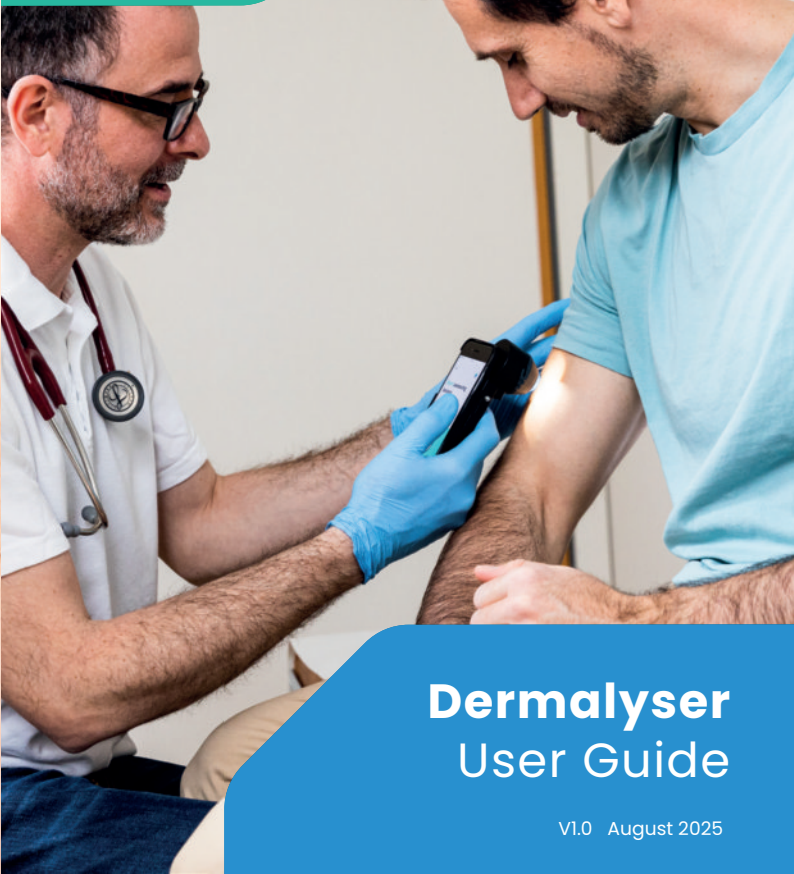




AI Medical
Technology



Dermalyser User Guide

V1.0 August 2025

Dermalyser is an image analysis software application empowered with clinically validated artificial intelligence (AI). The application is developed and trained on thousands of quality-controlled dermatoscopic images of skin lesions. The medical device software functions as a decision-support system for medical professionals when assessing suspected lesions for skin cancer.

Images of skin lesions are captured through a smartphone-compatible dermatoscope mounted onto a smartphone camera. Based on image processing algorithms, the application assesses the captured skin lesion and informs the user if evidence of melanoma is detected.

Intended use

Dermalyser is intended to be used as a decision support system for assessing cutaneous lesions suspected of being melanomas. The output from the device is not intended to be used as the sole source of information for diagnosis. The device should be used in combination with a medical professional assessment of the suspected lesion.

Patient target group and intended users

The intended population is patients aged 18 or above having suspicious skin/cutaneous lesions where malignant melanoma cannot be ruled out, with Fitzpatrick skin phenotypes I, II, III and IV. The intended users are medical professionals. These include primary care physicians, general practitioners, as well as skin specialists such as dermatologists.

Environment

Dermalyser shall be used in a healthcare setting such as primary healthcare centres, hospitals and healthcare clinics.

You can download the full list of instructions on how to use Dermalyser in English and Swedish via our website: aimedtech.com/dermalysers



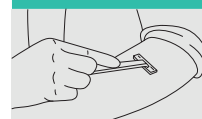
0123 Medical device according to EU MDR 2017/745

STEP 1



Clean the skin lesion with an alcohol wipe.

STEP 2



If the lesion is hairy, remove the hair with a razor.

STEP 3



Wet the lesion with alcohol gel or water.

STEP 4



Attach your dermatoscope to the phone.

STEP 5



Turn on the dermatoscope light and set it to polarized (the default setting).

STEP 6



Make sure the edge of the scope cannot be seen in the app.

STEP 7



In the app, zoom in/out to try to make the lesion about the same size as the circle.

STEP 8



If the lesion is blurry, tap on the screen to focus.

STEP 9



Take the photo, send it for analysis and receive your result.



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