ACE BRIEF FOR NEW AND EMERGING HEALTH TECHNOLOGIES

DermaSensor as an adjunctive diagnostic tool for lesions suspicious for skin cancer

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Contents

Summary of Key Points

- Skin cancer is a common malignancy in Singapore, ranking sixth among males and eighth among females. Nonmelanoma skin cancers, including basal cell carcinoma (BCC) and squamous cell carcinoma (SCC), constitute most cases. While melanoma is less prevalent, it accounts for most skin cancer-related deaths. Early detection significantly improves survival outcomes.
- Current standard of care involves visual inspection by primary care physicians (PCPs) and referral of suspicious lesions to dermatology services. Histopathologic examination is the diagnostic gold standard. Detection accuracy relies on physician expertise, meaning limited dermatological training among PCPs can lead to missed malignant lesions or unnecessary referrals of benign cases.
- DermaSensor (DermaSensor Inc.) is a handheld, software-aided device that utilises elastic scattering spectroscopy and a machine-learning (ML) algorithm to assess skin lesions non-invasively. It is an adjunctive diagnostic device that supports PCPs in evaluating lesions suspicious for melanoma, BCC and SCC in primary care settings.
- Based on five diagnostic accuracy studies, DermaSensor was found to be safe but its benefit on diagnosis accuracy, management decisions and healthcare resource savings remained unclear.
    - There were no major safety concerns anticipated for the use of the software with no device-related adverse effects reported.
    - DermaSensor demonstrated high sensitivity (81.7% to 97%), negative predictive value (NPV; 83.3% to 98.9%), and area under the receiver operating characteristic curve (AUROC; 0.77 to 0.82), but low to moderate specificity (20.7% to 60.7%) and positive predictive value (PPV; 13.6% to 64.6%) in the diagnosis of suspicious skin lesions. Observation was consistent across cancer subtypes and in FDA-indicated age group.
    - Comparative analyses showed that PCPs assisted by DermaSensor reported significant sensitivity gain (p=0.0085) over unaided PCPs, and comparable performance to dermatologists (p=0.82). However, lower specificity was observed with DermaSensor when compared with both dermatologists and unaided PCPs, suggesting higher likelihood for DermaSensor to falsely identify benign lesions.
    - In terms of clinical utility, when compared to unaided PCPs, DermaSensor-aided PCPs demonstrated higher management sensitivity, reducing false-negative rate by approximately half (18% to 8.6%). However lower management specificity was observed with an additional of 11.8% benign lesions being incorrectly referred with use of DermaSensor.
    - PCPs reported increased confidence and improved lesion assessment with the use of the device, potentially leading to fewer unnecessary biopsies and more efficient triage.

- Key limitations of the evidence include low representation of Asian population in included evidence with potential funding bias, and the higher reported skin cancer incidence in the studies than local rates.
- The cost-effectiveness of DermaSensor remains uncertain. Based on a subscription-based service, the cost per device is S$543 per month.
- Only one ongoing trial was identified to investigate the real-world use of DermaSensor on skin lesions suspicious for melanoma.
- Key implementation considerations include compliance with the Ministry of Health Artificial Intelligence in Healthcare Guidelines, robust clinical governance, proper information technology infrastructure and standardised training.
- Local clinical experts noted that DermaSensor may improve diagnostic confidence of PCPs with limited dermatology training, however, overall clinical need is low with uncertain cost-effectiveness in primary care settings given the relatively low local skin cancer burden.
- DermaSensor is the only FDA-approved spectroscopy-based tool that provides PCPs with a risk assessment for suspicious skin lesions. There are some other artificial intelligence (AI) image- or camera-based ML tools that have obtained overseas regulatory approval to assist in the evaluation, triage, and management of suspicious skin lesions.

I. Background

Skin cancer is a malignant tumour originating in the epidermis.[1] It is generally classified into melanoma (originates from melanocytes), and nonmelanoma (originates from keratinised epithelial cells).[1] Nonmelanoma skin cancer can be further classified as basal cell carcinoma (BCC), squamous cell carcinoma (SCC), or other types of skin cancers, which are usually slow growing and locally invasive. Compared with the other skin cancer cells, melanoma proliferates rapidly and is highly invasive and metastatic.[2]

The global age-standardised incidence rate (ASIR) of skin cancer was 77.66 per 100,000 persons in 2021, with an age-standardised disability-adjusted life years rate of 33.96 per 100,000 persons.[3] The ASIR is projected to increase to 101.73 per 100,000 persons over the next decade.[3] In Singapore, nonmelanoma skin cancer constitutes the majority of skin cancer incidence, being the sixth and eighth most common in males and females, respectively, and is associated with five-year survival rates of 93.8% for male and 97.3% for female from 2019 to 2023.[4] Given its high incidence and recurrence rates, nonmelanoma skin cancer often requires extensive healthcare resources.[5, 6] Although melanoma is less prevalent, with an incidence of 0.5 cases per 100,000 persons locally, it remains the leading cause of skin-cancer-related deaths.[6, 7] Delayed diagnosis at advanced stage is also associated with a higher likelihood of metastasis and fatality despite treatment.[8] When diagnosed early, with disease localised to the skin, the five-year survival rate approaches 100%. However, it declines to

around 30% for patients diagnosed after metastasis to regional lymph nodes or distant sites.[6-8]

