

Instructions For Use

Dermalyser 1.0.0



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Introduction

This Instructions For Use (IFU) is applicable to *Dermalyser* version 1.0.0. Read this IFU prior to use. The content includes important information on how to use the software safely and correctly. *Dermalyser* is only available on the Swedish market.

Product Description

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.

Indications for use

Dermalyser can be used for assessing cutaneous lesions with one or more signs of melanomas or when melanoma cannot be ruled out. The application can be used as a decision support tool by medical professionals seeking more information prior to the decision on further triage or treatment of the lesion.

Improper Use and Contraindications

It is NOT recommended to analyse lesions in the following situations.

- Lesions with any form of modifications such as tattoos, pen markings, and/or pigments covering or surrounding skin lesions.
- Lesions located on areas such as genitalia, acral skin (foot sole or palm of the hand), mucosal surfaces (mouth, eye, nose etc.), psoriasis or similar skin conditions.
- Lesions are masked by an excessive amount of hair, generally found in armpits, scalp, moustaches, bears and other hairy parts of the body.
- Lesions that are scarred, non-intact, injured, previously biopsied or undergone surgery.
- Lesions with white spots or located on sunburned skin.
- The lesion size is too small or too large to fit the white circle in the screen even after zooming in and out at its maximum. The lesion should not be < 2 mm or > 20 mm in diameter.
- Lesion on skin types V and VI according to Fitzpatrick's scale (dark brown or black coloured skin).
- Cutaneous lesions on non-human subjects.

Residual risks and undesirable side effects

Dermalyser does not have any undesirable side effects since the imaging analysis process does not physically affect the patient nor the healthcare provider.



Warnings and precautions

- *The software shall be used by trained medical professionals.*
- *Make sure to use a compatible dermatoscope with a polarised light source.*
- *Make sure the camera lenses of the smartphone and dermatoscope are not cracked or broken.*
- *Do not use the smartphone's flashlights when the dermatoscope light source is not operating.*
- *Make sure that the borders/shades of the dermatoscope are not blocking the field of view on the screen.*
- *Make sure to clear the lesion area from excessive hairs. Image analysis on hairy lesions could produce an incorrect assessment.*
- *Make sure to capture the whole lesion in the centre of the screen. Insufficiently captured lesions could produce an incorrect assessment.*
- *Make sure to capture a clear and focused image by placing the dermatoscope directly on the skin.*
- *Make sure to use the latest version of the application.*
- *Make sure that a reliable internet connection is available throughout the use of the application.*

Before using the application

The *Dermalyser* application requires a smartphone and a smartphone-compatible dermatoscope to function.

IMPORTANT: This software application requires an accessory, a smartphone-compatible dermatoscope for optimum digital assessment of lesions. Users must make sure to use a compatible dermatoscope together with the smartphone's camera function to capture images of lesions. Some dermatoscopes require an adaptor/connection kit to attach the dermatoscope to the phone, whereas some dermatoscopes come with an attached smartphone mounting case.

- **Specification of compatible dermatoscopes**

Check the correct operation of the dermatoscope before use! It's recommended to go through the instructions provided by its manufacturer on how to set up and use them.

AI Medical Technology is recommending the following models of dermatoscopes.

1. DermLite DL3N (Click for [Instructions for use](#)).

DermLite DL3N is a smartphone-compatible dermatoscope designed to view skin lesions using cross-polarized or non-polarized light and high magnification and clarity. To use DL3N, adapters/connection kits for smartphones from DermLite are recommended. Before initial use, please charge the device.

2. HEINE iC1 (Click for [Instructions for use](#)).

HEINE iC1 is a reflected-light microscope for the noninvasive, visual inspection of intact skin by a healthcare professional. The mounting case for the iC1 dermatoscope enables the integration of a smartphone, which optimises macro photography. Before initial use, please charge the device.

- **Specification of compatible smartphones**

Dermalyser should be used on smartphones running iOS 13 or Android Pie 9, or later versions, with 250 kbps or faster internet, with at least:

- 2GB RAM
- Full HD Camera (1080p)
- 4.7 Inches Display
- 1 GB free storage

- **Dermalyser user account**

You need a user account to be able to use the application. User accounts are generated for individual users or clinics as per the need. Your user account is specific to your health care centre and should not be used by unauthorised personnel.

More information can be found at www.aimedtech.com.

