), with melanoma, BCC, and SCC accounting for 3, 9, and 10, respectively (Table I). The ESS device identified 138 lesions as "Investigate Further" and 12 as "Monitor." Sensitivity for detecting malignant lesions was 100%, negative predictive value (NPV) was 100%, specificity was 9.4%, and positive predictive value (PPV) was 15.9%. For lesions with a spectral score of 7 to 10, sensitivity was 86.4%, NPV 96.6%, with specificity increasing to 67.2% and PPV to 31.1%. Compared to dermatologists' decisions, sensitivity was 95.5%, NPV 75%, specificity 10.7%, and PPV 45.7% (Table II). Overall AUC of the device compared to malignant lesions was 0.79 (Supplementary Fig 1, available via Mendeley at https://data.mendeley.com/datasets/vpxw849f6p/1), identical to a validation study in primary care.[4] Frequency counts of benign and malignant lesions compared to corresponding spectral score are also visualized (Supplementary Fig 2, available via Mendeley at https://data.mendeley.com/datasets/vpxw849f6p/1).

These results demonstrate that the ESS device maintains robust sensitivity and NPV for detecting malignant lesions, even in a dermatology setting with patient-identified lesions, and support its role as an adjunctive rule-out tool in skin cancer triage. Despite a relatively low specificity (9.4%) and PPV (15.9%), most false positive results (59.5%) were actively managed by dermatologists through biopsy or treatment. Furthermore, given dermatologist assessment was used as the gold standard, all unbiopsied lesions had a biased specificity of 100%. Spectral score was a reliable positive predictor of malignancy, with those results (using a threshold of spectral score 7 to 10 for

Table I. Patient demographics, research for concern, lesion location, classification, and dermatologist management decision

| | |
|---|---|
| Patient demographics | n (%) |
| Sex (male) | 72 (48.0) |
| Sex (female) | 78 (52.0) |
| Age (mean ± SD; range) | 59.6 ± 17.5; 22-92 |
| Reason for concern | n (%) |
| Worry for skin cancer | 120 (80.0) |
| Causes discomfort | 15 (10.0) |
| Aesthetic concern | 8 (5.3) |
| Other | 7 (4.7) |
| Lesion location | n (%) |
| Trunk | 50 (33.3) |
| Head | 42 (28.0) |
| Upper extremity | 19 (12.7) |
| Lower extremity | 23 (15.3) |
| Other | 16 (10.7) |
| Lesion classification | n (%) |
| Melanoma | 3 (2.0) |
| Basal cell carcinoma | 9 (6.0) |
| Squamous cell carcinoma | 10 (6.7) |
| Actinic keratosis | 15 (10.0) |
| Seborrheic keratosis | 57 (38.0) |
| Dermatofibroma | 5 (3.3) |
| Nevus | 34 (22.6) |
| Other | 17 (11.3) |
| Dermatologist management | n (%) |
| Biopsy | 66 (44.0) |
| Treat | 31 (20.7) |
| Monitor | 13 (8.7) |
| Reassurance | 40 (26.7) |





Link to Publication

## Objective

This investigator-initiated, matched comparison study aimed to evaluate device performance on patient-identified lesions in a dermatology setting to assess its utility for screening lesions appropriate for referral across clinical contexts.

## Trial Design

The authors prospectively evaluated 150 patients presenting with self-identified lesions of concern to 3 outpatient dermatology offices. Diagnostic accuracy of device readout (classifying lesions as either "Monitor," alone, or "Investigate Further," alongside a score of 1 to 10, indicating spectral similarity to malignant tissue) was compared to blinded dermatologist management decisions and histopathology.

## Enrollment

The study included 150 lesions in 72 males and 78 females, with a mean age of 59.6 years. Malignant lesions were identified in 14.7% of cases (22/150), with melanoma, BCC, and SCC accounting for 3, 9, and 10 cases, respectively.

## Results and Conclusions

This study suggests that the ESS device, as a complementary tool, may enhance triage and decision-making for patient-identified lesions to be employed by non-specialists in any clinical setting.

The ESS device identified 138 lesions as "Investigate Further" and 12 as "Monitor." Sensitivity for detecting malignant lesions was 100%, negative predictive value (NPV) was 100%, specificity was 9.4%, and positive predictive value (PPV) was 15.9%. For lesions with a spectral score of 7 to 10, sensitivity was 86.4%, NPV 96.6%, with specificity increasing to 67.2% and PPV to 31.1%. Compared to dermatologists' decisions, sensitivity was 95.5%, NPV 75%, specificity 10.7%, and PPV 45.7% (Table II)

- These results were similar to those found in the DERM-SUCCESS pivotal study for sensitivity and AUROC as well as lesion distribution across spectral scores.
- Applicability of the device in the PCP setting can be enhanced with development of clear management guidelines for specific lesion types.