Locally, the current standard of care for skin lesion examination is conducted by primary care physicians (PCPs) through visual inspection, which may include naked-eye inspection, dermoscopy, or tele-dermatology, depending on available resources. Visual inspection relies on expert judgement on several morphologic features pertaining to the shape, elevation, surface, and colour of the lesion.[9] Lesions considered suspicious are subsequently referred to specialist dermatology centres for diagnosis through biopsy and histopathological examination if required.[10] The accuracy in detection is largely dependent on the physicians' expertise and experience, while insufficient training may lead to skin cancers being inadvertently overlooked or high volumes of benign skin lesions being needlessly excised.[11] As such, there remains a potential clinical need for a non-invasive and easy-to-use tool to improve skin cancer identification by PCPs, and reduce unnecessary referrals for biopsy.

II. Technology

DermaSensor (DermaSensor Inc.) is a software-aided adjunctive diagnostic device that employs optical spectroscopy and machine learning (ML) algorithm to provide non-invasive analysis of intact skin lesions.[12] The device is intended for use in primary care settings, to support physicians not trained in clinical diagnosis and management of skin cancer to evaluate lesions suspicious for skin cancer. The system comprises two main components:

- A handheld diagnostic device that transmits broadband white light from a xenon arc lamp through a small fibre-optic probe onto a skin lesion, then captures the backscattered light reflected from the tissue.
- A base station that provides wireless charging for the handheld unit and contains calibration materials to ensure measurement accuracy.

The device performs spectral scans on suspicious lesions to measure the elastic scattering spectroscopy (ESS) recording. ESS is the unique spectral pattern created by the backscattered light, reflecting the tissues' structure and architecture at different lesion locations (e.g. nuclear and chromatin characteristics).[13] The reported ESS is then analysed by a built-in ML algorithm to identify potential melanoma, SCC, or BCC.[12]

The lesion is classified as either low-risk or high-risk for malignancy, with a binary output of "Monitor" for a negative result, or "Investigate Further" for a positive result. For a positive output, the device displays a similarity score of 1 to 10 based on the degree of its resemblance to known malignant signals, with a higher score indicating greater similarity with that of malignant lesions (Figure 1).

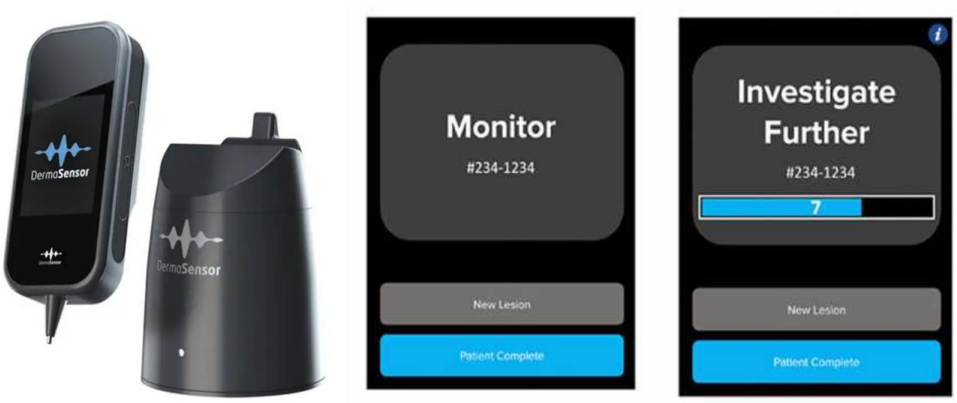

Figure 1: Illustration of DermaSensor device and its output. Image adapted from Tepedino, M., Baltazar, D., Hanna, K. (2024).

As a point-of-care device, DermaSensor has the potential to provide objective, standardised and immediate risk assessment, improving diagnostic confidence for PCPs who lack specialised dermatological training. This may potentially improve diagnostic accuracy and reduce inter-observer variability, leading to fewer specialist referrals and unnecessary biopsies, subsequently improving patient experience, and reducing demand and costs to specialist services.[7]

III. Regulatory and Subsidy Status

In February 2023, the United States Food and Drug Administration (FDA) granted *de novo* clearance (DEN230008) to DermaSensor as the first FDA-authorised software-aided adjunctive diagnostic device for use to evaluate skin lesions suggestive of melanoma, BCC, or SCC in patients aged 40 years and above, to assist in decisions regarding referral of the patient to a dermatologist. It is worth noting that the device should be used in conjunction with the totality of clinically relevant information from clinical assessment by physicians who are not dermatologists. It is not intended as a screening tool or sole diagnostic device, but as an adjunct to clinical evaluation of lesions already suspicious of skin cancer.[12]

IV. Stage of Development in Singapore

☒	Yet to emerge	☐	Established
☐	Investigational / Experimental (subject of clinical trials or deviate from standard practice and not routinely used)	☐	Established *but* modification in indication or technique
☐	Nearly established	☐	Established *but* should consider for reassessment (due to perceived no/low value)