How to use the Application

Step 1: Installing the application and getting started

- Download the application *Dermalyser* from Google Play or the App Store. Log into the application with your username and password.

Step 2: Performing the assessment of the lesion

- Securely attach the dermatoscope to the smartphone and switch on the dermatoscope lights. Wipe off any dust or fingerprints on the dermatoscope and smartphone.
- Clean the skin lesion with an alcohol wipe. Remove excess hair if needed.
- Place the dermatoscope directly on the patient's skin lesion. Ensure the skin lesion is focused, zoomed to about the same size as the white circle, and not covered by hair or other obstructions.
- You can either pinch in/out or move the slider on the screen to zoom in/out to capture greater details. Make sure the lesion's size matches the circle on the screen. Tap on the button to capture the image.
- Once the image is taken, review it. If necessary, retake it to capture a clear and focused image of the lesion. Once you have taken an acceptable-quality image, tap "Analyse" to send it for assessment.
- Based on the characteristics of the lesion, *Dermalyser* informs if evidence of melanoma is found. This risk assessment is NOT a complete diagnosis, but a decision support in the triage of melanoma.

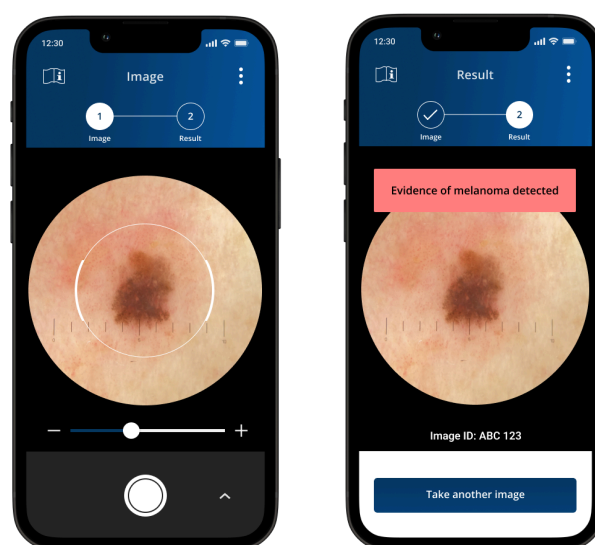


Figure 1. A two-step process of using Dermalyser.

Clinical benefits

The clinical benefit of *Dermalyser* is indirect since it is used as a diagnostic decision support system. The diagnostic informational message given by the device is not considered to be a final diagnosis of melanoma and should be reviewed by a medical professional who will decide the further necessary actions. However, it could potentially lead to more skin lesions being referred to histopathological diagnosis. Thus, *Dermalyser* has a significantly positive impact on the early detection and diagnosis of cutaneous malignant melanoma.

- *Dermalyser* aids in the triage/diagnosis of melanoma
- Reduces the time to diagnosis by streamlining and enhancing the clinical workflow.

Performance characteristics of the device

The *Dermalyser* has an easy-to-use and intuitive user interface. *Dermalyser* has proven through clinical studies that their performance is acceptable compared to medical professionals. *Dermalyser*'s algorithm can correctly detect melanoma with a sensitivity of 95% and specificity of 80%.

The device has an acceptable performance when used in the intended setting by its intended users, which is aligned with the state of the art. It has also been concluded that:

- *Dermalyser* is a diagnostic support tool that correctly identifies suspicious lesions as melanomas.
- *Dermalyser* is user-friendly (easy-to-use) in a clinical setting.
- *Dermalyser* is safe to be used by primary care physicians at primary care centres as a diagnostic decision support system, when used according to IFU.

Troubleshooting

This section lists all possible error messages. Beneath the cautions, there are instructions on how to proceed. Please read the caution and instruction message. In case you are unable to solve the error, you can receive support by contacting us via the information available on the Contact Us page in the application.

