Summary of DermaSensor Safety and Effectiveness Results From Three Clinical Studies

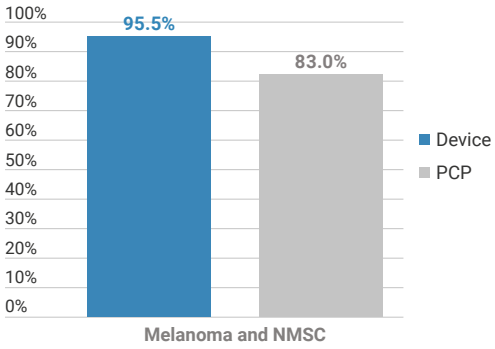
FDA Cleared

DermaSensor™

DERM-SUCCESS Prospective Skin Cancer Validation Study[1]

22 Primary Care Study Sites (18 U.S. and 4 Australia)
1,005 Patients, 1,579 Biopsied Lesions (224 Malignant Lesions)

DermaSensor and PCP Sensitivity for Skin Cancer



Malignant Lesion Likelihood based on Spectral Scores		
Spectral Score Groupings	**PPV**	**NNB**
1-3	5.9%	17
4-7	18.4%	6
8-10	39.6%	2.5

Note: Number needed to biopsy (NNB) reflects the proportion of biopsied lesions to malignant lesions for the given device result. It is calculated as 100%/PPV. **For patients aged 40 and above, device melanoma sensitivity was 90.2% (n=41), BCC was 97.8% (n=90), and SCC was 97.7% (n=86).**

- Device sensitivity (95.5%) was found to be superior to that of study PCP investigators' (83.0%), p-value<0.0001
- Additionally, DermaSensor sensitivity was non-inferior to the 90% performance goal (based on literature published sensitivity of dermatologists[2-5]), p-value <0.0001
- Device specificity was 20.7%, i.e. the device correctly classified as benign 20.7% of lesions that the PCPs biopsied
- Overall NPV of the device was 96.6%, meaning a negative "Monitor" device result had a 3.4% chance of being malignant
- Overall device accuracy (i.e. AUROC) was 79%; physician accuracy was 74% for all lesions and 56% for lesions in which they had low confidence in their clinical assessment

PPV was 16.6% overall; it increased with increasing scores, with scores of 8-10 that were scanned by PCPs having the highest likelihood of cancer at 39.6% (NNB of 2.5)[1]

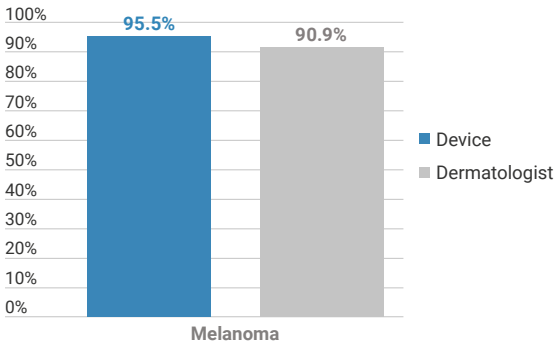
General Notes:

- *Dermatopathologist review used as reference standard*
- *There were no device-related safety issues*

DERM-ASSESS III Prospective Melanoma Validation Study[6]

10 Dermatology Study Sites (8 U.S. and 2 Australia)
311 Patients, 440 Biopsied Lesions (88 Melanomas)

DermaSensor and Dermatologist Sensitivity for Melanoma



Melanoma Likelihood based on Spectral Scores		
Spectral Score Groupings	**PPV**	**NNB**
1-3	10.3%	10
47	20.5%	5
8-10	47.4%	2

Note: Number needed to biopsy (NNB) reflects the proportion of biopsied lesions to malignant lesions for the given device result. It is calculated as 100%/PPV. **Device sensitivity was 95.5% for melanoma (n=44) and 90.9% for melanoma including severely atypical nevi (n=88)**

