



# Skin Cancer Evaluation. **Simplified.**

An objective, non-invasive skin cancer evaluation platform, accessible at the point of care.

FDA Cleared. Available in the United States.

## DermaSensor™ **Features**



Handheld, point-and-click application



Non-invasive optical spectroscopy



Beneath the skin, cellular-level analysis



AI-powered, ultra-miniaturized ESS technology

## Major Findings from **Clinical Studies**

- ✓ 96% device sensitivity for detecting all skin cancers<sup>1</sup>
- ✓ PCPs' overall skin cancer sensitivity was found to increase by 6-9%; their relative decrease in false negative referrals (i.e. missed skin cancers) decreased by 30-52%<sup>2,3</sup>
- ✓ PCPs' melanoma sensitivity was found to increase by 7-9%; their relative decrease in false negative referrals (i.e. missed skin cancers) decreased by 21-30% <sup>2\*</sup>
- ✓ PCPs' confidence significantly increased in managing suspicious lesions <sup>2,3</sup>
- ✓ Device correctly classified 21-33% of benign lesions that physicians biopsied <sup>1,4</sup>
- ✓ With increasing positive predictive value for malignancy, higher the device scores can be used to objectively, systematically prioritize patient referrals <sup>1,3</sup>

## Major Product **Firsts**

- ✓ First FDA-cleared skin cancer device developed for PCPs
- ✓ First FDA-cleared FDA Breakthrough device for skin cancer
- ✓ First FDA-cleared automated device indicated for all three common skin cancers (Melanoma, BCC and SCC)
- ✓ Only FDA-cleared skin cancer device available that provides any risk assessment using any type of imaging or optical technology

## **Only FDA-cleared** AI Skin Cancer Device For PCPs

### Rapid and Reliable Recordings

Take five recordings in seconds, each of which takes a non-invasive sample of lesion tissue of approximately 0.7 mm (length) × 0.4 mm (width) × 0.5 mm (depth)

### Easy To Learn and Use

No training seminars or courses needed, just minutes of reading the device Instructions for Use

### FDA Breakthrough, Non-Invasive Technology

Show patients that their skin health is your priority by using FDA-cleared, objective, AI-powered technology

### No Up-Front Capital Expense

An affordable way to add an additional service for patients, without a large up-front expense



# Know More. Detect Now.

Set your practice apart by being one of the first physicians in the U.S. to provide non-invasive, point-of-care skin cancer testing. DermaSensor empowers physicians by providing objective, actionable results to aid in skin cancer detection by assessing cellular and sub-cellular features that cannot be seen visually or dermoscopically.



## SOFTWARE UPDATES

Software updates are sent to the device from DermaSensor's server as they become available. Stay updated and you'll always be connected to the latest assessment technology.



## REMOTE DEVICE MONITORING

Device functionality issues can be determined and assessed remotely. If device issues are identified, our field support team can resolve the issues remotely or arrange for a replacement device.



## VALIDATED, AI-POWERED

The AI algorithm was developed and validated on over 20,000 scans, comprised of over 4,000 benign and malignant lesions. The device provides a real-time, objective result for skin cancer risk to augment the physician's management decision



## ALGORITHM ACCESS

Your device customer agreement provides for your desired usage level of our proprietary, FDA-cleared algorithm to benefit you and your patients.



## CLOUD STORAGE ACCESS

Connect the device to Wi-Fi for its data to synch with DermaSensor's cloud-based server. This allows the device spectral data to be transferred from your device and stored for quality and record-keeping purposes.



## ON DEMAND CUSTOMER SUPPORT

Get on demand customer support, supplementary literature for ongoing education, and access to the latest publications.

The only skin cancer detection device designed specifically for PCPs.

Scan this QR code for DermaSensor device labeling indications for use, contraindications, warnings and precautions.



[support.dermasensor.com/labeling-guidance](https://support.dermasensor.com/labeling-guidance)

For more information go to:

[www.dermasensor.com](https://www.dermasensor.com)

or Contact Us

(855)-373-6767

## References

1. Merry SP, Chatha K, Croghan I, Nguyen VL, McCormick B, Leffel D. Clinical Performance of Novel Elastic Scattering Spectroscopy (ESS) in Detection of Skin Cancer: A Blinded, Prospective, Multi-Center Clinical Trial. *J Clin Aesthet Dermatol* 2023 April; 16(4 Suppl): s16-17.
2. Data on file
3. Seiverling EV, Agresta T, Cyr P, Caines L, Nguyen VL, Chatha K, Siegel DM. Clinical Utility of an Elastic Scattering Spectroscopy Device in Assisting Primary Care Physician's Detection of Skin Cancers. *J Clin Aesthet Dermatol* 2023 April; 16(4 Suppl): s16-17.
4. Hartman RI, Trepanowski N, Chang MS, Tepedino K, Gianacas C, McNiff JM, Fung M, Braghiroli NF, Grant-Kels JM. Multicenter Prospective Blinded Melanoma Detection Study with a Handheld Elastic Scattering Spectroscopy Device. *JAAD International* (2023), doi: <https://doi.org/10.1016/j.jdin.2023.10.011>.
5. J. Boyer, J. R. Mourant, and I. J. Bigio, "Theoretical and Experimental Investigations of Elastic Scattering Spectroscopy as a Potential Diagnostic for Tissue Pathologies," in *Advances in Optical Imaging and Photon Migration*, (Optica Publishing Group, 1994), paper OPTM.265.

\*Melanoma false negative results are only reported from the two studies powered for analysis by individual skin cancer types, DERMUCCESS pigmented reader study and DERM-ASSESS III reader study



## About

DermaSensor Inc. is a health technology company designing noninvasive 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. DermaSensor's mission is to provide broad access to effective skin cancer checks. The DermaSensor device is currently FDA-Cleared, CE-Marked and is available for sale in the U.S.