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Instructions For Use - Out of United States (OUS)
Deep Ensemble for Recognition of Malignancy (DERM) V3
(Class IIA)

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Instructions for Use

Deep Ensemble for Recognition of Malignancy (DERM)

1. Manufacturing Information 4
2. Intended Use and Indication for Use 4
3. Contraindications 4
4. Document Information 5
   - Purpose 5
   - How to obtain a paper copy of this document 5
   - Definitions 5
   - Glossary of Symbols used in DERM Labelling 7
5. Warnings and Prerequisites 7
   - Prerequisites 7
   - Warnings 8
6. Product Information 9
   - How does DERM work? 9
   - Device Inputs and Outputs 10
   - Product Lifetime 13
7. Installation and Configuration 14
   - Installation and Updates 14
   - Configuration 14
     - Operating Parameters 14
     - Analysis result wording 15
   - Submitting Images for Analysis 15
   - Updates 18
8. Legal 18
9. Troubleshooting 18
10. Clinical Evaluation of DERM 21

The Deep Ensemble for the Recognition of Malignancy (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 employs artificial intelligence (AI)-based algorithms to analyse images of a skin lesion and return a suspected diagnosis and referral recommendation for the lesion.

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1. Manufacturing Information

DERM is manufactured by Skin Analytics Limited, 4th Floor, Kingsbourne House, 229-231 High Holborn, London, WC1V 7EG, United Kingdom.

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.

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 a dermoscopic image of a skin lesion and return a suspected diagnosis and, if applicable, a referral recommendation for the lesion.

DERM is indicated for use on dermoscopic 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 tested on images of skin lesions representative of the incidence of skin cancer in a powered prospective study run in the UK. Given the prevalence of the disease in the general population, DERM has been evaluated on Fitzpatrick skin types I-IV. DERM should be used with caution on lesions of other skin types.

3. Contraindications

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 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 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

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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 to clinicians with lesions suspicious for skin cancer
- Healthcare Professionals who are using DERM in the screening, triage and assessment of skin lesions suspicious for skin cancer
- Patients or healthcare professionals who are taking and submitting dermoscopic 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/resources/).

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 in your email 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

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Camera Device	An image capture device, such as a smartphone, that is used in conjunction with a Dermoscope 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 is used in conjunction with a Camera Device to take an image of a skin lesion to send to DERM for analysis
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	Combination of Camera Device, Dermoscope and Connection Kit, which together are validated for use with DERM
Input Image	The image taken by the User and submitted to DERM for analysis. This should be a Dermoscopic image of a Skin Lesion.
Lesion Priority	The prioritisation logic that allows DERM to return the label of 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
OUS	Out of United States
SCC	Squamous Cell Carcinoma
Sensitivity	The percentage of positive cases that DERM finds as positive

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Specificity	The percentage of negative cases that DERM finds as negative
Reference Sensitivity	Minimum acceptable 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

Date of Manufacture

UK Conformity Assessed

Model Number

Caution

Medical Device

Unique Device Identifier

5. Warnings and Prerequisites

Prerequisites

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- 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 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 V3 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 dermoscopic Image Capture Hardware. Images must be captured using a Camera Device connected to a Dermoscope using a Connection Kit. For details of the latest approved hardware, please refer to the Skin Analytics website: https://skin-analytics.com/derm/resources/

Warnings

DERM does not provide a definitive diagnosis. The result provided by DERM should be viewed alongside all other clinical information when using DERM to support decisions on patient management, and care should be taken when giving results to the patients in order to minimise anxiety.

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.

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

When deployed as a 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. Care should be taken when giving results to the patients in order to minimise anxiety.

DERM will reject images which are not dermoscopic images of a skin lesion, or which do not pass an image quality check (i.e. images which are too dark or blurred). Good image-taking technique is therefore an

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important prerequisite for successful use of DERM. For information on how to take good images for DERM analysis, please refer to the “How to take good quality images” section of this manual.

DERM does not screen for any lesions not listed in the “Product Description - Device Inputs and Outputs” section (e.g Merkel Cell Carcinoma).

DERM should not be used for staging disease, or for ongoing monitoring of lesion treatment.

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.

The accuracy of DERM’s assessment of lesions on mucosal surfaces, under nails or on the soles of feet / palm of hands has not been established, and its use on these lesions is contraindicated

6. Product Information

How does DERM work?

DERM employs artificial intelligence (AI)-based algorithms to check whether the image is a dermoscopic image of a skin lesion and for quality of the image prior to analysing the image and returning a suspected diagnosis for the lesion. DERM can return a suspected diagnosis and, if applicable, a referral recommendation[1] for the following conditions:

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

DERM operates a sequential, 3-step process.