V. Treatment Pathway

Based on the clinical pathway reported in the National Institute for Health and Care Excellence (NICE) health technology evaluation (HTE24 [2025])[8] and a local quantitative study[10], the initial assessment of a person presenting with a suspicious skin lesions occurs at the primary care settings to determine the appropriate referral pathway (see Table A1 in Appendix A). Skin lesions are assessed by PCPs who consider clinical history, risk factors and visual inspection.[8, 14] Lesions suspicious of cancer will be referred for dermatologist assessment. In circumstances where the decision is uncertain, patients may be referred to a dermatologist, or if available, to tele-dermatology, where digital photographs of the suspicious skin lesion are forwarded to a dermatologist for further investigation.[10] Following referral, dermatologists supplement patient history and visual inspection with dermascopy or confocal microscopy, and take a skin biopsy if needed to confirm diagnosis.[8]

The integration of DermaSensor into clinical workflows may serve as an adjunct tool to the standard of care in primary care settings, especially for lesions with diagnostic uncertainty, supporting PCPs' referral for formal assessment of suspicious skin lesions by dermatologists (Personal communication: Family Physician from National Healthcare Group Polyclinic. November 2025).

VI. Summary of Evidence

The assessment was conducted based on the Population, Intervention, Comparator and Outcome (PICO) criteria listed in Table 1. Literature searches were conducted in relevant health technology assessment (HTA) databases, Cochrane Library, PubMed and Embase. The key evidence consists of five studies, including four diagnostic accuracy studies and one clinical utility study. Two studies[15, 16] were conducted in the specialist dermatology settings that compared DermaSensor's diagnostic performance with dermatoscopic assessments.[15, 16] The other three studies,[13, 17, 18] were performed in primary care settings to assess the impact of the device's outputs on diagnostic and management decision-making by PCPs.[13, 17, 18] Two of these primary care studies[17, 18] were based on populations from the FDA pivotal trial DERM-SUCCESS, with one being a clinical utility study[17] that analysed a subset of lesions from the pivotal trial.[17] In all included studies, investigators were blinded to device output during the study.

All studies used histopathologic diagnoses as reference standard. One study[13] used dermatologist panel assessment as reference when biopsy results were not available.[13] The study design and characteristics of the key evidence sources are presented in Table B1 and Table B2 in Appendix B.

Table 1: Summary of PICO criteria

Population	Adults with skin lesions suggestive of skin cancer (e.g., melanoma, basal cell carcinoma, and/or squamous cell carcinoma)
Intervention	DermaSensor
Comparator	Comparator: Standard of care by primary care physicians

	Reference standard: Histopathologic diagnoses or dermatologist panel assessment when biopsy results are not available
Outcome	Safety, clinical effectiveness (e.g., diagnostic accuracy, diagnostic yield, change in clinical management), cost and cost-effectiveness

Safety

As a ML-based, adjunct diagnostic tool, no major safety concerns are anticipated for DermaSensor. No device-related adverse effects (AEs) were reported in two studies with relevant data.[13, 15] However, as outlined by the FDA, the risk of false-positive or false-negative results may lead to unnecessary or delayed treatment, although these may not be easily quantified.[12]

Effectiveness

Accuracy

Overall, in four studies[13, 15, 17, 18] using histopathological assessment or dermatologist panel assessment as the reference standard for detecting malignant lesions,[13, 15, 17, 18] DermaSensor demonstrated sensitivity of 81.7% to 97%, specificity of 20.7% to 60.7%, positive predictive value (PPV) of 13.6% to 64.6%, negative predictive value (NPV) of 83.3% to 98.9% and an area under the receiving operator curve (AUROC) of 0.73 to 0.82 (Table 2).

Comparative diagnostic accuracy was reported in three studies.[13, 15, 17] DermaSensor demonstrated sensitivity comparable to that of dermatologists (97.0% *vs.* 96.5%; p=0.82) and outperformed unaided PCPs (81.7% to 90.0% *vs.* 40.0% to 71.1%) with statistical significance reported in one study (p=0.009).[13, 15, 17] In contrast, DermaSensor consistently demonstrated lower specificity against both dermatologists (21.7% *vs.* 37.4%; p=0.01)[15] and unaided PCPs across two studies (54.7% to 60.7% *vs.* 60.9% to 85%, Table 2). [13, 17]

No consistent patterns were observed for other diagnostic metrics across comparison groups. Compared with dermatologists, DermaSensor showed similar PPV (64.6% *vs.* 69.4%), AUROC (0.73 *vs.* 0.70) and NPV (83.3% *vs*. 87.8%).[15] When used by PCPs, DermaSensor showed higher AUROC (0.82 *vs*. 0.64), with similar NPV (98.9% *vs.* 95.0%) and PPV (13.6% *vs.* 15.0%), although their statistical significance remained unclear (Table 2).[13]

Table 2: Diagnostic accuracy of DermaSensor with histopathological assessment as reference standard

Study	Outcome	N[a]	With Device	Without Device	P-value
Specialist care setting					
Manolakos et al. (2023)[15]	Sensitivity, % (95% CI)	284	97.0 (92.4 to 98.9)	96.5 (91.8 to 98.5)	0.8203
	Specificity, % (95% CI)		21.7 (15.3 to 29.9)	37.4 (28.4 to 47.4)	**0.0096**
	PPV, % (95% CI)		64.6 (NR)	69.4 (NR)	—
	NPV, % (95% CI)		83.3 (NR)	87.8 (NR)	—
	AUROC		0.73	0.70	—

