



Skin Analytics

**Instructions For Use
Deep Ensemble for Recognition of Malignancy (DERM) v5.1**

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Instructions for Use

Deep Ensemble for Recognition of Malignancy (DERM)

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Instructions for Use – DERM

DERM is a standalone software device that employs artificial intelligence (AI)-based algorithms to analyse a dermoscopic and/or macroscopic (non-dermoscopic) images of a skin lesion and return a suspected diagnosis and referral recommendation for the lesion. The device is intended to be integrated with a third party client software system through which images are transmitted to and results are displayed from DERM. Only images captured using approved hardware systems are permitted for submission to DERM for analysis.

DERM is primarily intended to be used by healthcare organisations as an automated clinical management tool to help screen, triage or assess patients presenting with one or more lesions where there is a concern of skin cancer. In such cases, the outputs from DERM may be used to issue management instructions without any review from a human clinician.

1. Manufacturing Information

DERM is manufactured by Skin Analytics Limited, Smithfield Business Centre 2nd Floor, 5 St John's Lane, London, EC1M 4BH, United Kingdom.

This device fulfils the provisions of the UK Medical Device Regulation 2002 (as amended), EU Medical Device Regulation 2017/745, Australia Therapeutic Goods (Medical Devices) Regulations 2002 and New Zealand Medicines (Database of Medical Devices) Regulations 2003. This device has been developed in accordance with Skin Analytics' ISO 13485:2016 certified Quality Management System.

For questions or help, please contact Skin Analytics Support at support@skinanalytics.co.uk

2. Intended Use and Indication for Use

DERM is an artificial-intelligence (AI)-based skin lesion analysis device intended for use in the screening, triage and assessment of skin lesions suspicious for skin cancer. DERM will analyse dermoscopic and/or macroscopic (non-dermoscopic) images of a skin lesion and return a suspected diagnosis and/or a referral recommendation for the lesion.

DERM is indicated for use on dermoscopic and/or macroscopic images of cutaneous lesions where there is a suspicion of skin cancer in patients aged 18 years or over in any body location except where specific exclusions apply.

DERM does not provide a definitive diagnosis for skin cancer.

DERM has been validated on images of skin lesions that represent the population of patients and lesions DERM may be used on, in powered prospective studies run the UK, US and Italy. Given the prevalence of skin cancer in the general population, DERM has primarily been evaluated on patients with Fitzpatrick skin types I-IV. DERM should be used with caution on lesions of other skin types.

DERM is intended to be used by:

- Patients as a self-check tool to support decisions regarding self-referral to a healthcare professional.

Instructions for Use – DERM

In this use environment, DERM outputs are tailored for patient-use.

- Primary care clinicians / providers (e.g. general practitioners, nurse practitioners) and secondary care clinicians / providers (e.g. dermatology specialists) as an automated clinical management tool or to augment other clinical data points to support clinical decision-making. Within a healthcare-provider use environment, healthcare support staff (e.g. healthcare assistants or medical photographers) and patients may be authorised to capture images to submit to DERM but are not intended to be users of the outputs generated by DERM, as DERM outputs in this use environment are configured solely for use by healthcare providers.

3. Limitations of Use

DERM should not be used on:

- Patients under the age of 18
- Assessing skin conditions where the concern is not of skin cancer (e.g. rashes, eczema, infectious diseases, lupus)
- Monitoring treatment
- Staging of disease
- Images other than dermoscopic or macroscopic (non-dermoscopic) images of skin lesions
- Images of skin lesions from a subject other than the identified patient
- Open or ulcerated skin lesions
- Skin lesions unable to be entirely imaged using the image capture hardware
- Skin lesions obscured by hair, tattoos or scars
- Skin lesions beneath nails, in eyes or on mucosal surfaces or on soles of feet or palms of hands
- Skin lesions which have previously been biopsied

4. Document Information

Purpose

This document contains the instructions necessary to use DERM in accordance with its function and intended use.

This Instructions for Use document is intended for use by:

- Healthcare Providers (customer organisations) considering the use of DERM by their healthcare professionals as a decision support tool in the screening, triage and assessment of skin lesions suspicious for skin cancer
- Healthcare Providers (customer organisations) considering the use of DERM as an automated clinical management tool to screen or triage patients presenting with lesions suspicious for skin cancer

Instructions for Use – DERM

- Patients or healthcare professionals who are taking and submitting dermoscopic and/or macroscopic images to DERM for analysis

The latest version of this Instructions For Use, provided in pdf format, can be downloaded from the website (<https://skin-analytics.com/derm-medical-device-resources-for-healthcare-organisations/>).

A Summary of Safety and Clinical Performance (SSCP) for DERM is available in the European Database on Medical Devices (EUDAMED): <https://ec.europa.eu/tools/eudamed>. The SSCP is linked to the DERM Basic UDI-DI, which is provided on page 2 of this document.

How to obtain a paper copy of this document

To obtain a paper copy of this document, send an email to support@skinanalytics.co.uk. Please include your organisation name, full address, the product for which you are requesting a manual and the version of the software. Skin Analytics aims to send a paper copy within 7 days of a request at no additional cost.

Definitions

Term	Definition
AI	Artificial Intelligence
API	Application Programming Interface
AK	Actinic Keratosis
AN	Atypical Nevus
BCC	Basal Cell Carcinoma
Camera Device	An image capture device, such as a smartphone, that is used to take an image of a skin lesion to send to DERM for analysis
Client System	Third party client software able to send requests to DERM for analysis and retrieve the outputs from DERM
User	A healthcare professional, non-medical clinical user or patient using a client system via a clinical organisation.
Connection Kit	A clip that attaches the Dermoscope to the Camera Device
Dermoscope	A specialised lens that may be used in conjunction with a Camera Device to take an image of a skin lesion to send to DERM for analysis