## Key Findings

- As the first independent investigator-initiated study conducted with DermaSensor in the US, this study at UPMC found that the 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].
- Sensitivity and specificity of the device were 100% and 9.4%, respectively, using Investigate Further vs Monitor as the cut point 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.

# Likelihood of Malignancy and Number Needed to Biopsy in the DERM-SUCCESS Clinical Study*

| Device Result | Likelihood of Malignancy (i.e., Positive Predictive Value (PPV)) | Number Needed To Biopsy (NNB) or Refer (NNR) | Device Result Frequency |
|---|---|---|---|
| **Monitor** | 3% | 29 | 18% |
| **Investigate Further 1-3** | 6% | 17 | 29% |
| **Investigate Further 4-7** | 18% | 5.5 | 37% |
| **Investigate Further 8-10** | 40% | 2.5 | 16% |

* Merry SP, Croghan IT, Dukes KA, et al. Primary Care Physician Use of Elastic Scattering Spectroscopy on Skin Lesions Suggestive of Skin Cancer. J Prim Care Community Health. 2025;16:21501319251344423. doi:10.1177/21501319251344423

# Summary of DermaSensor Early Clinical Effectiveness Studies

| Summary of Early Clinical Effectiveness Studies | | | |
|---|---|---|---|
| **Clinical Study Name** | **Design, Setting and Sample Size** | **Objective** | **Effectiveness Results** |
| DermaSensor Use in the Assessment of Skin Lesions Suggestive of Cancer (DERM-ASSESS II)<br>Link to Publication | US-based, multicenter, prospective, blinded clinical study at four dermatology sites in the US<br>333 lesions (169 malignant, 164 benign) | To train the device algorithm and validate clinical performance for melanoma, BCC, and SCC | Device sensitivity of 97.0% (95% CI: 92.4-98.9%) and specificity of 26.2% (95% CI: 20.3-33.2%) |
| Use of an ESS-based Adjunctive Tool in the Assessment of Lesions Suggestive of Skin Cancer (Skin Center Investigator-initiated Study (IIS))<br>Link to Publication | Single-site, prospective, blinded clinical study at one dermatology site in New Zealand<br>410 lesions (50 malignant, 360 benign) | To evaluate DermaSensor device performance as an adjunctive tool for evaluating patients with skin lesions suggestive of melanoma, BCC, and SCC | Device sensitivity of 96.0% (95% CI: 86.3-99.5%) and specificity of 31.4% (95% CI: 26.6-36.5%) |
| Use of DermaSensor on Patient-Selected Lesions that are Concerning for Skin Cancer (PATIENT-SELECT)<br>Link to Publication | US-based prospective, blinded clinical study at one primary care site in the US<br>155 lesions (10 malignant, 145 benign) | To assess device performance on skin lesions identified by patients as concerning for skin cancer | Device sensitivity of 90.0% (95% CI: 71.4-100.0%) and specificity of 60.7% (95% CI: 52.5-68.4%) |
| A Multi-Reader Multi-Case Companion Study to the DERM-ASSESS II Clinical Study (DA-II Reader Study)<br>Link to Publication | US-based prospective multi-reader, multi-case study; 57 primary case physicians (PCPs) completed 5,700 lesion assessments | To assess and compare the management sensitivity and specificity of primary care physicians for the most common types of skin cancer (Melanoma, BCC, SCC), with and without use of the device result | PCP sensitivity with device result of 94.2% (95% CI: 91-96%) was superior to PCP sensitivity without device result of 81.4% (95% CI: 77-85%) (p=0.0009). Management specificity with (31%) and without (36%) device use was not significantly different (P = 0.3558) |

