



Skin Analytics

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

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Instructions for Use (For Patients)

Deep Ensemble for Recognition of Malignancy (DERM)

1. Manufacturing Information	4
2. Intended Use and Indication for Use	4
3. Limitations of Use	5
4. Document Information	6
Purpose	6
How to obtain a paper copy of this document	6
Definitions	6
Glossary of Symbols used in DERM Labelling	7
5. Warnings and Precautions	8
Precautions	8
Warnings	9
6. Product Information	10
How does DERM work?	10
Conditions Assessed	10
Images and Results	10
Images Used by DERM	10
Results Provided by DERM	11
Example Results	12
Understanding Your Results	13
After Receiving a Result	14
Product Lifetime	14
7. Device Performance	14
8. Requirements for Safe Use	14
9. Legal	15
10. Troubleshooting	15

DERM is a software device that uses artificial intelligence (AI) to analyse images of a skin lesion. It provides information about what the lesion may be and, where appropriate, what you should do next.

DERM is used to help assess skin lesions where there is a concern about skin cancer. It may be used by healthcare professionals or directly by patients as a self-check tool.

DERM analyses images that are taken using a smartphone camera, and may also use more detailed images taken with a specialised lens, known as a dermoscope.

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 in 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:

Instructions for Use (For Patients) – DERM

- Patients as a self-check tool to support decisions regarding self-referral to a healthcare professional. 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 and patients may be authorised to capture images for submission 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:

- If you are under 18 years old.
- If your concern is about a general skin condition (such as a rash, eczema, acne, psoriasis, or an infection) rather than a mole or skin lesion.
- If you are using this to monitor a skin condition that is already being treated by a healthcare professional.
- If your mole or skin lesion has already been diagnosed as skin cancer and needs further tests or ongoing care.
- If the image(s) are of someone else's skin.
- If the mole or skin lesion is oozing, bleeding, or has an open sore.
- If the whole mole or skin lesion is not visible within the image (e.g. part of it is cut off or outside the frame).
- If the mole or skin lesion is covered by thick hair, tattoos, or scars that makes it difficult to see clearly.
- If the mole or skin lesion is:
 - Under a nail
 - In the eye
 - Inside the nose
 - On the lips or inside the mouth
 - On the palms of the hands (including fingers) or soles of the feet (including toes)
 - On the genitals
- If the mole or skin lesion has already been biopsied (a small piece of tissue taken for testing) or partially removed.



If DERM is used in these situations, the device may not give reliable results. If any of these apply, you should speak to a healthcare professional.

4. Document Information

Purpose

This document provides the instructions necessary to use DERM safely and to understand the results it produces. It is intended for patients who may capture and submit images of a skin lesion and/or receive and act on the results provided by DERM when used as a self-check tool.

The latest version of this Instructions For Use, provided in pdf format, can be downloaded from the Skin Analytics website: <https://skin-analytics.com/derm-medical-device-resource-for-patients/>

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's 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 name and full address. Skin Analytics aims to send a paper copy within 7 days of a request at no additional cost.

Definitions

Term	Definition
AI	Artificial Intelligence
Benign	A mole or skin lesion that is non cancerous.
Dermoscope	A specialised lens that can be used with a smartphone to take detailed images of a skin lesion. Attached using a magnetic case/clip.
Image(s)	The photo(s) of your skin lesion that you submit for analysis.
False Negative	A cancer that is incorrectly identified as not suspicious.
False Positive	A non-cancerous lesion that is incorrectly identified as suspicious.
Mole	A very common type of skin lesion, usually appearing as a brown, black or pink mark on the skin. Most moles are harmless, however, may require assessment if they change in appearance or look unusual.

Instructions for Use (For Patients) – DERM

Skin lesion	An area of skin that is abnormal in appearance or texture compared to the surrounding skin. A skin lesion may include a mole, growth, sore, or other visible mark on the skin that may need checking for skin cancer.
Sensitivity	A measure of how well a test identifies lesions that may represent skin cancer. A highly sensitive test is designed to miss as few cancers as possible.