- Device melanoma sensitivity (95.5%) similar to that of expert dermatologists (90.9%)
- Device specificity was 32.5%, i.e. the device correctly classified as low risk 32.5% of biopsied lesions
- DermaSensor NPV was 98.1% for melanoma alone and 93.0% for all high risk melanocytic lesions
- Device AUROC of 0.758 was comparable to the study dermatologists' AUROC of 0.747

PPV for melanoma was 16.0% overall; it increased with increasing scores, with scores of 8-10 that were scanned by dermatologists having the highest likelihood of melanoma at 47.4% (NNB of 2)

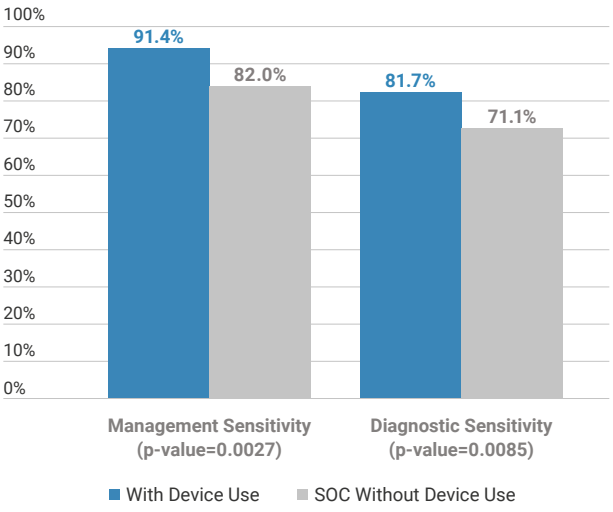
General Notes:

- *Dermatopathologist review used as reference standard*
- *There were no device-related safety issues Device performance in these high-volume melanoma dermatology practices may not reflect how the device performs in the primary care setting.*

DERM-SUCCESS Prospective Clinical Utility Study[7]

108 U.S. Board Certified Primary Care Providers
Over 10,000 lesion assessments

PCP Sensitivity for Skin Cancer with and without DermaSensor



- PCP device use resulted in a significant improvement in both management and diagnostic sensitivity compared to standard of care alone; physician false negative referrals decreased by half, from 18.0% to 8.6%
- PCPs' device-assisted accuracy (i.e. AUROC) was 76%, compared to 71% with their standard of care alone; for lesions in which PCPs had low confidence in their clinical management decision, their device-asissted accuracy was 68% and unassisted was 57%.
- Nearly all (99%) of PCP participants reported the device provides at least one benefit, including:
  - "Detecting more skin cancer" (82%)
  - "Providing you with greater confidence in your clinical assessments and management decisions" (81%)
  - "Helping you to prioritize the risk level of concerning lesions to prioritize patient management, e.g. a prioritized dermatology referral" (72%)
  - Increasing your frequency of assessing patients for skin cancer" (63%)

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.

Indicated User Considerations

The DermaSensor FDA pivotal validation study (DERM-SUCCESS) included 1,579 lesions biopsied by 22 primary care study centers, and a supplemental melanoma validation study (DERM-ASSESS III) was conducted with biopsied lesions by 10 dermatology study centers. Note that the device indications for use describes non-dermatologist physicians since the FDA's clearance was based on the benefit-risk evaluation for physicians who are not already experts in the clinical diagnosis and management of skin cancer.

Risks

False-positive and false-negative device results may lead to unnecessary referrals or to a malignant skin lesion not being correctly referred, respectively. For the more clinically harmful risk, a false negative device result, the DERM-SUCCESS study found the overall device sensitivity to be 95.5%, with a lower bound of 91.7%. While the device can produce false negative results, as does gold standard dermatopathology, when the device result is used to aid PCPs in their referral decisions, the reader study showed that the device decreases PCPs' false negatives by half, with the PCPs' false negative rate decreasing from 18.0% without device use to 8.6% with device use.

References

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3. Soyer H, Argenziano G, Zalaudek I, Corona R, Sera F, Talamini R, et al. Three-point checklist of dermoscopy. A new screening method for early detection of melanoma. Dermatology. 2004;208:27-31.
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