Primary care setting					
Tepedino et al. (2024)[13]b	Sensitivity, % (95% CI)	177	90.0 (71.4 to 100)	40.0 (10.0 to 70.0)	—
	Specificity, % (95% CI)		60.7 (52.5 to 68.4)	85.0 (78.0 to 90.0)	—
	PPV, % (95% CI)		13.6 (7.1 to 24.6)	15.0 (2.0 to 29.0)	—
	NPV, % (95% CI)		98.9 (93.4 to 99.8)	95.0 (90.0 to 98.0)	—
	AUROC		0.82	0.64	—
Merry et al. (2025)[18]cd	Sensitivity, % (95% CI)	1579	95.5 (91.7 to 97.6)	—	—
	Specificity, % (95% CI)		20.7 (18.5 to 23.1)	—	—
	PPV, % (95% CI)		16.6 (14.2 to 19.3)	—	—
	NPV, % (95% CI)		96.6 (93.5 to 98.2)	—	—
	AUROC		0.78	—	—
Ferris et al. (2025)[17]d	Sensitivity, % (95% CI)	50	81.7 (72.4 to 90.9)	71.1 (63.4 to 78.8)	**0.0085**
	Specificity, % (95% CI)		54.7 (42.3 to 67.1)	60.9 (52.5 to 69.3)	0.1896

Notes:

[a] Included biopsied lesions, with histopathological diagnosis serving as the reference standard, unless otherwise specified, in which case a dermatologist panel consensus was used as the reference comparator.

[b] Include all lesions. The reference standard was the histopathologic (available for 22 lesions) or panel consensus results.

[c] Merry et al. (2025) is a single-arm pivotal trial that evaluated diagnostic accuracy against histopathology as the reference standard.

[d] Merry et al. (2025) and Ferris et al. (2025) share the same patient pool from the FDA multicentre pivotal trial.

Abbreviations: AUROC, area under the receiver operating characteristic curve; CI, confidence intervals; NPV, negative predictive value; NR, not reported; PPV, positive predictive value

Subgroup analyses that aligned with FDA-approved indications are summarised in Table 3. Consistently high sensitivity was reported across cancer subtypes, including melanoma (87.5% to 96.7%), BCC (97.2% to 97.8%) and SCC (97.0% to 97.7%; see Table 3).[15, 16, 18] Moreover, these sensitivity findings remained consistent in the FDA-approved population (patients aged ≥ 40 years), at 96.3% across all skin cancer and 90.2% for melanoma (see Table C1 in Appendix C), meeting the prespecified target of 90%[18] based on the published dermatologist sensitivity range, and achieving superiority (p=0.002).[18]

Table 3: Subgroup diagnostic sensitivity of DermaSensor with histopathological assessment as reference standard

Subgroup outcomesa	Diagnostic sensitivity, % (95% CI)		
	Manolakos et al. (2023)[15]	Hartman et al. (2024)[16]	Merry et al. (2025)[18]
Specialist care			
BCC	97.2 (89.0 to 99.4)	—	—
SCC	97.0 (88.6 to 99.4)	—	—
Melanoma	96.7 (NR)	95.5 (84.5 to 98.8)	—
Primary care			
BCC	—	—	97.8 (91.3 to 99.5)
SCC	—	—	97.7 (91.1 to 99.4)
Melanoma	—	—	87.5 (76.4 to 93.8)
≥ 40 years			96.3 (92.9 to 98.4)

Notes:

[a] Include all biopsied lesions with histopathological diagnoses as the reference standard.

Abbreviations: BCC, basal cell carcinoma; CI, confidence interval; NR, not reported; SCC, squamous cell carcinoma

Clinical utility

Two studies[13, 17] evaluated the accuracy of PCPs' management decisions (defined as the number of true positive cancers that were referred for further evaluation) with and without DermaSensor.[13, 17] The device significantly improved the ability of PCPs to correctly identify malignant lesions requiring referral, although this was at the cost of increased false positive referrals of benign lesions.

Compared to unaided PCPs, DermaSensor-aided assessment resulted in a higher management sensitivity (88.2% to 91.4% *vs.* 40.0% to 82.0%),[13, 17] with one study reporting a significant halving of the false negative rate from 18% to 8.6% (91.4% *vs.* 82.0%, Table 4).[13, 17] However, management specificity was lower when PCPs used the device (32.4% to 70.4% *vs.* 44.2% to 84.8%, Table 4),[13, 17] with an additional of 11.8% benign lesion cases being incorrectly referred when aided by DermaSensor.[13, 17] The wide variability in specificity across studies may partly be influenced by the differences in study populations and reference standard used, with Tepedino et al. (2024) largely relying on dermatologist panel consensus and Ferris et al. (2025) using histopathologic assessment. Similar trends were also observed in patients aged ≥40 years, with an improved DermaSensor-aided management sensitivity and overall management performance (AUROC), despite numerically lower management specificity (32.6% *vs.* 41.5%, Table 4), that highlighted the potential of DermaSensor to falsely refer benign lesions.[17]

Table 4: Comparative management accuracy of DermaSensor for suspicious skin lesions in primary care settings.