Glossary of Symbols used in DERM Labelling



Consult instructions for use or consult electronic instructions for use



Manufacturer



Date of Manufacture



EU Conformity Assessed



EU Authorised Representative



EU Importer



Model Number



Caution



Medical Device



Unique Device Identifier

5. Warnings and Precautions

Precautions

- DERM should be used in accordance with these instructions.
- The accuracy of DERM depends on the quality of the images provided. Images that are blurry, out of focus, too dark, or do not show the full lesion are not suitable for analysis. Images should:
 - Be clear and in focus
 - Be well lit
 - Show the full lesion
 - Not include other external objects (such as rulers, pens, markings, or stickers) that cover or interfere with the lesion
- To ensure DERM works correctly, images must be taken using a supported device. DERM may not work correctly on all smartphones. You should only use a smartphone that is supported by the application or service you are using. For details of the latest approved hardware, please refer to the Skin Analytics website: <https://skin-analytics.com/derm-medical-device-resource-for-patients/>
- If a specialised lens (dermoscope) is required, you should only use the dermoscope provided to you. Using other devices or attachments may affect the quality of the image and the accuracy of the result.
- DERM only assesses the image(s) of the lesion that are submitted. You should make sure that the image(s) are of the lesion of concern.
- You should not repeatedly submit images of the same lesion to try to obtain a different result. If you are unsure about a result, you should seek medical advice.
- 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.
- DERM has primarily been evaluated with lighter skin types (Fitzpatrick I - IV). Its performance with darker skin types has been less extensively evaluated.



Warnings

DERM does not provide a diagnosis of skin cancer. Results suggesting a possible or suspicious condition do not confirm a diagnosis and require further medical assessment.

DERM assessment is based only on the images you provide and does not replace a full examination by a healthcare professional. DERM does not consider other information such as your symptoms, medical history, or changes in the lesion over time.

If DERM is used in the scenarios listed in the [Limitations of Use](#) section, the device may not give reliable results.

Poor quality images may result in DERM being unable to return a result or may reduce the accuracy of the result.

DERM may produce incorrect results. This includes:

- False negative results, where a cancerous lesion is identified as non-suspicious
- False positive results, where a non-cancerous lesion is identified as suspicious

DERM is designed to identify most cancers and, as a result, may classify some non-cancerous lesions as suspicious to reduce the risk of missing a cancer.

DERM does not assess all possible skin conditions and may not identify rare types of skin cancer. The conditions assessed by DERM are listed in the [Conditions Assessed](#) section.

If DERM is unable to provide a result, you should not rely on the system. You should retake the image if instructed, or seek medical advice if you remain concerned.

If DERM recommends medical assessment, you should arrange this as advised. Delaying medical assessment may delay diagnosis or treatment.

You should follow the recommendation provided by DERM. If no action is recommended, you should continue to monitor your skin, and seek medical advice if the lesion changes or if you remain concerned.

6. Product Information

How does DERM work?

DERM is a software device that uses advanced AI-based algorithms to analyse images of skin lesions and provide a suspected diagnosis and, where applicable, a recommendation for next steps.

DERM processes each image in three stages. First, it checks whether the image is of skin and of the correct type. Second, it assesses the quality of the image to ensure that it is suitable for analysis. Third, it analyses the image and produces a result. If the image does not meet the required criteria, no result will be provided.

Conditions Assessed

DERM may provide outputs relating to the following conditions:

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

Images and Results

DERM analyses images of a skin lesion and provides information to help you decide what to do next.

Images Used by DERM

To use DERM, you will need to take one or more images of your skin lesion.

These may include:

- Standard smartphone photos of the skin, and/or
- A detailed image taken using a specialised lens (dermoscope), if available

Instructions for Use (For Patients) – DERM

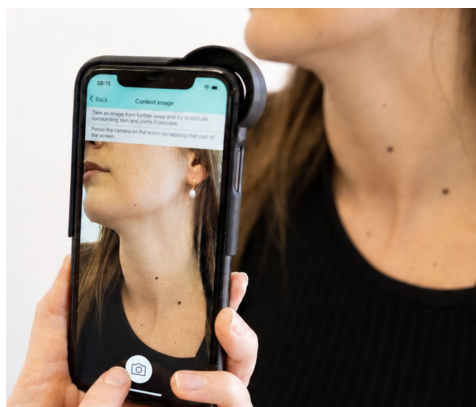


Figure 1. Example of a smartphone image being taken.