Instructions for Use – DERM

False Negative	A malignant lesion classified as a benign lesion
False Positive	A benign lesion classified as a malignant lesion
Healthcare Provider	See “Organisation”
IEC	Intraepidermal Carcinoma/Bowen’s disease
Image Capture Hardware	The Camera Device (with/without Dermoscope and Connection Kit) which together are validated for use with DERM
Input Image(s)	The dermoscopic and/or macroscopic images image(s) taken by the User and submitted to DERM for analysis
Lesion Priority	The prioritisation logic that allows DERM to return an output for the more severe condition in the event that a lesion exceeds the threshold for multiple classification labels
Lesion Classification	The clinical term for the lesion classification returned by DERM e.g. possible Melanoma, probable BCC, etc
Organisation	Network of hospitals or clinics purchasing the use of DERM. Examples include a Hospital Trust, or a Clinical Commissioning Group from the NHS
SCC	Squamous Cell Carcinoma
Sensitivity	The percentage of positive cases that DERM finds as positive
Specificity	The percentage of negative cases that DERM finds as negative
Target Sensitivity	Target sensitivity DERM achieves for each lesion type

Glossary of Symbols used in DERM Labelling



Consult instructions for use or consult electronic instructions for use



Manufacturer

Instructions for Use – DERM



Date of Manufacture



EU Conformity Assessed



EU Authorised Representative



EU Importer



Model Number



Caution



Medical Device



Unique Device Identifier

5. Warnings and Precautions

Precautions

- All Users must follow the instructions for use, including the intended use and indications for use (Section 2) and the safety and cautionary information (this section).
- DERM must be integrated with a Client System, so that Users of the Client System can submit dermoscopic and/or macroscopic images of skin lesions for analysis by DERM, receive the outputs of the analysis performed by DERM, and/or enable automated clinical management activities to be triggered by DERM outputs via the client system (such as patient referral letters). The integration must be completed according to the instructions set out in the DERM API User Manual. Skin Analytics operates an Onboarding process to enable and support integration of Client Systems. For further details, please contact support@skinanalytics.co.uk.
- In order to assure that DERM operates with the stated sensitivity and specificity, the images submitted to DERM for analysis must be captured using approved Image Capture Hardware. For dermoscopic images, the images must be captured using an approved Camera Device connected to a Dermoscope using a Connection Kit, whereas for macroscopic images, the images must be captured using an approved Camera Device only. For details of the latest approved hardware, please refer to the Skin Analytics website: <https://skin-analytics.com/derm-medical-device-resources-for-healthcare-organisations/>
- Users should regularly ensure that the Client System is operating on a computer that is free of viruses and malware and compliant with local cybersecurity policies.
- DERM will only analyse the image(s) that has been submitted to it. Make sure that the image(s) is of the correct lesion of concern.
- Do not take a photograph of another photograph or image displayed on a phone, computer, tablet, or other screen. Images must be taken directly of the skin being assessed.
- When macroscopic images alone are used for analysis DERM offers high sensitivity for the detection of skin cancer, but is expected to have lower specificity compared with multimodal or dermoscopic-only modalities. The macroscopic only modality should be used only when patients do not have access to dermoscopic image capture, or when the lesion is too large to be imaged using a dermatoscope. The commissioning organisation is responsible for determining when macroscopic only mode is appropriate within a skin cancer pathway. See Section 10 for a summary of the device's clinical performance data across different modalities.



Warnings

DERM is to be used only by a healthcare provider or by a clinical organisation's client system in the screening, triage and assessment of skin lesions suspected of skin cancer.

DERM does not provide a definitive diagnosis of skin cancer.

When deployed as part of an automated clinical management system, the DERM classification output may be used to trigger an automated clinical management response via a clinical organisation's client system. The content and format of the response, such as a referral letter, is created under the responsibility of the commissioning clinical organisation. Where applicable, the organisation is expected to take into account the explicit clinical safety warnings for automation detailed in the "Pathway Responsible Owner User Manual" and in this section.

When DERM is used to augment other clinical data points, or support a clinical decision for a patient, the result provided should be viewed alongside all other relevant information before issuing a clinical management decision.

If DERM is unavailable, clinical users should continue with the patient assessment, in accordance with existing clinical practice (e.g. traditional teledermatology or face-to-face review).

DERM should not be used for cases or excluded lesion types listed in the '[Limitations of Use](#)' section.

DERM does not directly screen for any lesions not listed in the "Product Information - Device Inputs and Outputs" section (e.g. rare malignant lesions such as Merkel Cell Carcinoma).

DERM should be used with caution on Fitzpatrick skin types V-VI. DERM has been validated on images of skin lesions that represent the population of patients and lesions DERM may be used on, in powered prospective studies run in the UK, US and Italy. Given the prevalence of skin cancer in the general population, DERM has been evaluated mostly on Fitzpatrick skin types I-IV. DERM should be used with caution on lesions of other skin types.

DERM will check that an image is a dermoscopic or macroscopic image of skin, and that it is of sufficient quality for analysis (i.e. not too dark or blurred). Good image-taking technique is therefore an important prerequisite for successful use of DERM. For information on how to take good images for DERM analysis, please refer to the "Hardware, Image Capture, Exclusions & Consent" manual, the latest version of which can be downloaded from the website - Guidance on image capture (<https://skin-analytics.com/derm-medical-device-resources-for-healthcare-organisations/>).

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The images sent to DERM should not be captured with the use of an immersion fluid as these may introduce image artefacts that could adversely impact the performance of DERM.

The images sent to DERM should not contain any other external objects or markings within the image and/or obscuring the lesion, e.g. felt-tip marker, sticker, ruler, as this could adversely impact the performance of DERM.

DERM only assesses dermoscopic and/or macroscopic images of skin. The Client System used to access DERM may also capture other information related to the patient or lesion (e.g. age, lesion location, or change). This additional data is not included in the DERM assessment. If more than one lesion has been submitted for assessment by DERM, each lesion will be assessed in isolation and independent of the other.

The rate of false positives and false negatives produced by DERM is dependent on the configured operating parameters used (as set out in "[Configuration - Operating Parameters](#)" Section). High sensitivity settings to minimise false negatives necessarily means that there will be some positive classifications which turn out to be benign.

Care should be taken when giving results to patients in order to minimise anxiety.

6. Product Information

How does DERM work?

