Evaluating **Pathways for AI Dermatology** in Skin Cancer Detection

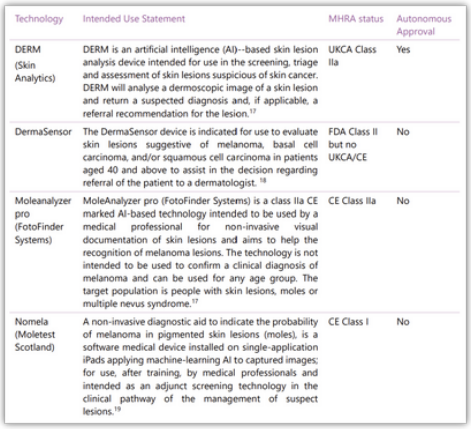
An overview of an independent evaluation by **Edge Health** commissioned by the **NHSE Outpatient Recovery and Transformation Programme**

NHSE Outpatient Recovery and Transformation Programme (OPRT) commissioned Edge Health to write an independent report to look at the use of AI in skin cancer pathways. The report aims to evaluate the adoption of autonomous Artficial Intelligence as a Medical Device (AIaMD) in suspected skin cancer pathways, focusing on performance, current implementation, and economic considerations. It is also the **first to practically assess safety standards and recommendations for the post-market surveillance (PMS)** of autonomously used AI.

Edge Health were tasked with exploring all AI technologies appropriately regulated to be deployed within autonomous pathways. Skin Analytics' AIaMD, **DERM was the only technology that met the requirements, so much of the report focuses on our performance.**

Key findings

AIaMD can be used **autonomously in the NHS** if certified under classes UKCA IIa and CE III. DERM is noted as the **only AIaMD with the necessary evidence base** demonstrating its safety and effectiveness for regulatory clearance at this level.



Technology	Intended Use Statement	MHRA status	Autonomous Approval
DERM (Skin Analytics)	DERM is an artificial intelligence (AI)--based skin lesion analysis device intended for use in the screening, triage and assessment of skin lesions suspicious of skin cancer. DERM will analyse a dermoscopic image of a skin lesion and return a suspected diagnosis and, if applicable, a referral recommendation for the lesion.[17]	UKCA Class IIa	Yes
DermaSensor	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.[18]	FDA Class II but no UKCA/CE	No
Moleanalyzer pro (FotoFinder Systems)	MoleAnalyzer pro (FotoFinder Systems) is a class IIa CE marked AI-based technology intended to be used by a medical professional for non-invasive visual documentation of skin lesions and aims to help the recognition of melanoma lesions. The technology is not intended to be used to confirm a clinical diagnosis of melanoma and can be used for any age group. The target population is people with skin lesions, moles or multiple nevus syndrome.[17]	CE Class IIa	No
Nomela (Moletest Scotland)	A non-invasive diagnostic aid to indicate the probability of melanoma in pigmented skin lesions (moles), is a software medical device installed on single-application iPads applying machine-learning AI to captured images; for use, after training, by medical professionals and intended as an adjunct screening technology in the clinical pathway of the management of suspect lesions.[19]	CE Class I	No

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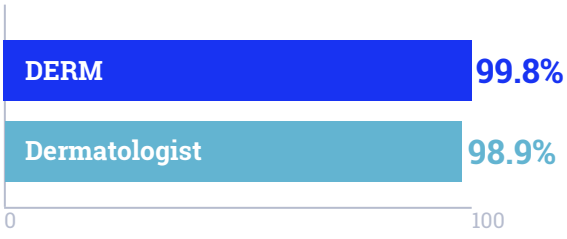
DERM performance is **at least as good as face-to-face dermatologist evaluations**.The Negative Predictive Value (NPV) for correctly excluding melanoma in a matched-prevalence population were...



Based upon:
1. An independent analysis of 33,693 real-world lesions assessed by DERM (including 835 melanoma)
2. A systematic review and meta-analysis of all studies involving consultant dermatologists up to April 2024

AI-enabled pathways allow for lower system costs by reducing the need for face-to-face reviews and biopsies. Illustrative budget impact modelling suggests **up to £86 in savings per case in autonomous pathways**.

AIaMD can rapidly process initial assessments, which could reduce waiting times for secondary care reviews, thereby **enhancing patient experience** and service delivery.

The dermatology scenario in England

170%

increase in Urgent Suspected Cancer referrals in England within the last 10 years.

140%

increase in melanoma incidence rates in the UK since the early 90s - rising each year.

82% **increase in Referral to Treatment** waiting lists between April 2021 and March 2024.

24%

of dermatology Consultant positions are unfilled.

48%

of melanoma diagnoses arose from routine referrals in Nov 2023 - a notable increase from 38% in 2018.

Post-Market Surveillance (PMS) recommendations and how we comply

PMS recommendation	Skin Analytics' standards & evidence
Data collection & Data sharing Requires strong NHS IT infrastructure and streamlined data sharing in line with data privacy regulation	• ISO 27001 • ISO 13485 • NHS DSP Toolkit • Cyber Essentials • DTAC compliant
Equipment, Training & Intended use monitoring Regular communication, training, SOPs and audits to ensure appropriate use of AIaMD and associated hardware	• In-person & online image capture training • Image quality & lesion suitability audits • DERM medical device resources for healthcare organisations
Algorithm validation & Risk management Clinical safety documentation updates with algorithm updates that are based on real-world performance with repeat attendance and adverse event monitoring	• DCB 0129 & support with DCB 0160 • Model card (available on request) • MHRA yellow card scheme
Performance monitoring, Service evaluation & Root cause analysis Regular AIaMD accuracy reporting including subpopulation analysis with false negative case reviews	• DERM Performance • Equality and Health Inequalities Impact Assessment (EHIA) • Clinical advisory case reviews

This independent evaluation **demonstrates the safety of DERM** and the clinical value that regulated AIaMD can deliver for **you and your patients.**

Talk to us to learn more about AIaMD for dermatology.

Full evaluation

skin analytics

08/24