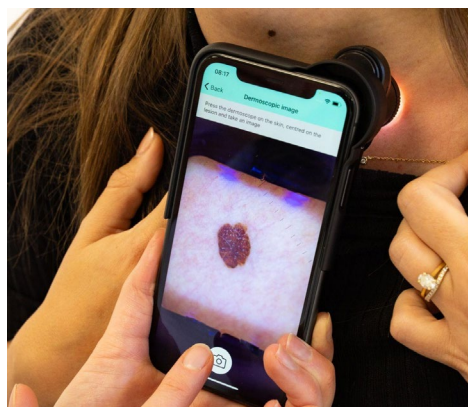


Figure 2. Example of a dermoscopic (more detailed) image being taken.

If a dermoscopic (detailed) image is required, you will be provided with the kit which includes a magnetic clip/case and a dermatoscope.

You should follow the instructions provided to ensure that the images are clear, in focus, well lit, and show the full lesion. Poor quality images may result in DERM being unable to analyse the image or may reduce the accuracy of the result.

If you are unable to take a clear image of the lesion, for example due to its location, you may ask someone to help you. If you are still unable to obtain a suitable image, you should seek medical advice.

Results Provided by DERM

After analysing your image(s), DERM may provide:

Referral Recommendation

This explains what you should do next. Recommendations may include:

- No further action
- Arranging a routine appointment
- Arranging an urgent appointment

Suspected Diagnosis

This describes what the lesion may be based on the image(s) submitted.

For example, the result may indicate that the lesion appears to be benign (harmless), or that it shows features that may represent a type of skin lesion, growth or cancer that should be checked by a healthcare professional (such as your GP or a dermatologist). See examples below.

Instructions for Use (For Patients) – DERM

Interpretation Guidance

This provides additional information to help you understand the result and what it means for you.

For example, it may:

- explain when you should seek medical advice
- clarify whether the recommendation is urgent or non-urgent
- remind you that the assessment is based only on the image(s) provided and does not replace a full examination by a healthcare professional

Analysis Error Message (if applicable)

This indicates that DERM was unable to analyse your image(s).

This may happen, for example, if:

- The image is too blurry
- The image is too dark
- The image is not recognised as skin or is not of the correct type
- There is a system error (technical error with DERM)

If this occurs, you should retake the image following the guidance provided and submit it again.

If you continue to receive this message or are unable to obtain a result, you should seek medical advice.

Example Results

Examples of DERM results include:

Referral Recommendation	Suspected Diagnosis	Interpretation Guidance
No further action recommended	Based on the images submitted, the area assessed shows features consistent with [seborrhoeic keratosis], a common harmless skin lesion or growth.	No appointment is recommended at this time. You should seek advice from a healthcare professional if the lesion changes in size, shape, or colour, becomes painful, starts to bleed, or causes ongoing concern. This assessment is based only on the images you provided and does not replace a full examination by a healthcare professional.
Further action recommended (non-	Based on the images submitted, the area assessed shows features that	This is not urgent, but you should arrange a routine appointment with a healthcare

Instructions for Use (For Patients) – DERM

urgent)	may represent a type of skin lesion or growth that should be checked by a healthcare professional, such as actinic keratosis or Bowen’s disease.	professional. This assessment is based only on the images you provided. It is not a definitive diagnosis and does not replace a full examination by a healthcare professional.
Urgent action recommended	Based on the images submitted, the area assessed shows features that may represent a more serious type of skin cancer, such as melanoma or squamous cell carcinoma.	Please arrange an urgent appointment with a healthcare professional as soon as possible, ideally to be seen within the next 1-2 weeks. This assessment is based only on the images you provided. It is not a definitive diagnosis and does not replace a full examination by a healthcare professional.
Not assessed	Image quality failed - Image(s) too dark	Repeat the assessment. Alternatively, see a healthcare professional if you are concerned.

If your submission includes more than one lesion, the recommendation applies to the case as a whole. You should follow the recommendation provided. If you are unsure which lesion the result relates to, or if you are concerned about any lesion, you should seek medical advice.

