



DERM Class IIa Patient Information Leaflet

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Introduction

You have received this document as part of an appointment to have your skin lesion (commonly called a mole) investigated. At this appointment, a medical device called DERM will be used. DERM works by electronically assessing a detailed image of your lesion/mole that is taken with a special lens called a dermatoscope. DERM then provides a suspected diagnosis and what the most appropriate next steps should be for your care.

DERM was developed by Skin Analytics, a UK based, research led company working in partnership with the NHS to assess and drive appropriate management of a range of skin conditions. DERM is approved as a Class IIa medical device, is supported by published clinical research, and has been used in the NHS since 2020 seeing over 32,000 patients by September 2022.

We would like to reassure you that skin cancer is rare and most lesions are found to be benign and present no problems at all.

What to expect

Note: This document explains how DERM works in general. As part of your appointment you should also receive information from your healthcare provider that explains some of the practicalities about your appointment (e.g. where to go, who you will see, what time, and what will happen next). If you're unsure about this information please contact your healthcare provider.

At your appointment, you will be seen in a private room by a healthcare professional.

First, they will seek your consent. This is to ensure that you fully understand the process, which is non-invasive, but does involve automatic processes which may or may not, depending on how your healthcare provider works, be overseen by a health professional.

They will then ask you a few questions concerning your medical history and check that DERM is appropriate to assess your lesion before taking a smartphone photograph of your skin lesion. Your medical history and smartphone photograph images of your skin lesion are captured for use and reference by your healthcare provider.

They will then take a deeper and more detailed image with a special lense called a dermatoscope. Figure 1 shows an example how the dermoscopic image capture process is performed. This is generally painless but it might be a little sore on tender lesions/moles. Only this dermoscopic image will be analysed by DERM, which will provide a suspected diagnosis, using highly developed software to decide what the most appropriate next steps should be for your care.



Figure 1. The dermoscopic image capture process

At the end of this assessment process, your healthcare professional will discuss the next steps for your care.

What happens if DERM suspects your lesion may be skin cancer?

- Your healthcare provider will arrange for onward care to have the lesion assessed in line with the risk of the condition identified. See the appendix for more details about skin conditions. This may involve a referral to an Urgent Suspected Cancer Skin appointment with the local Dermatology team. You can find out more about this process at the following website, or in any detailed information you have received from your healthcare provider - <https://www.cancerresearchuk.org/cancer-symptoms/what-is-an-urgent-referral>
- DERM is set up to catch as much skin cancer as possible. As a result, although you are being referred, in the vast majority of cases subsequent review or investigation will discount skin cancer.

What happens if DERM determines your lesion is benign?

- Your healthcare provider will communicate your results back to you. In some cases even though the lesion is benign they may recommend some topical treatments.
- It is unlikely that you do have skin cancer, but it is not certain. It is always worth continuing to monitor your skin. You can find out more about how to keep an eye on your skin and reduce your future risk of skin cancer by reading the information on the following links:
 - <https://www.nhs.uk/conditions/moles>
 - <https://www.skinhealthinfo.org.uk/sun-awareness/the-sunscreen-fact-sheet/>

Have more questions?

You can contact Skin Analytics at the following link: <https://skin-analytics.com/contact-us/> if you have any feedback, questions or issues. To see more about how we protect your data, see the Skin Analytics Privacy Policy at <https://skin-analytics.com/Privacy/>.

If you're interested, the full instructions for use for healthcare professionals using DERM can be found at this link: <https://skin-analytics.com/derm/resources/>.