Step 1: Identification of dermoscopic image

DERM checks whether the submitted image corresponds to a dermoscopic image of the skin or not. This ensures that accidentally submitted images that are not a dermoscopic image are not further processed. DERM returns an error message if it identifies the image as a non-dermoscopic image of the skin.

[1] See Page 12 for a list of default labels. The wording of the labels may be modified, under a controlled and risk assessed process, to suit a healthcare providers specific clinical pathway

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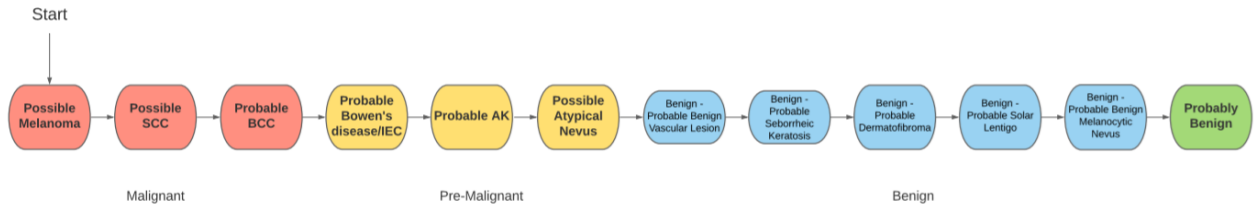
Step 2: Image quality assessment

If the image is identified as a dermoscopic image of the skin (Step 1), DERM assesses the quality of the image, ensuring that it is neither too blurry nor too dark. If the image fails the quality assessment, DERM does not process the image and outputs an error message indicating the reason for the failure (i.e too dark or too blurry).

Step 3: Image analysis

If the image is a dermoscopic image of the skin and presents an acceptable level of quality, DERM proceeds to analyse the image, where the image is labelled with a suspected diagnosis (e.g. possible melanoma; probable BCC). In order to label the image, DERM first identifies the skin lesion within the image. If more than one skin lesion is identified within the image, DERM outputs a suspected diagnosis for each of the lesions identified. Despite this behaviour, DERM uses the entire image to calculate the suspected diagnosis for each lesion.

When a lesion exhibits features of more than one lesion type, DERM prioritises the riskier skin conditions over benign conditions by implementing a risk hierarchy in its final analysis. This order of processing (shown below with priority running from left to right) is used to ensure that 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.

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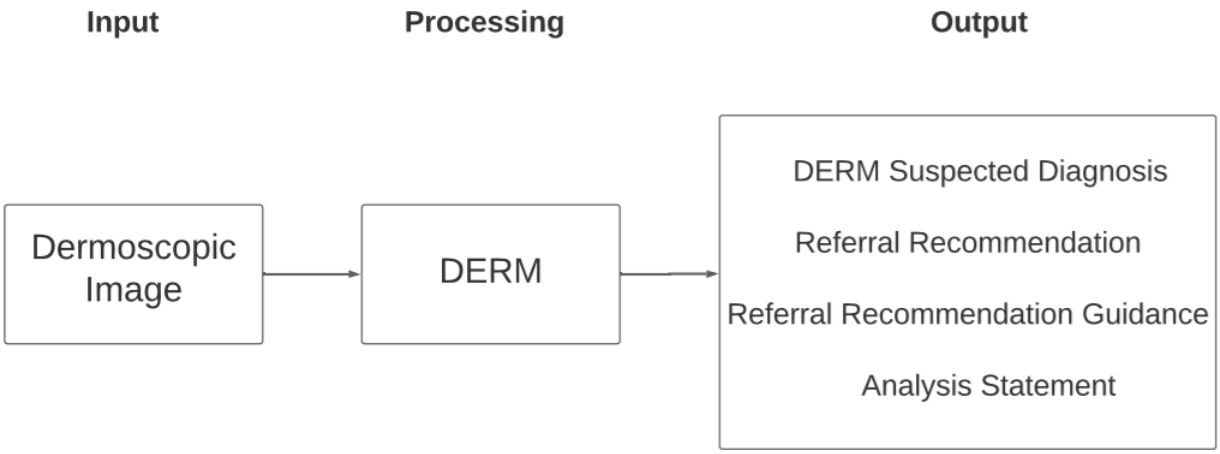

Please note: Referral Recommendation and Referral Recommendation Guidance are optional fields and may not be shown under your configuration.

The device inputs are described in the table below:

Input	Description
Image	Dermoscopic image submitted to DERM through the API.