Understanding Your Results

DERM assessment is based only on the image(s) submitted and does not provide a diagnosis of skin cancer.

A result suggesting a possible cancerous or pre-cancerous condition does not confirm a diagnosis. These cases require further medical assessment.

DERM is designed to identify most skin cancers when used as intended. Because of this, some people may be advised to seek further assessment even when the lesion later turns out to be harmless. This approach helps reduce the risk of missing a cancer.

A result indicating a lesion is likely to be benign (harmless) means that the lesion has been assessed as non-cancerous based on the image(s) submitted. However, no test is perfect, and there remains a small risk that a cancer could be missed.

Some types of skin cancer can become more serious if not identified and treated early. It is therefore important to monitor your skin and seek medical advice if you notice any changes or remain concerned about a lesion. For more information about skin cancer, speak to a healthcare provider.

After Receiving a Result

After receiving a result, you should carefully review the information provided and follow any recommendation given.

You should seek medical advice if you are advised to do so by the system, by contacting your GP or another appropriate healthcare professional (e.g. dermatologist).

If the lesion of concern changes in size, shape, or colour, becomes painful, or bleeds, or if you remain concerned about the lesion, even if the result is reassuring, you are advised to seek medical advice

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. Device Performance

DERM is designed to identify most cancers and may classify some non-cancerous lesions as suspicious to reduce the risk of missing a cancer.

In clinical studies and in real world use, DERM has demonstrated consistently high sensitivity for detecting skin cancers when used as intended. The ability of DERM to identify skin cancers has been shown to be at least as good as a dermatologist.

However, no test is perfect. Some cancers may not be identified as suspicious, and some non-cancerous lesions may be identified as suspicious.

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.

8. Requirements for Safe Use

DERM must be used through the application or service provided to you and requires a functioning internet connection. The device will only operate correctly if images are captured and submitted in accordance with the instructions provided.

Instructions for Use (For Patients) – DERM

DERM may be accessed through different applications or services. The way information is displayed and the steps for capturing and submitting images may vary depending on the system you are using. You should follow the instructions provided within the system you are using.

9. Legal

To review the Terms & Conditions, please refer to the Skin Analytics website for the latest version:
<https://skin-analytics.com/terms-and-conditions/>

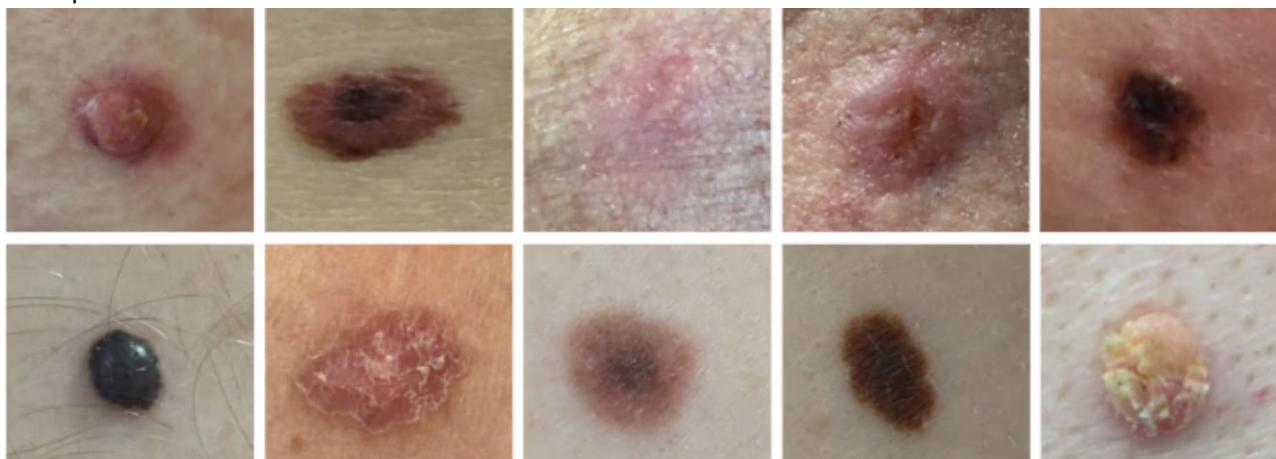
To review the Privacy Policy, please refer to the Skin Analytics website for the latest version:
<https://skin-analytics.com/privacy-policy/>

10. Troubleshooting

This section describes common problems you may experience when using DERM and what to do next. If you are unsure what to do, or remain concerned about your skin, you should seek medical advice or contact support@skinanalytics.co.uk.