Glossary

Conditions detected by DERM	More information
Benign (this includes Benign Vascular Lesion, Seborrheic Keratosis, Dermatofibroma, Solar Lentigo and Melanocytic Benign Nevus)	<p>The vast majority (more than 90%) of patients who are referred to a Dermatologist by the GP do not have skin cancer. In most cases the suspicious lesion turns out to be benign with no danger of causing harm or spreading to other parts of the body.</p> <p>Some common examples of benign lesions that can be mistaken for skin cancer include: Benign Vascular Lesion, Seborrheic Keratosis, Dermatofibroma, Solar Lentigo and Melanocytic Benign Nevus. You can find out more information about each of these by searching the British Association of Dermatologists Patient Information Leaflets at https://www.bad.org.uk/patient-information-leaflets/</p>
Melanoma	<p>Melanoma is a type of skin cancer that can spread to other organs in the body. DERM is configured to detect at least 95% of melanomas, comparable to specialists/dermatologists.</p> <p>You can find out more information about melanoma by visiting the NHS website at https://www.nhs.uk/conditions/melanoma-skin-cancer/</p>
Squamous Cell Carcinoma (SCC)	<p>Squamous cell carcinoma (SCC) is a type of non-melanoma skin cancer (NMSC). It can spread locally and rarely spread to other organs in the body. SCC accounts for about 20 in every 100 NMSC. DERM is configured to detect at least 95% of SCCs, comparable to specialists/dermatologists.</p> <p>You can find out more information about SCC in the British Association of Dermatologists Patient Information Leaflet at https://www.bad.org.uk/pils/squamous-cell-carcinoma/</p>
Basal Cell Carcinoma (BCC)	<p>Basal cell carcinomas (BCCs) are by far the most common type of skin cancer. They are typically slow-growing and whilst they can be locally invasive they are not known to spread to other parts of the body. They account for around 80 in every 100 NMSC.</p> <p>You can find out more information about BCC in the British Association of Dermatologists Patient Information Leaflet at https://www.bad.org.uk/pils/basal-cell-carcinoma/</p>
Intraepidermal Carcinoma (IEC)	<p>Intraepidermal Carcinoma (aka Bowen's Disease) is a precancerous form of Squamous cell carcinoma and is sometimes referred to as squamous cell carcinoma <i>in situ</i>. It develops slowly and is easily treated in order to prevent it becoming an SCC.</p> <p>You can find out more information about Bowen's disease in the British Association of Dermatologists Patient Information Leaflet at https://www.bad.org.uk/pils/bowen-disease-squamous-cell-carcinoma-in-situ/</p>
Actinic Keratosis (AK)	<p>Actinic keratoses, also known as solar keratoses, are dry, scaly patches of skin caused by damage from years of sun exposure.</p>

	<p>Like Bowen's disease, there is a small risk of developing into SCC if left untreated.</p> <p>You can find out more information about Actinic keratosis in the British Association of Dermatologists Patient Information Leaflet at https://www.bad.org.uk/pils/actinic-keratoses/</p>
Atypical Naevus (AN)	<p>An atypical naevus describes a mole which is 'odd looking' but not cancerous. If a lesion is excised, looking at under a microscope it is described as being 'dysplastic' reflecting that the cells are irregular.</p> <p>You can find out more information about Atypical Naevus in the British Association of Dermatologists Patient Information Leaflet at https://www.bad.org.uk/pils/dysplastic-atypical-naevus/</p>

Other terms	More information
Consent for automated decision making	This section of the consent process explains any decisions that are made by DERM without a healthcare professional reviewing the outputs. This doesn't apply to all healthcare providers so please review this information to make sure you are comfortable about the care you will receive.
DERM	Skin Analytics's medical device
Excluded	<p>There are certain situations where DERM shouldn't be used. Your healthcare professional will check these before using DERM. Those that are most relevant to you are listed below:</p> <ul style="list-style-type: none"> ● Patients under the age of 18 ● Open or ulcerated skin lesions ● Skin lesions too large to be entirely imaged within the dermoscopic device used ● 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

DERM Manufacturing Information

DERM is manufactured by Skin Analytics Limited, 4th Floor, Kingsbourne House, 229-231 High Holborn, London, WC1V 7EG, United Kingdom . Skin Analytics Limited is registered in England and Wales No. 07919560

This device fulfils the provisions of the UK Medical Device Regulation 2002 (as amended) and the Australian Therapeutic Goods (Medical Devices) Regulations 2002. This device has been developed in accordance with Skin Analytics' ISO 13485:2016 certified Quality Management System.

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Document Reference Number and Version: SA-001201-LB v4, Review Date: September 2022

Document: SA-001201-LB

Approved version: 4

Title: DERM Class IIa Patient Information Leaflet

Approved By:

Clinical Safety Director - Jenny Dean Fri Sep 30 15:52:23 GMT 2022

Reviewed and Approved 34ZUz2OyNSAKHgbX6L2+2/7weX8

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Reviewed and Approved L+23Ag75yz4JlKVvKdpn3Yia600

Operations Director - David Puttergill Mon Oct 3 08:06:41 GMT 2022

Reviewed and Approved KEjNonL2w5x+9o/JqDDWsMm9VcQ

Approval History:

Version	Approved on	Status	Issued by
4	Mon Oct 3 2022	Approved	Bokyung Kim
3	Tue Jul 26 2022	Superseded	Bokyung Kim
2	Mon Apr 25 2022	Superseded	Bokyung Kim
1	Thu Sep 16 2021	Superseded	James Hamlyn
A		Draft	James Hamlyn
Version	Approved on	Status	Issued by