DERM is a standalone software device that employs artificial intelligence (AI)-based algorithms to analyse dermoscopic and/or macroscopic (non-dermoscopic) images of a skin lesion and return a suspected diagnosis and referral recommendation for the lesion. The device is intended to be integrated with a third party client software system through which images are transmitted to and results are displayed from DERM. Only images captured by approved hardware are permitted for submission to DERM for analysis. DERM can return a suspected diagnosis and, if applicable, a referral recommendation¹ for the following conditions:

- Melanoma
- Squamous Cell Carcinoma (SCC)
- Basal Cell Carcinoma (BCC)
- Intraepidermal Carcinoma (IEC)
- Actinic Keratosis (AK)
- Atypical Naevus (AN)
- Benign (including Benign Vascular Lesion, Seborrheic Keratosis, Dermatofibroma, Solar Lentigo and Benign Melanocytic Nevus)

¹ See Page 14 for a list of example labels. The wording of the labels may be modified, under a controlled and risk assessed process, to suit a healthcare provider's specific clinical pathway.

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DERM is primarily intended to be used by healthcare organisations as an automated clinical management tool to help screen, triage or assess patients presenting with one or more lesions where there is a concern of skin cancer. In such cases, the outputs from DERM may be used to issue management instructions without any review from a human clinician. However, depending on an organisation's clinical governance requirements / procedures, some organisations may opt to use the device's output to augment other clinical datapoints, support a clinical decision, or require that the outputs from DERM are reviewed by a second (human) reader before issuing a clinical management decision.

DERM is intended to be deployed by healthcare organisations who have the necessary clinical governance procedures in place to establish and oversee a skin cancer pathway. Prior to implementation, all pathways are required to be approved by both Skin Analytics and the healthcare organisation to ensure that DERM is deployed per its intended use.

DERM operates a sequential, 3-step process.

Step 1: Identification of dermoscopic and/or macroscopic image

DERM checks whether each submitted image corresponds to the expected image type (dermoscopic or macroscopic) and represents an image of the skin. This ensures that images submitted in error - such as non-skin images or images of the incorrect type (e.g. dermoscopic image submitted in place of a macroscopic image, or vice versa) - are not further processed. DERM returns an error message if it identifies that the image is not a valid dermoscopic or macroscopic image of the skin.

Step 2: Image quality assessment

If one or more valid dermoscopic or macroscopic images are identified (Step 1), DERM assesses the quality of each image, ensuring that it is neither too blurry nor too dark. Images failing the quality assessment are not used in the analysis and DERM provides an error message indicating the reason for the failure (i.e. too dark/abnormal lighting or too blurry).

Step 3: Image analysis

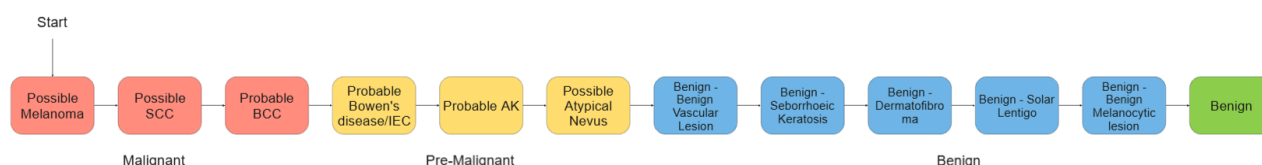
Depending on which images pass Step 1 and Step 2, DERM will proceed to analyse the image(s) and provide a suspected diagnosis (e.g. possible melanoma; probable BCC, etc) and referral recommendation. Depending on the approved pathway determined by the commissioning healthcare provider and enforced by the client system, the following conditions may apply:

- When both a dermoscopic image and at least two macroscopic image(s) are submitted, DERM may use both image types together to perform a multimodal analysis. However:
 - When a dermoscopic image passes but fewer than two macroscopic images pass image suitability checks, DERM performs a dermoscopic-only analysis.
 - When a dermoscopic image fails, DERM terminates further processing, regardless of the status of any submitted macroscopic images.
- When only a dermoscopic image is submitted and passes the image suitability checks, DERM performs dermoscopic-only analysis.
- When only macroscopic images are submitted, DERM performs macroscopic analysis if at least two macroscopic images pass image suitability checks.

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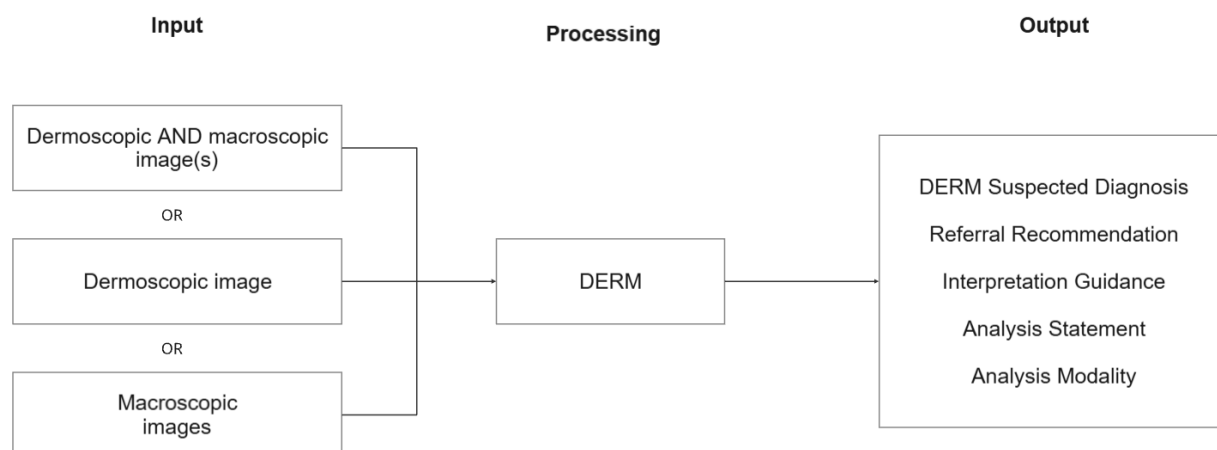
If a dermoscopic image is available and used in the analysis, DERM first identifies the skin lesion within the dermoscopic image. If more than one skin lesion is identified within the image, DERM outputs a suspected diagnosis and referral recommendation for each of the lesions identified. In addition, DERM uses contextual information from the entire dermoscopic image to determine the suspected diagnosis for each lesion. If only macroscopic images are submitted, DERM outputs a suspected diagnosis and referral recommendation based on the entire image.