| Title, Authors, Journal | Key Findings |
|---|---|
| Artificial Intelligence in Skin Cancer Care | |
| Title: Mapping the landscape of artificial intelligence in skin cancer research: a biblio-metric analysis<br>Authors: Qianwei Liu, Jie Zhang, and Yanping Bai<br>Journal: Frontiers in Oncology<br>Liu Q, Zhang J, Bai Y. Mapping the landscape of artificial intelligence in skin cancer research: a bibliometric analysis. Front Oncol. 2023 Oct 13;13:1222426. doi: 10.3389/fonc.2023.1222426.<br>PMID: 37901316; PMCID: PMC10613074. | Publications related to AI date back to 1990, and AI in relation to skin cancer research to 1991. From 1991-2023, there have been 512 publications on the topic of AI in skin cancer.<br>To date, there are no FDA approved imaging or optical products on the market that use AI for the purpose of skin cancer detection other than DermaSensor's device, despite there being over three decades of research.<br>According to the global cancer statistics for 2020, skin cancer accounted for 1,198,073 new melanoma cases and environmental factors will contribute to the increase in skin cancer worldwide. |
| Title: Artificial Intelligence in the detection of skin cancer<br>Authors: Eric Beltrami, Alistair Brown, Paul Salmon, David J Leffell, Justin Ko, Jane Grant-Kels<br>Journal: Journal of the American Academy of Dermatology<br>Beltrami EJ, Brown AC, Salmon PJM, Leffell DJ, Ko JM, Grant-Kels JM. Artificial intelligence in the detection of skin cancer. J Am Acad Dermatol. 2022 Dec;87(6):1336-1342. doi: 10.1016/j. jaad.2022.08.028. Epub 2022 Aug 23. PMID: 35998842. | Recent advances in artificial intelligence (AI) in dermatology have demonstrated the potential to improve the accuracy of skin cancer detection.<br>Ultimately, the development and validation of AI technologies, their approval by regulatory agencies, and widespread adoption by dermatologists and other clinicians may enhance patient care. Technology augmented detection of skin cancer has the potential to improve quality of life, reduce health care costs by reducing unnecessary procedures, and promote greater access to high-quality skin assessment. |
| Title: Learnings from the first AI- enabled skin cancer device for primary care authorized by FDA<br>Authors: Kaushik P. Venkatesh, Kushal T. Kadakia and Stephen Gilbert<br>Journal: Nature Portfolio of Journals<br>Venkatesh, K.P., Kadakia, K.T. & Gilbert, S. Learnings from the first AI-enabled skin cancer device for primary care authorized by FDA. npj Digit. Med. 7, 156 (2024). https://doi.org/10.1038/s41746-024-01161-1 | FDA's recent authorization of DermaSensor, an AI-enabled device for skin cancer detection in primary care, marks authorization of the first AI-enabled device for use by non-specialists for detecting skin cancer<br>Approval of DermaSensor reinforces the feasibility of digital health technologies to bridge gaps in access and expertise in medical practice.<br>DermaSensor's authorization also establishes a new regulatory precedent for FDA authorization of medical devices incorporating AI and machine learning (ML) technologies within dermatology. |
| Title: The state of artificial intelligence-enabled skin cancer diagnostics: Why are there two spectroscopy devices available yet no imaging devices?<br>Authors: Jay Gopal, Albert E Zhou, Ashfaq A Marghoob, Christian Gronbeck, Jane M Grant-Kels<br>Journal: Clinics in Dermatology<br>Gopal J, Zhou AE, Marghoob AA, Gronbeck C, Grant-Kels JM. The state of artificial intelligence-enabled skin cancer diagnostics: Why are there two spectroscopy devices available yet no imaging devices?. Clin Dermatol. Published online May 7, 2025. doi:10.1016/j. clindermatol.2025.05.001 | Although there are many new AI tools promoted to be helpful to dermatologists and primary care physicians, especially in the recognition of melanoma and non-melanoma skin cancers, there is a major obstacle that the sponsoring companies must overcome before it is possible to integrate any of these innovative AI-enabled technologies into clinical practice. The regulatory process of the Food and Drug Administration (FDA) is demanding and requires proof of safety and effectiveness for each of these devices before the FDA gives their approval.<br>The FDA's evolving regulatory framework for AI-enabled devices adds further complexity, underscoring the need for investment in this field. Future research should prioritize direct comparisons between spectroscopy- and image-based AI tools, combination of both modalities, and rigorous evaluations of real-world impact to provide invaluable insights into the strengths of these modalities. Spectroscopy-based tools have shown much promise in improving diagnostic accuracy, and expanding access to care.<br>Image based tools have been shown to have limited efficacy when tested on novel populations, including general visibility across lesion types and in skin of color. |

