DERM Patient Information Leaflet

Introduction

You are receiving this leaflet as part of an assessment to take a closer look at a skin lesion (commonly called a mole). During this assessment, a medical device called **DERM** will be used.

DERM (Deep Ensemble for the Recognition of Malignancy) is a software that uses advanced artificial intelligence designed to identify skin cancer. DERM works by electronically assessing images of your lesion or mole to provide a suspected diagnosis of what the lesion might be and what should happen next.

DERM is developed by a UK company called Skin Analytics, a research-led company, working in partnership with the UK National Health Service (NHS) and other healthcare providers, to assess and manage a range of skin lesions. DERM is approved as a CE Class III medical device. It is supported by published clinical research, has been used in the NHS in the UK since 2020 and was supported by a review from NICE (the UK's National Institute for Health and Care Excellence). To date, it has been used to assess more than 250,000 patients.

We want to reassure you that skin cancer is rare. Most skin lesions or moles are completely harmless (benign). If you receive a recommendation to see a healthcare professional (referral), it does not mean something is seriously wrong. A referral will allow a healthcare professional to take a closer look at your skin and ensure you receive the right care and peace of mind. In many cases, that extra check shows there is nothing to worry about and that your skin lesion is harmless.

What to expect

Note: This document explains how DERM works in general. Your healthcare provider will give you separate information about the practical details of your care (e.g. where to go, who you will see, what time, and what will happen next) or how to capture and submit images yourself. If you are unsure about this information please contact your healthcare provider.

DERM works by assessing images of a skin lesion. Photos of the lesion will be taken using a smartphone camera. In some cases, a more detailed photo may also be taken using a special magnifying device called a dermatoscope which is placed gently on your skin.

The photos are securely sent to DERM, which uses artificial intelligence to assess the images and provide a **suspected diagnosis and recommendations for the best next steps for your care.**

Taking photos for DERM is painless. If the magnifying device is used, it is placed on your skin. This should not hurt, but if your mole or lesion is a little sore, it might feel slightly uncomfortable for a moment.

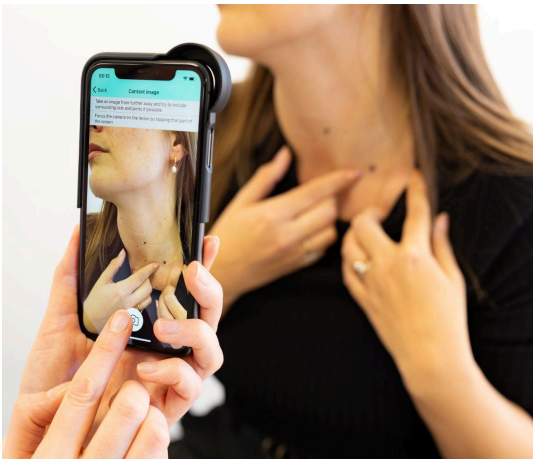

Figure 1 Example smartphone images being taken.

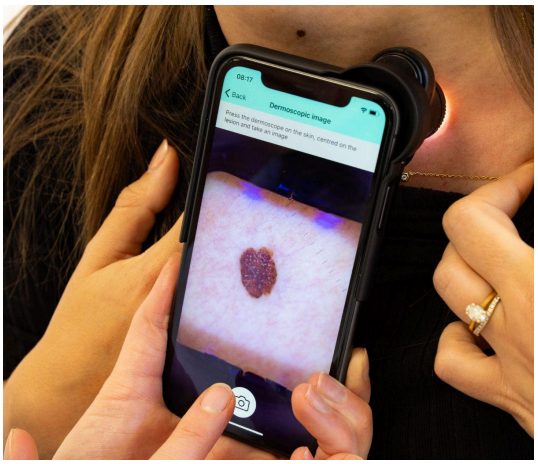

Figure 2. Example of a dermoscopic (more detailed) image being taken.

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

- If DERM finds anything that may suggest skin cancer, you may be advised to have your lesion looked at by a healthcare professional. Depending on your care pathway, you may be sent for an in-person appointment, a dermatologist may review the images virtually or you may be asked to arrange a further assessment yourself.

- This does not necessarily mean something is seriously wrong. It simply allows your healthcare professional to take a closer look at your skin and make sure you receive the right care. In many cases, further checks will show that the lesion is not skin cancer.