When a lesion exhibits features of more than one lesion type, DERM prioritises the higher risk condition over the lower risk condition by implementing a risk hierarchy in its final output. This order of processing (shown below with priority running from left to right) is used to ensure that, in a scenario where more than one label could be returned, DERM always returns the more severe suspected diagnosis.



Device Inputs and Outputs

The inputs and outputs of the device are shown in the schematic below.



Please note: Referral Recommendation and Interpretation Recommendation Guidance are optional fields and may not be shown under your configuration.

The device inputs are described in the table below:

Input	Description
Image(s)	Dermoscopic image and/or macroscopic images submitted to DERM through the API.

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The device outputs are described in the table below:

Output Field	Description	Example Output(s)
DERM Suspected Diagnosis	DERM's suspected diagnosis for a given skin lesion.	• Possible Melanoma • Possible Squamous Cell Carcinoma (SCC) • Probable Basal Cell Carcinoma (BCC) • Probable Bowen's Disease / Intraepidermal Carcinoma (IEC) • Probable Actinic Keratosis (AK) • Possible Atypical Nevus • Benign - Benign Vascular Lesion • Benign - Seborrhoeic Keratosis • Benign - Dermatofibroma • Benign - Solar Lentigo • Benign - Benign Melanocytic Nevus • Benign
Analysis Statement	Text describing whether the request has been successfully processed, or if an error has occurred. If there are insufficient valid images for successful processing (e.g. image(s) identified as not dermoscopic or macroscopic images of the skin, image(s) identified as too dark or too blurry) the message 'Case suitability checks failed' will appear, alongside granular reasons for each image.	• Skin lesion detected and successfully processed • Case suitability checks failed • System Error
Analysis Modality	Text describing which analysis modality was used to complete the lesion assessment, based on the images submitted.	• Multimodal (dermoscopic and macroscopic) analysis • Dermoscopic only analysis • Macroscopic only analysis
Referral Recommendation (optional)	Associated text supplementing DERM's Suspected Diagnosis, indicating the recommended next step in the patient management pathway. This content is configurable at the request of the organisation / user commissioning the use of DERM.	Examples: • Urgent Suspected Cancer Referral • Refer according to local pathway • Manage according to local pathway • Manage as Atypical Nevus • Discharge and give safety netting advice Where the specific referral recommendations are not implemented, a generic safety-net statement can be configured.

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Interpretation Guidance (optional)	Associated text supplementing DERM's Referral Recommendation. This content is configurable at the request of the organisation / user commissioning the use of DERM.	Examples: • Refer on urgent suspected cancer pathway for specialist review. • Consider urgent referral pathway if there is a particular concern that a delay may have a particular impact such as site or size. See NICE guidance. • Follow local pathway for Actinic Keratosis. • Manage as Atypical Nevus. • Discharge patient, recommend self-monitoring and further GP review if there are any changes or they remain concerned. If you are concerned despite this result consider referral. Where the specific referral recommendations are not implemented, a generic safety-net statement can be configured.
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Notes:

- Additional outputs, not displayed to the user, are provided for technical and administrative purposes and are detailed in the DERM API User Manual.
- Whether probable or possible is used is determined using the Positive Predictive Value (PPV). 'Probable' is used when a PPV for that lesion type is >30% and 'Possible' for lesion types with a PPV of <30%.
- The ability to submit macroscopic images only, without a corresponding dermoscopic image, is determined by the commissioning healthcare organisation, via the approved pathway process, through their chosen client system.

Product Lifetime

Skin Analytics defines the lifetime of DERM as 5 years.

Skin Analytics will continue to support DERM for at least one year after the latest version update.

7. Installation and Configuration

Installation

As DERM is an online hosted service, no installation is necessary. To use DERM, requesting organisations must register for a DERM account with Skin Analytics.

Configuration

DERM is deployed with a set of threshold settings which have been selected and optimised by Skin Analytics during device development. Any changes from the standardised settings must be agreed by Skin Analytics and the commissioning organisation following a defined procedure before being implemented.

DERM configuration relates to two aspects of the analysis:

Operating parameters – the threshold settings which determine the trade-off between DERM's false positive and false negative rates. Each set of threshold settings includes a single sensitivity value for each of the conditions identified by DERM.

Analysis result wording - the text used to explain the results of the analysis. Analysis result wording can be mutually agreed for the following DERM Outputs:

- DERM Suspected Diagnosis. Only changes consistent with the product's intended use will be permitted; for example, replacing the term 'possible melanoma' with 'suspicious lesion'.
- DERM Referral Recommendation: Only changes consistent with the product's intended use will be permitted, but there may be some local configuration to align with the clinical pathway where DERM is implemented. Examples of possible outputs are provided in the Device Outputs table above.
- DERM Interpretation Guidance: Further detail on the referral recommendation, which may be tailored to the local pathway where DERM is implemented, but following a rigorous approval process to ensure it is in line with the intended use. Examples of possible outputs are provided in the Device Outputs table above.