The device outputs are described in the table below:

Output Field	Description	Default 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

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		• Benign - Probable Benign Vascular Lesion • Benign - Probable Seborrheic Keratosis • Benign - Probable Dermatofibroma • Benign - Probable Solar Lentigo • Benign - Probable Benign Melanocytic Nevus • Probably Benign
Analysis Statement	Text describing whether the request has been successfully processed, or if an error has occurred. If the image is not a dermoscopic image of the skin, or if it's too blurry or too dark, the message will appear here.	• Skin lesion detected and successfully processed • Image Quality failed - too dark • Image Quality failed - too blurry • Image not a dermoscopic image of the skin • System Error
Referral Recommendation (optional)	An 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 clinical organisation / user commissioning use of DERM.	• Urgent Refer 2WW • Refer according to local pathway • Manage according to local pathway • Manage as Atypical Nevus • Reassure and give safety netting advice Where the referral recommendations are not implemented, the output will be as follows: *Clinical User to decide management outcome*

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Referral Recommendation Guidance (optional)	An associated text supplementing DERM's Referral Recommendation	• Refer on two week-wait pathway for specialist review. • Consider urgent (2ww) 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 • Reassure patient, recommend self-monitoring and further GP review if there are any changes or they remain concerned. If you are clinically concerned despite this result consider referral Where the referral recommendations are not implemented, the output will be as follows: *DERM is an adjunctive tool. It does not provide a diagnosis and is not intended to replace the clinical decision-making process led by a Clinical User*

Notes:

- Additional outputs, not displayed to the Clinical User, are provided for technical and administrative purposes and are detailed in the DERM V3 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 is >30% and 'Possible' for lesions with a PPV of <30%.

Product Lifetime

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

7. Installation and Configuration

Installation and Updates

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 default settings which have been selected and optimised by Skin Analytics across the development of the device. Any changes from the default settings will be agreed by Skin Analytics and your organisation following a defined procedure before being implemented.

DERM configuration relates to two aspects of the analysis:

Operating parameters – the settings which determine the trade-off between the false positives and false negatives of DERM. The settings consist of a single sensitivity value for each of the conditions identified by DERM.

Analysis result wording - the words used to explain the results of the analysis. Analysis result wording is agreed for the following DERM Outputs:

a. 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'.

b. 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 and options of possible outputs are given in the Device Outputs table above.

c. DERM Referral Recommendation 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 and options of possible outputs are given in the Device Outputs table above.

Operating Parameters

The analysis performance of DERM can be configured to suit the clinical context and pathway. For each lesion type, the trade-off between sensitivity and specificity can be tuned. For example, it may be more desirable to have a high sensitivity for melanoma to minimise the chance of false negatives. Alternatively, a

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higher specificity may be preferred when the burden of potential over-referrals is a consideration. Skin Analytics onboards all organisations with a set of default settings, which ensure the minimum sensitivity levels observed in the table below are achieved for each lesion type.

Lesion Priority	Lesion Type	Reference Sensitivity
1	Melanoma	95%
2	Squamous Cell Carcinoma (SCC)	95%
3	Basal Cell Carcinoma (BCC)	90%
4	Bowen's disease / Intraepidermal Carcinoma (IEC)	90%
5	Actinic Keratosis (AK)	90%
6	Atypical Nevus	90%

Analysis result wording

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

- DERM's Suspected Diagnosis
- Referral Recommendation
- Referral Recommendation Guidance
- Analysis Statement

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.

How to take Good Quality images

Tips for taking dermoscopic images :

- Ensure that the dermoscope is attached to the image capture device in line with the manufacturer's instructions.
- Make sure the light on the dermoscope is switched on.

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- Press the dermoscope against the skin, centered on the lesion you want assessed, but not pressing so hard as to deform the lesion.
- Check that the image is clear and focused, then capture the image.
- Review the image quality. A good test is whether you can clearly see the lesion and also any scale markers (depending on your dermoscope) on the image.