Problem	Troubleshooting
<i>The image is too dark for analysis.</i>	The analysed image was too dark and needs to be re-taken. Ensure the light source on the dermatoscope is activated and functional before re-taking the image.
<i>The image is too blurry for analysis.</i>	The analysed image was too blurry to be assessed. Take a new image and ensure it meets the specified criteria before trying again. If the error message repeats, please contact support.
<i>Something went wrong!</i>	Some unexpected errors occurred when analysing the image. Try again by following the instructions. If the error message re-occur, please contact the support.
<i>Unknown server error.</i>	Some server errors occurred during the image analysis request. Try again by following the instructions. If the error message re-occur, please contact the support.
<i>Took too long to respond.</i>	The application timed out due to the analysis taking too long. Try again by following the instructions. If the error message re-occur, please contact the support.
<i>Could not connect to the internet.</i>	Displayed when the smartphone is not connected to the internet during log-in or image analysis request. Please check that you are either connected to WiFi or using mobile data.
<i>Unauthorised request.</i>	The authentication process was not fulfilled, hence not allowing the user to proceed. Please login again to be able to use the application.
<i>Email and password combinations could not be found.</i>	The wrong username or password was entered when trying to log in. Please make sure that the right username and password have been entered before trying again. If the error message re-occur, please contact the support.
<i>Could not open the camera.</i>	Please ensure that the application has permission to use the camera on the smartphone. If your camera is unresponsive to the application, make sure your camera functions properly. If the message repeats when you try again, please contact support.

Updating the application

To ensure proper operational functionality and safety of the software, the user should regularly look for software updates on app store platforms for iOS and Android operating systems. We recommended to check for updates every six months.

To dispose of the application, the user can uninstall it on their phone. Kindly reach out to support@aimedtech.com to delete your account and related data.

Access to Instructions for Use

Instructions to use for *Dermalyser* are provided within the application under the 'Information' page, as well as on our website. If you require a paper version of instructions for use, it is available at no additional cost. Kindly reach out to support@aimedtech.com, and we shall send one to you via post.

Reporting

Any serious incidents or adverse events that occur in relation to the device shall be reported as soon as possible to both AI Medical Technology and the Swedish Medical Products Agency (Läkemedelsverket). The notification must be submitted if any of the below has led to, or could have led to, death or serious deterioration in someone's health:

- Malfunctions
- Deterioration in a device's performance
- Inaccuracies in a device's labelling or instructions for use

If you are unsure whether an event falls within the reporting requirements, you should inform AI Medical Technology and the Swedish Medical Products Agency of the occurrence anyway.

Please report incidents to AI Medical Technology at support@aimedtech.com.

Incident reports are submitted to Läkemedelsverket (SMPA) through their e-service form. More information on which information to submit can be found at the Swedish Medical Products Agency site: www.lakemedelsverket.se Although the submission form is only available in Swedish, it clearly states which information to include. The form can be found and filled in at [Notification form](#).

IT Security

Always ensure you are connected to a trusted and secure WiFi network or mobile data when using our app. Public Wifi can often be unsecured and vulnerable to unauthorized access.

Dermalyser ensures a robust level of security and data privacy within our application. We continuously monitor the application for any security incidents or data breaches. In the unlikely event of such an occurrence, the matter will be promptly contained and resolved following our established protocols. As a user, you will soon be informed about the steps to be taken to ensure your continued safe and secure use of the application.

It is highly advisable to select a strong password in order to safeguard your account against unauthorized access. While it is not recommended, should you opt to share your login credentials with someone, please be aware that you assume the associated risks. Dermalyser typically does not solicit emails asking for your password unless you have initiated a password reset process through our support.

Contact information of the manufacturer

Name of the Manufacturer:	AI Medical Technology AIM AB
Address:	Universitetsvägen 8 Stockholm 114 18 Sweden
Website:	www.aimedtech.com
Device name:	Dermalyser
Email address:	support@aimedtech.com
Phone number:	(+46) 08 522 351 91

We declare that this product meets all applicable requirements of Regulation (EU) 2017/745 for medical devices (MDR) and bears the CE mark.

Symbols used in the application



Legal Manufacturer

*AI Medical Technology AIM AB
Universitetsvägen 8, Stockholm 114 18, Sweden*



Date of the manufacture

*2024-05-13
Version 1.0.0*



Consult Instructions for use

Instructions for use are available in an electronic format.



Caution

Inform that caution is necessary when operating the device.



Medical Device

Class IIa Medical Device Software



CE mark

Medical device according to EU MDR 2017/745

The following documents were signed Thursday, June 20, 2024



ART 23-001 Instructions for Use -
Dermalyser (EN) Ver 06.docx.pdf

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6/20/2024 5:55:14 PM (CET)



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You can also do this by visiting <https://app.assently.com/case/verify>

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