Operating Parameters

The analysis performance of DERM can be configured to suit the clinical context and pathway. The trade-off between sensitivity and specificity for each lesion type and image analysis modality (multimodal, macroscopic only or dermoscopic only) has been tuned to provide three operation settings, which can be selected for use in different clinical settings. For example, it may be more desirable to have a high sensitivity for melanoma to minimise the chance of false negatives. Alternatively, a higher specificity may be preferred when the burden of potential over-referrals is a consideration. By default, Skin Analytics onboards all organisations with a set of standard settings, which have been configured to provide the following pathway sensitivity levels for each lesion type listed below:

Lesion Priority	Lesion Type	Target Sensitivity
1	Melanoma	95%
2	Squamous Cell Carcinoma (SCC)	95%

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3	Basal Cell Carcinoma (BCC)	90%
4	Bowen's disease / Intraepidermal Carcinoma (IEC)	90%
5	Actinic Keratosis (AK)	90%

Analysis result wording

For each lesion assessment, the results returned by DERM include:

- DERM's Suspected Diagnosis
- Referral Recommendation (optional)
- Interpretation Guidance (optional)
- Analysis Statement
- Analysis Modality

Submitting Images for Analysis

Once the DERM account is set up and configured, and the Client System is integrated, please refer to the instructions for your Client System to submit images to DERM for analysis. DERM is expected to complete an image analysis result in less than 20 seconds.

Updates

Updates to the DERM service will be managed by Skin Analytics. Updates which alter the connection between DERM and the Client System will only become available to the Client System once it is updated to connect to the new DERM connection. Skin Analytics can provide more information about our Software Bill of Materials (SBOM) if requested by healthcare providers.

Decommission and Disposal

Once DERM is deployed into service, the device will continue to operate until it is either upgraded to a new version, or retired from service. In the event of decommissioning or upgrade, requirements for data retention and transfer will align with EN/IEC 82304-1 standards and applicable regulatory requirements.

Skin Analytics will manage the decommissioning process. When decommissioning the software, Skin Analytics will create a backup of DERM data and store the backup in the company's electronic storage facility. Once the backup is completed, Skin Analytics will shutdown the cloud infrastructure / account hosting the DERM software following the AWS guidelines.

8. Legal

The terms related to your use of DERM will be set out in the contract between Skin Analytics Ltd and your organisation.

To review the Privacy Policy, please refer to the Skin Analytics website for the latest version:
<https://skin-analytics.com/privacy-policy/>

9. Troubleshooting

This section covers the most common problems encountered by users who are submitting images and receiving results from DERM. If, after reading this section, you still have doubts on what to do next, please email support@skinanalytics.co.uk.

I have submitted an image but I can only see “Image not a dermoscopic image of the skin” or “Image not a macroscopic image of the skin”

When DERM displays “Image not a dermoscopic image of the skin” or “Image not a macroscopic image of the skin” message it means that the initial step (Step 1 Described in Product Information ‘How does DERM Work’) has determined that the image does not correspond to the expected image type (e.g. dermoscopic or macroscopic) or the image is not of skin. As a result, further processing has not been completed.

“Image not a dermoscopic image of the skin”

This message typically occurs when a non-dermoscopic image has been submitted in place of a dermoscopic image (e.g. when the dermoscope has not been attached to the smartphone) or the submitted dermoscopic image is not of skin.

“Image not a macroscopic image of the skin”

This message typically occurs when dermoscopic image(s) have been submitted in the place of macroscopic image(s), or when the submitted image does not contain skin (e.g. if an image of another object - such as a piece of paper - was submitted by mistake).

Make sure that you are taking the correct image type, as directed by the Client System instructions, then retake and resubmit.

On rare occasions, the original image(s) will be suitable but DERM will output this message. This is due to the accuracy of DERM to detect dermoscopic or macroscopic images of skin being slightly lower than 100%. Simply retake the image and resubmit if this happens.

I have submitted an image but I only receive “Image Quality failed - image too dark”

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When DERM provides the message “Image Quality failed - image too dark” it means that the quality assessment step (Step 2 Described in Product Information ‘How does DERM Work’) has determined that the image is too dark to be analysed and further processing has not been completed.

Why this may occur:

- For **dermoscopic images**, the dermoscope light may not be turned on or the device may not be properly attached.
- For **macroscopic images**, the ambient lighting may be insufficient for the camera to capture the skin clearly.

Make sure that the dermoscope’s light is switched on and that adequate lighting is available, then retake the image and resubmit.

On rare occasions, the original image(s) will be suitable, but DERM will output this message. This is due to the accuracy of DERM to detect adequately lit images being slightly lower than 100%. Simply retake the image and resubmit if this happens.

I have submitted an image but I only receive “Image Quality failed - image too blurry”

When DERM provides the message “Image Quality failed - image too blurry” it means that the quality assessment step (Step 2 Described in Product Information ‘How does DERM Work’) has determined that the image is too blurry to be analysed and further processing has not been completed.

Why this may occur:

- For **dermoscopic images**, the dermoscope may not be firmly in contact with the skin, or movement during image capture may have prevented the camera from focusing.
- For **macroscopic images**, the photo may have been taken before the camera had time to focus on the lesion, or the camera or patient may have moved during image capture.

When taking a dermoscopic image, make sure that the dermoscope is pressed against the skin as detailed by the Client System instructions and the camera has focused before taking the image, then retake and resubmit. When taking a macroscopic image, ensure that the camera is in focus and the patient still before taking the image.

Some lesions are located on a part of the body where it is difficult to achieve a fully in-focus image, such as when the lesion is on the ear or bony prominence. In these situations, it may not be possible to take an image that will be accepted by DERM.

On rare occasions, the original image(s) will be sufficiently in focus, but DERM will output this message. This is due to the accuracy of DERM to detect adequately focussed images being slightly lower than 100%. Simply retake the image and resubmit if this happens.

I have submitted an image but I only receive “System error”

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When DERM displays the “System error” message it means that an internal error in the communication between the Client System and DERM has occurred. This is usually due to authentication issues or a bug in the integration between the two software and is independent of the submitted image. Contact your local IT department and the organisation responsible for the maintenance of the Client System if you see this message.

I have submitted an image but I do not receive anything back

A lack of response after submitting an image for analysis usually implies a drop in your Internet connection or that the submit button may not have been clicked. Ensure that the Client System is connected to the Internet and that any local firewalls in your local system are not preventing the image from being submitted. Contact your local IT department and the organisation responsible for the maintenance of the Client System if you see this message.

My kit (smartphone, dermoscope or connection kit (clip)) is damaged. What should I do?