| Title, Authors, Journal | Key Findings |
|---|---|
| | |
| Title: Comparative Analysis of Diagnostic Techniques for Melanoma Detection: A Systematic Review of Diagnostic Test Accuracy Studies and Meta-Analysis<br><br>Authors: Alessia Blundo, Arianna Cignoni, Tommaso Banfi and Gastone Ciut Journal: Frontiers in Medicine<br><br>Blundo A, Cignoni A, Banfi T, Ciuti G. Comparative Analysis of Diagnostic Techniques for Melanoma Detection: A Systematic Review of Diagnostic Test Accuracy Studies and Meta-Analysis. Front Med (Lausanne). 2021 Apr 21;8:637069. doi: 10.3389/fmed.2021.637069. PMID: 33968951; PMCID: PMC8103840. | A systematic review of the available literature was performed using PubMed, Scopus and Google scholar databases (2010-September 2020). All human, in-vivo, non-invasive studies using various diagnostic techniques, alternative to dermoscopy, for melanoma diagnosis were included with no restriction on the recruited population.<br><br>Based on the SROC curves, optical spectroscopy achieved the best performance in terms of sensitivity (93%, 95% CI 92.8-93.2%) and specificity (85.2%, 95%CI 84.9-85.5%), even though there was high concern regarding robustness of metrics. Reflectance-confocal microscopy, instead, demonstrated higher robustness and a good diagnostic performance (sensitivity 88.2%, 80.3-93.1%; specificity 65.2%, 55-74.2%)<br><br>Central message: Optical spectroscopy performs superior to visual examination alone and similar to confocal microscopy which takes years to learn and costs over $100,000. |
| Title: Market-approved convolutional neural network tasked with classifying skin lesions under suspicion of melanoma: performance across primary care clinics within Australia<br><br>Authors: Ian J. Miller et al<br><br>Journal: PeerJ<br><br>Miller IJ, Stapelberg M, Hudson J, Coxon P, Milani N, Rosic N, Furness J, Walsh J, Climstein M. 2025. Market-approved convolutional neural network tasked with classifying skin lesions under suspicion of melanoma: performance across primary care clinics within Australia. PeerJ 13:e19876 http://doi.org/10.7717/peerj.19876 | The primary aim of this study was to investigate the clinical performance of a market-approved convolutional neural network (CNN), Moleanalyzer-Pro by FotoFinder Systems GmbH, to better differentiate skin lesions suspicious of being malignant melanoma (MM). This was a multicentre, cross-sectional study using a commercially available CNN on 373 melanocytic lesions (114 melanoma, 259 non-melanoma) from participants attending a skin examination within two Australian specialised, general practice clinics.<br><br>The CNN average sensitivity [Gold Coast vs Townsville study centres] was calculated as 63.2% [61.5% vs 68.6%], specificity as 53.9% [52.5% vs 55.1%], positive predictive value as 37.8% [28.9% vs 44.0%] and negative predictive value as 76.8% [71.4% vs 84.2%]. Likelihood ratios were 1.4 for positive likelihood ratio, 0.7 for negative likelihood ratio and a diagnostic odds ratio of 2.0 across both clinics. Accuracy was calculated as 56.6% [56.1% vs 57.5%] and the AUC of ROC for both clinics was 0.602 and 0.615 for Townsville and Gold Coast, respectively. Improvement of the performance of this CNN for the classification of images, particularly when suspecting MM, is necessary. |
| Title: Accuracy of Commercially Available Smartphone Applications For the Detection of Melanoma<br><br>Authors: MD Sun[1,2], J Kentley[1,3], P Mehta[1], S Dusza[1], AC Halpern[1], V Rotemberg[1]<br><br>Journal: British Journal of Dermatology<br><br>1. Dermatology Service, Memorial Sloan Kettering Cancer Center, 1275 York Avenue, New York, NY, USA<br>2. Icahn School of Medicine at Mount Sinai, New York, NY, USA<br>3. Department of Dermatology, Chelsea and Westminster Hospital, London, UK | This study was conducted to evaluate the accuracy of apps using an independent test set of clinical images comparable with those submitted through smartphones, this study included clinical images of 15 consecutive histologically proven invasive melanoma cases (pT1a–pT2b) and 15 histologically proven benign naevi, all in patients with lighter skin phototypes. The study also used five images of benign naevi in patients with skin of colour (SoC), diagnosed clinically by two dermatologists. Images were obtained as part of usual care at Memorial Sloan Kettering Cancer Center and retrieved from the MSKCC image database.<br><br>Across top-1 measures for all apps, mean sensitivity was 0·28 [95% confidence interval (CI) 0·17–0·39)], mean specificity was 0·81 (95% CI 0·71–0·91) and mean accuracy was 0·59 (95% CI 0·55–0·62). For diagnosis-based apps, risk-category-based apps and score-based apps, mean accuracy was 0·56, 0·60 and 0·64, respectively. In the 10 apps that returned at least three ranked diagnoses, mean top-1 accuracy (0·56) was higher than mean top-3 accuracy (0·41). When rejected images were classified as a benign output, mean accuracy dropped from 0·63 to 0·61 across four apps. Clinicians should be aware of app limitations and their widespread accessibility to lay users. Improved regulation and higher quality studies are necessary to bring prospectively validated algorithms to market. |

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## Contact

1.855.373.6767
DermaSensor.com
contact@DermaSensor.com

801 Brickell Ave.
#1610
Miami, FL 33131

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