Study	Outcome	N[a]	With Device	Without Device	P-value
Tepedino et al. (2024)[13][b]	Sensitivity, % (95% CI)	98	88.2 (64.1 to 96.9)	40.0 (9.6 to 70.4)	—
	Specificity, % (95% CI)		70.4 (59.6 to 79.3)	84.8 (78.2 to 89.7)	—
	PPV, % (95% CI)		38.5 (24.3 to 54.9)	13.6 (7.1 to 24.6)	—
	NPV, % (95% CI)		96.6 (87.7 to 99.1)	98.9 (93.4 to 99.8)	—
	AUROC		—	—	—
Ferris et al. (2025)[17]	Sensitivity, % (95% CI)	50	91.4 (85.7 to 97.1)	82.0 (76.4 to 87.6)	**0.0027**
	Specificity, % (95% CI)		32.4 (20.7 to 44.1)	44.2 (36.0 to 78.8)	0.0256[c]
	PPV, % (95% CI)		—	—	—
	NPV, % (95% CI)		—	—	—
	AUROC		0.708 (NR)	0.762 (NR)	—
Ferris et al. (2025)[17] *Subgroup analysis of biopsied lesions from patients ≥40 years.	Sensitivity, % (95% CI)	44	95.9 (94.5 to 97.2)	83.6 (81.0 to 86.1)	—
	Specificity, % (95% CI)		32.6 (29.5 to 35.9)	41.5 (37.8 to 45.1)	—
	PPV, % (95% CI)		—	—	—
	NPV, % (95% CI)		—	—	—
	AUROC		0.80 (0.79 to 0.81)	0.70 (0.69 to 0.72)	—

Notes:

[a] Included biopsied lesions, with histopathological diagnosis serving as the reference standard, unless otherwise specified, in which case a dermatologist panel consensus was used as the reference comparator.

[b] The reference standard was panel consensus results.

[c] Statistical significance is calculated by a 1-sided 0.025 level of significance. The p-value is 0.0256, showing no statistical significance.

Abbreviations: AUROC, area under the receiver operating characteristic curve; CI, confidence interval; NR, not reported; PPV, positive predictive value; NPV, negative predictive value

Moreover, one study[17] suggested that DermaSensor improved PCPs' confidence in clinical assessments.[17] Device-aided PCPs made high-confidence assessments more frequently compared to unaided assessments (53.4% *vs.* 36.8%), while low-confidence assessments remained similar (4.5% *vs.* 6%).[17] These findings were supported by physician-reported experiences, with 81% of PCPs citing greater confidence in clinical assessment and management decisions.[17]

Healthcare system benefits

The impact of DermaSensor on healthcare system benefits remains unclear. The FDA pivotal trial suggests potential resource savings if PCPs were unblinded to device output.[18] Specifically in the FDA-approved population aged ≥40 years, unblinding could reduce biopsy frequency by 18.4% (1288 *vs.* 1579 biopsies), with 3.7% of malignancies monitored rather than investigated further.[18] However, further studies are needed to validate the impact of DermaSensor on healthcare system benefits.

Cost-effectiveness

No cost-effectiveness studies for DermaSensor were identified.

Ongoing trials

One ongoing trial[19] was identified from the ScanMedicine database (NIHR Innovation Observatory; Table 5). Funded by DermaSensor Inc, the prospective study aims to investigate the real-world use of DermaSensor on skin lesions suspicious for melanoma.

Table 5: Ongoing clinical trial

Study (Trial ID)	Population & estimated enrolment	Brief description	Estimated study completion date
DermaSensor Postmarket Surveillance Study (NCT06666790)	Adults aged 40 years or older with skin lesion suspicious for melanoma n=396	The objective of this study is to evaluate the diagnostic accuracy of the DermaSensor device and primary care investigators on skin lesions suspicious for melanoma. These lesions were assessed by unaided primary care physicians followed by aided assessment with DermaSensor.	September 2027 Status: Recruiting

Summary

Based on published evidence, DermaSensor appeared to be safe with no device-related AEs reported. Using histopathology or dermatologist panel assessment as the reference standard for diagnostic performance, DermaSensor demonstrated high sensitivity (81.7% to 97%) and NPV (83.3% to 98.9%), but low-to-moderate specificity (20.7% to 60.7%) and PPV (13.6% to 64.6%), in detecting malignant lesions across the FDA-approved indications.

DermaSensor achieved sensitivity comparable to dermatologists (97.0% *vs.* 96.5%; p=0.82) and significant improvements compared to unaided PCPs (81.7% *vs.* 71.1%; p=0.0085). However, in both comparisons, DermaSensor's specificity was consistently lower, suggesting an increased likelihood of benign lesions being falsely identified as malignant compared with PCPs and dermatologists.