If you are concerned that the damage is affecting the quality of images that you are capturing, stop submitting cases to DERM. You should speak to the organisation that supplied your kit to arrange for replacement or repair as necessary.

I do not have an Internet connection. What should I do?

The Client System requires an Internet connection in order to send images to DERM and to transmit the results. Contact your local IT department to restore the connection in order to use DERM.

I cannot log in/I have forgotten my password. What should I do?

DERM does not have any login details from a user perspective. Users access DERM via a Client System. Please contact your local Client System administrator to retrieve your login details for accessing the Client System.

I do not agree with DERM's output, what should I do?

DERM is intended to be used by, or under, the direction of healthcare professionals or by a clinical organisation's client system in the screening, triage and assessment of skin lesions suspected of skin cancer.

When DERM is used as a decision support tool

DERM does not provide a definitive diagnosis of skin cancer. The output provided by DERM should be considered alongside other clinical information when making decisions on patient management, and care should be taken when giving results to the patient in order to minimise anxiety.

When DERM is used as an automated clinical management tool

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DERM's sensitivity settings are configured to find the right balance between minimising both false positives and false negatives, but in some occasions DERM will produce a false positive (i.e. classify a lesion as malignant when it is benign) or a false negative (i.e. classify a lesion as benign when it is malignant). It is the responsibility of the Pathway Responsible Owner to make the decision on patient management based on DERM's output.

What shall I do if I am concerned about the diagnostic performance of the device?

If you are concerned about the performance of DERM against expected performance, please contact Skin Analytics' help desk (support@skinanalytics.co.uk) or your point of contact so that we can look into it. In the UK, you can also report any adverse events to the MHRA using the yellow card scheme: <https://yellowcard.mhra.gov.uk/>. If adverse events occur in the EU, you can report the event to the national competent authority of the relevant member state in which the event occurred.

What happens when a failure to maintain security is detected?

DERM is continuously monitored for security incidents. In the event that a failure to maintain security is detected, Skin Analytics will communicate the impact of and actions needed to address the security incident with all affected users and organisations. Failure to detect a security breach may result in a loss of service, or - at worst - corrupted DERM outputs. Skin Analytics operates an ISO 27001-certified information security management system and has implemented robust cybersecurity controls in the device to limit the occurrence and impact of a security incident.

I am attempting to submit a macroscopic image of a skin lesion without a dermoscopic image, but it is not being accepted. What shall I do?

The commissioning organisation controls whether the device can accept macroscopic-only images via its client system. If the system is set to use a dermoscopic-only or multimodal pathway, the device will require a dermoscopic image to be provided.

10. Clinical Evaluation of DERM

Skin Analytics conducts clinical evaluation activities to ensure that there is sufficient clinical evidence to confirm that the device provides clinical benefit, and that this outweighs the clinical risks, when utilised in accordance with its Instructions for Use.

Clinical Benefits

- DERM can detect malignant, pre-malignant and benign lesions from dermoscopic images with a sensitivity, specificity and accuracy similar to or greater than dermatologists.
- DERM detects lesions histologically diagnosed as melanoma, SCC, BCC, IEC and AK with a greater sensitivity than defined Minimum Safety Requirements.
- DERM can reduce the number needed to biopsy to identify skin cancer.

Performance Characteristics

The performance of DERM has been evaluated through numerous clinical studies. The device has been deployed in the real-world across the UK since 2020 and Europe since 2025. The DERM risk benefit profile, in the intended use population for the detection of skin cancer, has been demonstrated to be favourable based on (1) state-of-the-art determination and (2) clinical evidence (including clinical validation studies and post market surveillance data). DERM's performance has been investigated using a range of different image capture hardware combinations.

Summary of Clinical Data from Conducted Clinical Investigations

DERM-003 Clinical Investigation: Effectiveness of an image analysing algorithm (DERM) to diagnose non-melanoma skin cancer (NMSC) and benign skin lesions compared to gold standard clinical and histological diagnosis

The DERM-003 study was a prospective, multi-centre, single-arm, masked clinical validation study that aimed to demonstrate the effectiveness of DERM to identify Squamous Cell Carcinoma (SCC), Basal Cell Carcinoma (BCC), pre-malignant and benign lesions from dermoscopic images of suspicious skin lesions (Clinicaltrials.gov NCT04116983)². The co-primary endpoints were the Area Under the Receiver Operating Characteristic Curve (AUROC) of the DERM result for SCC and BCC of biopsied lesions, using histopathological-confirmed diagnosis as the ground truth. Secondary endpoints included diagnostic measures for malignant and non-malignant lesions of both the DERM output and clinical diagnosis.

The AUROC for SCC and BCC produced by DERM on images of biopsied lesions captured on the iPhone 6S were 88.9% and 89.5%, respectively, 88.5% and 89.6% for images captured on the iPhone 11, and 84.9% and 87.2% for images captured on the Samsung 10. The AUROCs for BCC and SCC, when calculated on all lesions, were >90% except for SCC in images captured on the Samsung 10 camera, where the AUROC was 87%. The DERM AUROC for benign lesions was 85% on non-biopsied lesions and 81% for all lesions with images captured by the iPhone 11. The AUROCs produced by DERM using all lesions were higher than those calculated from the dermatologists' assessment of lesions for all lesion types, except AK (all image capture hardware) and atypical nevi when imaged by the Samsung 10. Using pre-determined diagnostic thresholds on images of all lesions taken on the iPhone 6S, DERM achieved a sensitivity and specificity of 95.4% (95% CI 83.3-99.2%) and 44.7% (95% CI 40.4-49.1%) for SCC; and 94.9% (95% CI 90.6-97.4%) and 41.6% (95% CI 36.2-47.2%) for BCC. All 16 lesions diagnosed as melanoma in the study were correctly classified by DERM.

The results from the DERM-003 study showed that DERM accurately identifies non-melanoma skin cancer and benign conditions, and that taking images for AI assessment was a quick and well tolerated process.