- DERM is designed to find as many cases of skin cancer as possible. Because of this, some people may be recommended to seek further checks even when the lesion later turns out to be harmless (benign). See the Glossary for more details about the different skin conditions.

What happens if DERM determines your lesion is not cancer (benign)?

- Your healthcare provider or service looking after you will let you know your results. Most of the time you will be given reassurance that no action is needed. In some cases, even though the lesion is benign (not cancer), you may be recommended some pharmacy treatments.

- Although it is very unlikely that the assessed lesion is skin cancer, no test is completely certain. It is important to continue to regularly check your skin and seek medical advice if the lesion changes in size, shape, colour, becomes painful, or bleeds. You can find out more about checking your skin and reducing your risk of skin cancer at:
    - 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 Centre at: https://skin-analytics.com/privacy-policy/ .

If you're interested, the DERM Instructions for Use for healthcare professionals can be found at this link: https://skin-analytics.com/derm-medical-device-resources-for-healthcare-organisations/ .

Glossary

Conditions detected by DERM	More information
Benign (this includes Benign Vascular Lesion, Seborrhoeic Keratosis, Dermatofibroma, Solar Lentigo and Melanocytic Benign Nevus)	The vast majority (more than 90%) of patients who are referred to a Dermatologist in the UK do not have skin cancer. In most cases the suspicious lesion turns out to be non-cancerous (benign) with no danger of causing harm or spreading to other parts of the body. Some common examples of benign lesions that can be mistaken for skin cancer include: benign moles (Melanocytic Benign Nevus), sun spots (Solar Lentigo), scaly patches (Seborrhoeic Keratosis), firm bumps (Dermatofibroma), and blood vessel marks (Benign Vascular Lesion). 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/
Melanoma	Melanoma is a type of skin cancer that can spread to other organs in the body. DERM is set up to detect at least 95% of melanomas, comparable to specialists/dermatologists. You can find out more information about melanoma by visiting the NHS website at https://www.nhs.uk/conditions/melanoma-skin-cancer/
Squamous Cell Carcinoma (SCC)	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% of all NMSC. DERM is set up to detect at least 95% of SCCs, comparable to specialists/dermatologists. 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/
Basal Cell Carcinoma (BCC)	Basal cell carcinomas (BCCs) are by far the most common type of skin cancer. They are typically slow-growing and whilst they can grow into the surrounding skin they are not known to spread to other parts of the body. They account for around 80% of all NMSC. 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/
Intraepidermal Carcinoma (IEC)	Intraepidermal Carcinoma (also called Bowen's Disease) is an early, pre-cancerous condition. It can also be called Squamous cell carcinoma in situ. It grows slowly and stays in the top layer of skin. It is easy to treat. Treatment will stop it turning into a type of skin cancer called squamous cell carcinoma. 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/
Actinic Keratosis (AK)	Actinic keratoses, also known as solar keratoses, are dry, scaly patches of skin caused by damage from years of sun exposure. Like Bowen's disease, there is a small risk of developing into SCC if left untreated. 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/
Atypical Naevus (AN)	An atypical naevus is a mole that looks different or odd, but it is not cancer. If the mole is cut out and checked under a microscope, it may be called 'dysplastic'. This just means the cells are not regular in shape. In some cases, atypical naevi can turn into melanoma. 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/

Other terms	**More information**
Dermatoscope	A dermatoscope is a small device with a light and magnifying lens. It is attached to the smartphone using a magnetic clip and is placed gently against the skin to take a detailed close-up image of a mole or skin lesion. This helps us see details below the skin's surface that cannot be seen with the naked eye.
Dermatologist	A dermatologist is a doctor who is an expert in skin. They have had special training to help people with problems affecting their skin, hair and nails.
DERM	Skin Analytics' medical device
Excluded	There are certain situations where DERM should not be used. Your healthcare professional will check these before using DERM. If you have been referred by a private partner or are self-referring, you will be asked to select any exclusions that apply to you before taking your photos. These include: ● Patients under the age of 18 ● 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 (e.g. in the mouth) 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, Smithfield Business Centre 2nd Floor, 5 St John's Lane, London, EC1M 4BH, 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 EU Medical Device Regulations 2017/745. This device has been developed in accordance with Skin Analytics' ISO 13485:2016 certified Quality Management System.

CE

3022

Document Reference Number and Version: SA-001201-LB 9, Review Date: March 2026