Common issues with dermoscopic images:

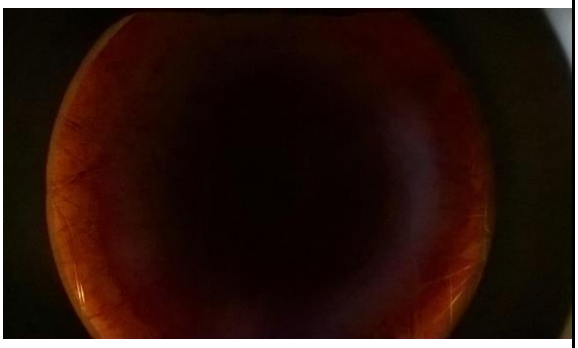
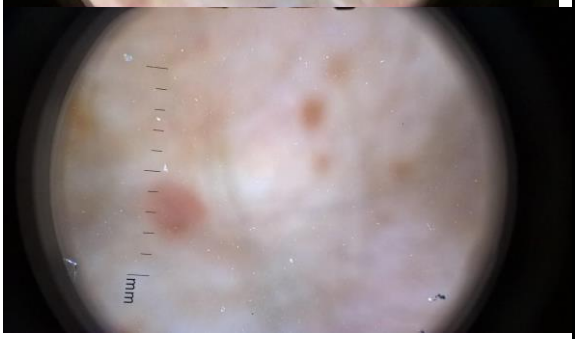
Issue	Details	Example
Light not turned on	Without the dermoscope light turned on, the image is unusable	
Dermoscope not pressed against the skin	If the dermoscope isn't pressed against the skin the image won't be clear, or you may see reflections from the dermoscope's lights	

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Image blurry	Although the light is on and the dermoscope is pressed against the skin, the camera didn't focus properly. This is probably due to not giving the camera time to focus.	

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Mole completely covered by hair	If the mole is covered by hair, the result from DERM may not be accurate.	

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.

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/

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"

When DERM displays "Image not a dermoscopic 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 a dermoscopic image of the skin and that further processing has not been completed. This usually happens because a context (non-dermoscopic) image has been submitted or because the

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dermoscope has not been attached to the smartphone. Make sure that the dermoscope is firmly attached to the smartphone and that you are taking a picture with the skin lesion in the center. Then retake the image and resubmit.

On rare occasions, the original image will be a dermoscopic image of the skin but DERM will output this message. This is due to the accuracy of DERM in detecting dermoscopic 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 dark”

When DERM displays “Image Quality failed - image too dark” message it means that the quality assessment step (Step 2 Described in Product Description) has determined that the image is too dark to be analysed and further processing has not been completed. This usually happens because the dermoscope does not have the light turned on. Make sure that the dermoscope’s light is switched on then retake the image and resubmit.

On rare occasions, the original image will be taken with the dermoscope’s light switched on, but DERM will output this message. This is due to the accuracy of DERM in detecting dark 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 displays “Image Quality failed - image too blurry” message 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. This usually happens because the dermoscope is not firmly pressed against the skin, or the photo was taken before the camera was able to focus on the lesion. Make sure that the dermoscope is firmly pressed against the skin as detailed in “Submitting images for analysis”. Then retake the image and resubmit.

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 tip of an ear, or bony prominence. In this case, it may not be possible to take an image that will be accepted by DERM.

On rare occasions, the original image will be fully focused, but DERM will output this message. This is due to the accuracy of DERM in detecting blurry 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”

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 due to a bug in the integration between the two softwares 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

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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 (dermoscope, smartphone, 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 a replacement, or repair as necessary.

I don't have an Internet connection. What should I do?

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

I can't log in/I have forgotten my password. What should I do?

DERM does not have any login details from a clinical 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 don't 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:

DERM does not provide a definitive diagnosis. The output provided by DERM should be viewed 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:

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 not) 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.

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If you are concerned about the performance of DERM against expected performance, please contact Skin Analytics' help desk or your point of contact so that we can look into it. You can also report any adverse events to the MHRA using the yellow card scheme: https://yellowcard.mhra.gov.uk/

10. Clinical Evaluation of DERM

Skin Analytics performs clinical evaluation activities to ensure that there is sufficient clinical evidence to confirm the devices' clinical benefit and its compliance with the relevant essential requirements for safety and performance when utilised in accordance with its Instructions for Use.

For further information on the clinical evidence of DERM's performance, please refer to:

Phillips, M., Greenhalgh, J., Marsden, H., Palamaras, I. (2019). Detection of Malignant Melanoma Using Artificial Intelligence: An Observational Study of Diagnostic Accuracy. Dermatol Pract Concept. 2019;10(1):e2020011. doi:10.5826/dpc.1001a11

Phillips, M., Marsden, H., Jaffe, W., Matin, R.N., Wali, G.N., Greenhalgh, J., McGrath, E., James, R., Ladoyanni, E., Bewley, A., Argenziano, G. and Palamaras, I. (2019). Assessment of Accuracy of an Artificial Intelligence Algorithm to Detect Melanoma in Images of Skin Lesions. JAMA Network Open, [online] 2(10), e1913436. doi:10.1001/jamanetworkopen.2019.13436

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

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