DERM-005 Clinical Investigation: Impact of an Artificial Intelligence Platform (DERM) on the Healthcare Resource Utilisation (HRU) Needed to Diagnose Skin Cancer When Used as Part of a United Kingdom-based Teledermatology Service

² Marsden et al. (2023). Effectiveness of an image analyzing AI-based Digital Health Technology to identify Non-Melanoma Skin Cancer and other skin lesions: results of the DERM-003 study. Front. Med. 10:1288521. doi: 10.3389/fmed.2023.1288521

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DERM-005 was a prospective, single-centre, single-arm, masked, non-inferiority study that aimed to demonstrate that the performance of DERM has the potential to reduce urgent referrals and biopsy requests for non-malignant lesions compared to teledermatologists (Clinicaltrials.gov NCT04123678)³. The primary endpoint was the rate of unnecessary referrals of non-cancerous lesions reviewed by teledermatology or DERM for the same cancer detection rate between Standard of Care (SoC) and DERM.

Using two different sensitivity settings, DERM achieved a significantly higher rate of identifying pre-malignant and benign lesions that did not need a biopsy or urgent referral (specificity) compared to SoC (p-value = 0.001) with comparable sensitivity for skin cancer. Of the 8 histology-confirmed melanomas, seven were correctly labelled as melanoma by both SoC and DERM; of the 13 histology-confirmed SCCs, 11 were labelled as SCC and 2 were labelled as BCC by DERM; and of the 46 histology-confirmed BCCs, 31 were labelled as BCC, 10 as melanoma or SCC, and 5 as premalignant or benign by DERM.

The results from the DERM-005 study demonstrate DERM has a high specificity for skin cancer, and that taking images for AI assessment was a quick and well tolerated process.

DERM-006 Clinical Investigation: A clinical validation study to demonstrate the effectiveness of an Artificial Intelligence algorithm (DERM) to identify skin cancer in patients undergoing a skin biopsy

DERM-006 was a prospective, international, multi-centre, single-arm, cross-sectional, masked clinical validation study that aimed to demonstrate the performance of DERM when used to identify malignant skin lesions from dermoscopic images of skin lesions (Clinicaltrials.gov NCT5126173). The co-primary endpoints were the sensitivity and specificity of detecting malignant lesions, while secondary endpoints included the sensitivity and specificity of DERM to identify melanoma, SCC and BCC lesions.

DERM achieved a sensitivity of 97.5% and specificity of 31.1% with images captured by the iPhone 11 + DL200HR hardware combination, while it achieved a sensitivity of 93.4% and specificity of 31.6% with the iPhone 11 + DL1 combination. In addition, DERM showed a high level of accuracy in detecting individual lesion conditions, in particular with images taken by the iPhone 11 + DL200HR lens combination. Specifically, DERM demonstrated a sensitivity of 94.3% and a specificity of 62.8% in detecting melanoma, a sensitivity of 92.5% and a specificity of 44% in detecting SCC, and a sensitivity of 98.7% and a specificity of 31.1% in detecting BCC.

The results from the DERM-006 study demonstrate DERM has a high sensitivity and specificity for skin cancer, and that taking images for AI assessment was a quick and well tolerated process.

DERM-011 Clinical Investigation: Repeatability and Reproducibility of a Skin Cancer Detection AI as a Medical Device (DERM+)

DERM-011 was a prospective, cross-sectional, single-arm, multi-centre, masked study investigating the reliability of the DERM+ outputs when assessing dermoscopic images of skin lesions undergoing biopsy for the presence of skin cancer (Clinicaltrials.gov NCT06654999). The DERM+ version of DERM provides a binary output: “high suspicion of malignancy” for lesions classified as melanoma, SCC, BCC,

³ Marsden H et al. (2024) Accuracy of an Artificial Intelligence as a medical device as part of a UK-based skin cancer teledermatology service. Front. Med. 11:1302363. doi.org/10.3389/fmed.2024.1302363

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and IEC and “low suspicion of malignancy for lesions” classified as Atypical, AK, and any benign condition. The diagnostic performance of DERM+ was included as exploratory analyses.

Multiple dermoscopic images of each lesion were captured and assessed by DERM+. The most frequent DERM+ output (“high suspicion” or “low suspicion”) for each lesion was compared to histopathology-confirmed diagnoses (including independent dermatopathology panel review for pigmented and/or melanocytic lesions). The sensitivity of DERM+ to detect melanoma was 100% (11/11, 95% CI: 71.5-100.0%), SCC was 100% (19/19, 95% CI: 82.4-100.0%), and BCC was 100% (24/24, 95% CI: 85.8-100%). DERM+ achieved a specificity of 18% (8.6-31.4%) in a biopsy-only population.

Summary of Other Clinical Data

DERM-007 IPD Meta-Analysis: The Diagnostic Accuracy of an Artificial Intelligence algorithm (DERM). A Prospective, Individual Patient Data (IPD) meta-analysis based on a synthesis of data from 3 prospective clinical studies across 21 sites in 3 countries

DERM-007 was a prospective, individual patient data meta-analysis based on a synthesis of data from 3 prospective clinical studies across 21 sites in 3 countries, which was designed to demonstrate the diagnostic accuracy of DERM across all lesion types. The co-primary endpoints were the sensitivity and specificity of DERM to detect pre-malignant lesions (SCC in situ (IEC / Bowen's Disease), AK and Atypical Nevus), while secondary endpoints included the sensitivity and specificity of DERM to identify individual lesion types. Exploratory endpoints included the performance of DERM to detect malignant lesions.

The three clinical studies (DERM-003, DERM-005 and DERM-006) recruited patients with at least one suspicious skin lesion. Lesions were imaged with an iPhone 11/X smartphone with a DermLite DL1 Basic dermoscopic lens.

Using a random effects model on a data set of images captured by the iPhone 11/X with the DL1 lens, the sensitivity and specificity of DERM to detect premalignant lesions was estimated to be 81.5% (95% CI: 75.1-87.1%) and 49.0% (95% CI: 21.8-76.4%), respectively. DERM demonstrated a sensitivity of above 90% for IEC and AK lesions, and above 65% for Atypical Nevi and specificity above the pre-defined study success criteria. In addition, the sensitivity of DERM to detect melanoma was 87.2% (95% CI: 80.6% - 92.8%), and SCC was 95.1% (95% CI: 90.3% - 98.5%).