Findings on clinical management decisions aligned with DermaSensor's diagnostic performance. Compared to unaided PCPs, device-aided PCPs achieved higher management sensitivity (88.2% to 91.4% *vs.* 40.0% to 82.0%) with a lower false-negative rate (18% to 8.6%), indicating improved identification and referral of malignant lesions. However, this was accompanied by reduced specificity (32.4% to 70.4%) and more false-positive referrals, suggesting limited potential to reduce unnecessary referrals. Despite this trade-off, device-assisted PCPs reported an improved rate of high-confidence assessment.

Nonetheless, these results should be interpreted with caution. The low incidence of skin malignancy in the local population and the sparse representation of Asian participants (0% to 0.9%) across key evidence may restrict their applicability to local clinical contexts. It is also worthwhile to highlight that all key studies were funded by DermaSensor Inc. Prospective validation in real-world settings and cost-effectiveness analyses to assess the clinical and economic value of DermaSensor will be useful.

VII. Estimated Costs

According to the DermaSensor website, the device operates on a subscription-based pricing model at US$399 (S$543)[1] per device per month. This subscription includes training, cloud storage access, accessories such as a charging dock, and remote device monitoring.[20]

VIII. Implementation Considerations

As an easy-to-use point-of-care device, there is no significant implementation barrier anticipated for adopting DermaSensor. However, training for PCPs on image-capturing standards is necessary to ensure consistent device operation, high-quality data acquisition, and accurate interpretation of results.[21] Standard device operation should ensure proper contact pressure and positioning, and correct lesion selection and scanning technique to minimise measurement variability and optimise device accuracy.

Beyond that, compliance with the Ministry of Health Artificial Intelligence in Healthcare Guidelines (AIHGle) is essential to ensure adherence to regulatory, data privacy, and cybersecurity requirements.[22] Clinical governance and oversight should be established to maintain implementation fidelity and ensure appropriate use of the device within existing clinical workflows, avoiding overreliance on AI and ensuring balanced clinical decision-making. Appropriate IT infrastructure, data standardisation procedures, and user adaptation protocols should also be implemented to support seamless integration with existing electronic medical records and alignment with established referral pathways, thereby enabling consistent documentation and reporting. Following implementation, continuous performance monitoring and evaluation should be undertaken to validate the device's safety, accuracy, reproducibility, and local representativeness of its ML training dataset through ground-truthing.[22]

[1] Based on the Monetary Authority of Singapore exchange rate as of 4 December 2025: US$1=S$1.3603. Figures were rounded to the nearest dollar.

In addition, the handling of lesion images and related patient information must comply with the Personal Data Protection Act (PDPA), ensuring secure data storage and transmission to safeguard patient health information.[22] As an AI device with cloud-based data storage, robust cybersecurity policies should be established to prevent, detect and mitigate potential digital threats and vulnerabilities.

IX. Concurrent Developments

Currently, DermaSensor is the only FDA-approved tool that provides PCPs with a risk assessment for suspicious skin lesions. Several other image-based AI/ML tools to assist in the evaluation, triage, and management of suspicious skin lesions (Table 6).

These include DERM (Skin Analytics),[8] which is implemented within UK's National Health Service (NHS) to aid in the triage of urgent suspected skin cancer referrals, and diagnostic support platforms such as Derma AI[23], Nomela[24] and 3Derm Systems[25], which assist healthcare professionals by classifying or analysing lesion images. Other smartphone-based imaging technologies such as canofyMD SCAI[26] and SkinVision[27], utilise AI algorithms to provide users with risk assessments and recommendations for medical follow-up.

Table 6: Similar technologies in development

Technology (Manufacturer)	Brief description	Status
Deep Ensemble for Recognition of Malignancy (DERM; Skin Analytics)[8]	DERM is an AI-based skin lesion analysis technology intended for screening, triage and assessment of suspicious skin lesions, including melanoma, SCC, BCC, intra-epidermal carcinoma, actinic keratosis, atypical nevus or benign lesions. It provides a suspected diagnosis of a lesion and where applicable, a referral recommendation.	CE-marked; DERM has been deployed in the UK NHS since April 2020, as a triage tool following a primary care referral.
Derma AI (Advanced Human Imaging Ltd.)[23]	Derma AI is a component of the CompleteScan SaaS platform that classifies skin conditions from an image captured with a smartphone to assist dermatologists, clinicians, physicians and nurses with the diagnosis of skin cancer.	CE-marked
Nomela (Moletest Ltd.)[24]	Nomela is an iPad-based AI system that aids in assessing melanoma probability in pigmented lesions for secondary care triage of urgent skin care referrals.	CE-marked
3Derm Systems (3Derm)[25]	3Derm is an AI imaging system that uses highly standardised skin images to autonomously detect melanoma, SCC and BCC to provide PCPs with recommendations to either refer the patient for a potential skin cancer or watchful waiting for a benign concern.	FDA Breakthrough Device Designation
canofyMD SCAI (LifeSemantics)[26]	canofyMD SCAI is an AI-based technology that uses convolutional neural network for image recognition and processing, to detect and assist with the diagnosis of skin cancer (melanoma, BCC, SCC and benign tumours) in images taken from smartphones.	South Korea MFDS approved
SkinVision (SkinVision B.V.)[27]	SkinVision app is an AI-based technology that uses smartphone cameras and algorithms to provide risk indication (low risk, low risk with symptoms, or high risk) and recommend appropriate medical follow-up for suspicious skin lesions for patients.	MDR-approved