What is a skin lesion or mole versus a general skin condition?

Examples of skin lesions and moles:



Instructions for Use (For Patients) – DERM

Examples of general skin conditions such as eczema, psoriasis, acne:



I cannot take a clear image of the lesion

This may happen if:

- the lesion is located in a hard-to-reach area (for example, the ear, back, or other areas difficult to see or access)
- it is difficult to hold the camera steady or in focus when taking the image

What to do:

- Follow the instructions provided by the application
- Ensure the image is clear, in focus, well lit, and shows the full lesion
- Retake the image and submit it again
- Ask someone to help you take the image

If you are still unable to obtain a suitable image, you should seek medical advice.

I received a message saying the image(s) is not recognised as skin

This means the image was not recognised as a suitable image of skin.

This may happen if:

- the image does not clearly show skin
- the image is not the correct type (for example, a smartphone image was taken when a dermoscopic image was required, or vice-versa)

What to do:

- Follow the instructions provided by the application
- Make sure you are taking the correct type of image
- Retake the image and submit it again

Instructions for Use (For Patients) – DERM

On rare occasions, the original image(s) will be suitable but DERM will output this message. Simply retake the image(s) and resubmit if this happens.

I received a message saying the image is too dark

This means the image is not bright enough to be analysed.

This may happen if:

- there is not enough lighting
- the dermoscope light is not turned on (if used)

What to do:

- Take the image in a well-lit area
- Ensure the dermoscopic light is turned on (if used)
- Retake and submit the image

On rare occasions, the original image(s) will be suitable, but DERM will output this message. Simply retake the image(s) and resubmit if this happens.

I received a message saying the image is too blurry

This means the image is not in focus.

This may happen if:

- the camera or body part moved during image capture
- the image was taken before the camera focused
- the device was not held steady

What to do:

- Hold the camera steady
- Wait for the image to come into focus before taking the photo
- Retake and submit the image

Some lesions may be difficult to capture clearly depending on their location. If you cannot obtain a clear image, you may ask someone to help you. If you are still unable to obtain a clear image, you should seek medical advice.

On rare occasions, the original image(s) will be sufficiently in focus, but DERM will output this message. Simply retake the image(s) and resubmit if this happens.

I received a “System error” message

Instructions for Use (For Patients) – DERM

This means there was a problem with the system (DERM) rather than your image(s).

What to do:

- Check your internet connection
- Try submitting the image again
- If the problem continues, contact support or the provider of the application you are using

I submitted an image but did not receive a result

This may happen if:

- your internet connection was interrupted
- the image was not successfully submitted

What to do:

- Check your internet connection
- Ensure the image has been submitted
- Try submitting the image again

If you are unable to obtain a result, you should seek medical advice if you are concerned.

My device or equipment is damaged

If your smartphone or any provided equipment is damaged and may affect image quality:

What to do:

- Stop using the device
- Contact the provider of the equipment for support or replacement (if equipment provided)

I do not have an internet connection

DERM requires an internet connection to analyse images and return results.

What to do:

- Connect to the internet and try again

I cannot access the application or log in

Access to DERM is provided through an application or service.

What to do:

Instructions for Use (For Patients) – DERM

- Contact the provider of the application or your account administrator

My image is not being accepted

In some cases, the system may require a specific type of image (for example, a detailed image using a dermoscope, as well as smartphone images).

What to do:

- Follow the instructions provided in the application
- Make sure you are taking the correct type of image
- If a dermoscope is required, ensure it is being used correctly

If you are unable to submit an image or are unsure what to do, seek medical advice if you are concerned.

I do not agree with DERM's output

If you do not agree with the result provided by DERM, you should seek medical advice.

DERM does not provide a definitive diagnosis for skin cancer and it does not replace a full examination by a healthcare professional.