The results from the DERM-007 study demonstrate DERM has a high sensitivity and specificity for pre-malignant lesions.

DERM-013 Clinical Investigation: A clinical validation study to demonstrate the effectiveness of an Artificial Intelligence algorithm (DERM+) to identify malignant lesions of the skin

DERM-013 was a prospective reanalysis of images captured in the DERM-006 study to evaluate the DERM+ version of DERM. In total, 1,074 dermoscopic images (from 983 patients) captured by the iPhone11/DL200HR hardware combination were analyzed by DERM+. Original histopathology reports were reviewed to identify severely dysplastic nevi. The DERM+ output was compared to the ground truth diagnosis.

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A co-primary endpoint was DERM+ sensitivity to detect melanoma. In the FA-performance population, the sensitivity of DERM+ to detect melanoma was 93.7% (95% CI: 87.9-96.8%). Powered secondary endpoints were DERM+ sensitivity to detect SCC (including SCC in situ/IEC and keratoacanthoma) and BCC. In the FA-performance population, the sensitivity of DERM to detect SCC was 100% (95% CI: 96.3-100%) and the sensitivity of DERM to detect BCC was 99.2% (95% CI: 96.8-99.8%). In exploratory analyses, DERM+ sensitivity to detect AK was 95.9% (95% CI: 93.8-97.3%) and DERM+ sensitivity to detect severely dysplastic nevi was 72.5% (95% CI: 56.9-84.0%).

The specificity of DERM+ to detect non-malignant lesions >20% was a co-primary endpoint. In the FA-performance dataset, 24.4% (95% CI: 20.8-28.5%) of non-malignant lesions were correctly classified as “low suspicion of malignancy”. A specificity significantly above 20% indicates that DERM+ achieved a significantly higher specificity than standard of care.

Post-Market Surveillance (ongoing)

The latest DERM performance data can be found at <https://skin-analytics.com/ai-pathways/derm-performance/>

Real-World Performance of DERM

Real-world data from deployment of DERM within skin cancer pathways at two UK hospitals (University Hospitals Birmingham, West Suffolk Foundation Trust) between July 2021 and October 2022 were published⁴. Two versions of DERM were used during this period, separated by time: DERM-version A (DERM-vA) (July 2021 to April 2022), and version B (DERM-vB) (April 2022 to October 2022). Each version used fixed sensitivity thresholds. DERM was accessible to adults of all ages (18–100 years) and was used to assess potential malignant skin lesions in all Fitzpatrick skin types I–VI. Both versions of DERM achieved a pathway sensitivity of >96% for skin cancer and >95% for melanoma.

Hardware

Performance data that supports the use of DERM with different approved hardware combinations primarily comes from clinical studies, which have shown that the hardware can have an impact on DERM performance. DERM should therefore only be used with images captured on the hardware that has undergone testing to validate acceptable performance.

Device usage

Real-world data confirms the usability of the device. Of 117,824 lesions sent for DERM assessment in 2025, only 1.0% of lesions (1167/117,824) were excluded from DERM analysis due to being unable to capture a dermoscopic image, 0.7% (786/117,824) due to images not passing suitability checks, and 0.2% (187/117,824) due to technical (network/connectivity) issues. As the patient will automatically be referred for clinician review in these cases, the risk of missed cancer from a failure of DERM to return an output is minimal.

DERM v5 Clinical Investigation: A clinical validation study to demonstrate the safety and effectiveness of the DERM v5 JackStack model

⁴ Thomas et al. (2023) Real-world post-deployment performance of a novel machine learning-based digital health technology for skin lesion assessment and suggestions for post-market surveillance. Front. Med. 10:1264846. doi: 10.3389/fmed.2023.1264846

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The performance of DERM v5 has been demonstrated using a prospectively captured, large, diverse real-world, consecutive data set⁵. Performance targets were met for histology-confirmed malignant (melanoma, SCC and BCC) and premalignant (SCC in situ and AK) lesions across all image assessment modalities and threshold settings. The performance of DERM v5 has been shown to meet performance targets when used with dermoscopic and/or macroscopic image inputs in line with its intended use.

Summary of DERM v5 Performance				
	Lesion routing with multimodal image inputs ¹	Image assessment modality		
		Multimodal	Dermoscopic	Macroscopic
Melanoma	96.9% [95.2-98.0%]	96.5% [94.4-97.8%]	96.0% [93.9-97.3%]	97.1% [95.3-98.2%]
Malignant lesions ²	98.1% [97.5-98.5%]	98.1% [97.4-98.5%]	97.8% [97.2-98.3%]	98.0% [97.4-98.4%]
SCC	98.3% [97.2-99.0%]	98.3% [97.0-99.0%]	98.4% [97.2-99.1%]	98.4% [97.2-99.1%]
BCC	98.5% [97.7-99.0%]	98.5% [97.7-99.1%]	98.4% [97.6-98.9%]	98.1% [97.2-98.7%]
SCC in situ ³	96.4% [93.4-98.1%]	95.9% [95% CI 92.2-97.9%]	96.8% [93.6-98.5%]	97.8% [94.9-99.1%]
AK ³	95.1% [92.9-96.7%]	95.0% [95% CI 92.6-96.7%]	94.8% [92.5-96.5%]	96.6% [94.6-97.9%]
Benign ⁴	76.9% [76.2-77.6%]	78.1% [77.4-78.8%]	77.5% [76.8-78.2%]	51.1% [50.3-52.0%]
Pathway sensitivity and specificity (using default threshold settings) are presented with 95% confidence intervals [1] With lesions identified as 'too large for dermoscopic imaging' routed to macroscopic assessment [2] Melanoma, SCC, BCC and rare skin cancers [3] Ground truths based upon histology outcomes [4] Ground truths based upon both histology outcomes and clinical diagnoses				

The latest information on the research supporting the use of DERM can be found at <https://skin-analytics.com/performance/>, or for further information please contact Skin Analytics for a summary of evidence.

⁵ Data held on file