Abbreviations: AI, artificial intelligence; BCC, basal cell carcinoma; CE, Conformité Européenne; FDA, Food and Drug Administration; MDR, Medical Device Regulation; MFDS, Ministry of Food and Drug Safety; NHS, National Health Service; PCPs, primary care physicians; SaaS, Software-as-a-Service; SCC, squamous cell carcinoma; UK, United Kingdom

X. Additional Information

A local clinical expert shared that limited specialised dermatological training among many PCPs can contribute to low confidence in evaluating suspicious skin lesions. This may lead to precautionary dermatology referrals, which can contribute to increased healthcare costs, patient anxiety and strain on specialist dermatology services. With incidence of skin cancer rising among local older adults, PCPs are increasingly likely to encounter suspicious skin lesions in the ageing population. Given current capacity constraints and extended dermatology wait times, an objective and standardised risk-assessment tool may enhance PCPs' diagnostic confidence, support more appropriate triage and reduce unnecessary specialist consultations whilst ensuring timely referral of suspicious lesions (Personal communication: Family Physician from NHG Polyclinic, November 2025).

Local experts noted that while DermaSensor may have some clinical utility to assist in the evaluation of suspicious skin lesions, the overall clinical need for the device in primary care may be limited (Personal communication: Senior Consultant from National University Hospital and Singapore General Hospital, November 2025 and February 2026). The clinician shared that referrals for suspected skin cancers are relatively infrequent compared with those for inflammatory skin diseases, which account for most dermatology referrals. Given the relatively low skin cancer burden, the cost-effectiveness of deploying DermaSensor across primary care should be carefully evaluated (Personal communication: Senior Consultant from National University Hospital, November 2025).

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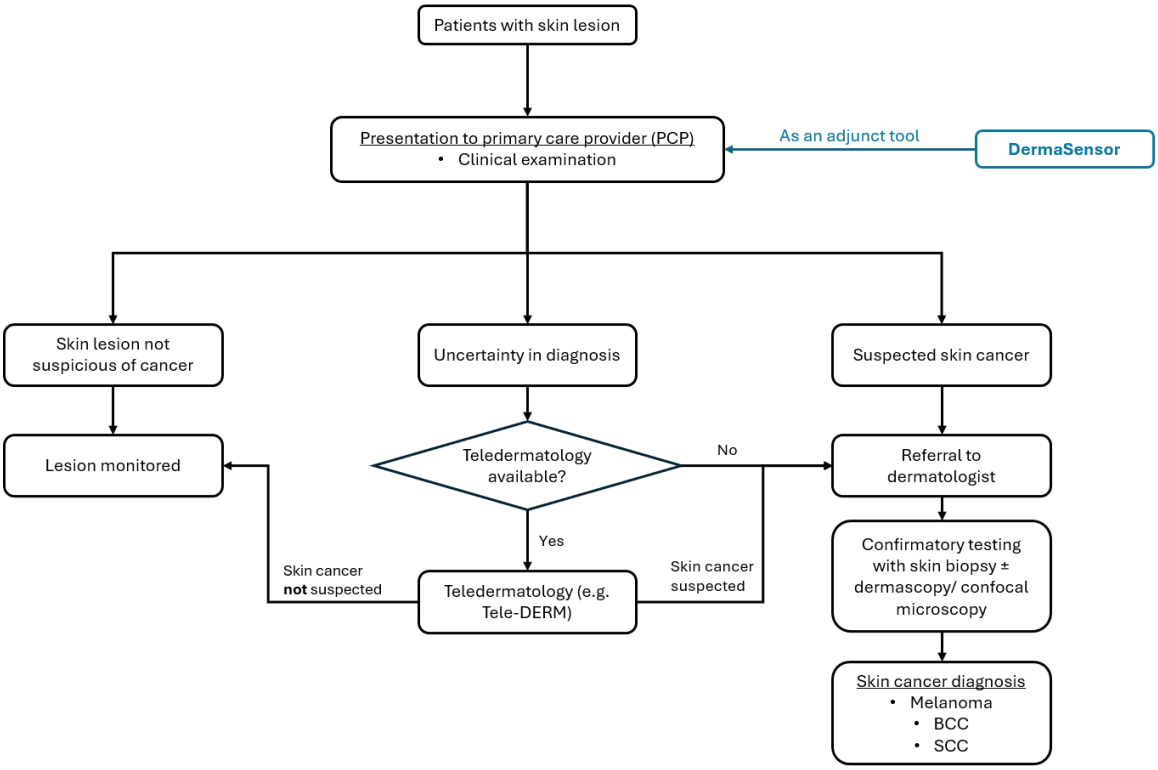
Appendix

Appendix A: Clinical pathways

Table A1*:* Clinical pathway for the referral of suspicious skin lesions based on NICE HTE24 and a local quantitative study.



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2. Artificial Intelligence technologies for assessing skin lesions selected for referral on the urgent suspected cancer pathway to detect benign lesions and reduce secondary care specialist appointments. National Institute for Health and Care Excellence; 2024 18 January 2024.

Abbreviations: BCC, basal cell carcinoma; HTE, Health Technology Evaluation; NICE, National Institute for Health and Care Excellence; SCC, squamous cell carcinoma

Appendix B: Studies identified and study design

Table B1: List of included studies

Type of study	Key evidence base	Supplementary evidence base
Diagnostic studies	4	—
Clinical utility	1	—

Note:
1. Inclusion criteria
   a. Studies that fulfil the PICO criteria listed in Table 1.
2. Exclusion criteria
   b. Studies only available in the abstract form.

Table B2: Design and characteristics of included studies

Study	Study design	Population (n)	Comparator	Reference standard	Outcomes
Manolakos et al. (2023)[15]	Diagnostic accuracy study	Adults aged 22 y/o or above with clinically suspicious lesions, in dermatology clinics. Total lesions: 333 Prevalence of malignant lesions: 14.2% Asian population: 0%	Clinical[a] and dermascopic[b] assessment by dermatologists	Histopathology	● Diagnostic accuracy (Sensitivity, Specificity, NPV, PPV, AUROC)
Hartman et al. (2024)[16]	Diagnostic accuracy study	Patients with lesions suspicious for melanoma, in dermatology clinics. Total lesions: 440 Prevalence: 15.9% Asian population: 0.3%	—	Histopathology	● Diagnostic accuracy (Sensitivity, Specificity, NPV, PPV, AUROC)
Tepedino et al. (2024)[13]	Diagnostic accuracy study	Adults aged 18y/o or above with at least 1 self-identified concerning skin lesion, in primary care. Total lesions: 177 Prevalence of malignant lesions: 12.4% Asian population: 0%	Clinical[a] and dermascopic[b] assessment by PCPs	Histopathology biopsy results when available and a panel of experts of 3 dermatologists when pathology was unavailable	● Diagnostic accuracy (Sensitivity, Specificity, NPV, PPV, AUROC) ● Management decision (Referral sensitivity, Specificity)
Merry et al. (2025)[18]	Diagnostic accuracy study	Adult aged 22 y/o or above with a skin lesion(s) suggestive of melanoma, BCC and/or SCC, in primary care (based on visual inspection by PCPs) requiring biopsy. Total lesions: 1579	—	Histopathology diagnosis by 2 or more dermatopathologists	● Diagnostic accuracy (Sensitivity, Specificity, NPV, PPV, AUROC)

		Prevalence of malignant lesions: 14.2% Asian population: 0.9%			
Ferris et al. (2025)[17]	Clinical utility study	Adult aged 22 y/o or above with a skin lesion(s) suggestive of melanoma, BCC or SCC, in primary care (based on visual inspection by PCPs) requiring biopsy. Total lesions: 50 Prevalence of malignant lesions: 50% Asian population: 0%	Visual inspection by PCPs		● Diagnostic accuracy (Sensitivity, Specificity) ● Management decision (Referral sensitivity, Specificity)

Notes:

[a] Clinical assessment of patient's medical history, including the identification of any risk factors for skin cancer, personal history of skin cancer and the patient's level of concern about the lesion.

[b] Lesion assessment with dermoscopy, objective measurements (anatomic location, size, and surface characteristics), clinical and dermatoscopic images, and the ABCDE characteristics for assessment for melanoma.

Abbreviations: BCC, basal cell carcinoma; PCPs, primary care physicians; SCC, squamous cell carcinoma; y/o, years old

Appendix C: List of supplementary tables and figures

Table C1: Diagnostic performance of DermaSensor across patient demographics.

Study	Subgroup	N	Sensitivity (95% CI)	Specificity (95% CI)
Manolakos et al. (2023)[15]	Pigmented lesions	51	96.1% (86.5% to 99.5%)	—
	Non-pigmented lesions	118	97.5% (92.8% to 99.5%)	—
Tepedino et al. (2024)[13]	Pigmented lesions	177	76.9% (62.8% to 96.8%)	—
	Seborrheic keratoses		70.2% (56.7% to 80.9%)	—
	Actinic keratoses		41.2% (22.2% to 86.2%)	—
	Benign melanocytic nevi		66.7% (43.5% to 83.8%)	—
Merry et al. (2025)[18]	All skin cancers (patient level)	1579	97.0% (93.6% to 98.9%)	—
	All skin cancers (patients ≥40 y/o)		96.3% (92.9% to 98.4%)	20.3% (18.0% to 22.7%)
	Melanoma (patient level)		93.6% (82.5% to 98.7%)	—
	Melanoma (patients ≥40 y/o)		90.2% (76.9% to 97.3%)	—
	Melanoma (patients ≥40 y/o, patient level)		95.1% (83.5% to 99.4%)	—
	BCC (patient level)		97.4% (90.9% to 99.7%)	—
	SCC (patient level)		98.7% (93.1% to 100%)	—
	Fitzpatrick skin type I through III		96.5% (92.6% to 98.7%)	18.7% (16.2% to 21.5%)
	Fitzpatrick skin type IV through VI		92.2% (81.1% to 97.8%)	25.1% (20.9% to 29.7%)

Abbreviations: BCC, basal cell carcinoma; CI, confidence interval; SCC, squamous cell carcinoma; y/o, years old