AI Medical Technology

DERMALYSER – Patient Information

1. Introduction

You have received this leaflet because your healthcare provider will use a device called **Dermalyser** during your skin examination. Dermalyser is an AI-powered, CE-marked medical device that supports the early detection and diagnosis of the most dangerous type of skin cancer, **melanoma**.

Dermalyser analyses a high-resolution image of your skin lesion, taken using a dermatoscope, and provides a decision-support assessment to guide the next steps in your care.

Dermalyser is developed under a certified Quality Management System according to ISO 13485:2016, and complies with the EU Medical Device Regulation (MDR) 2017/745. It is classified as a Class IIa medical device and has been validated through clinical trials.

2. What to Expect

You will be seen by a trained healthcare professional in a private clinical setting. The process is as follows:

Informed Consent

Before proceeding, you will be asked to give your consent. This includes understanding that Dermalyser is used as a decision support tool in your healthcare provider's workflow. The AI app helps your healthcare provider by giving additional information about your skin condition, but it does not make the final decision. Your provider carefully reviews the AI's suggestion along with their own medical knowledge and experience before making a diagnosis. Think of the AI as a second opinion that helps your provider make the best possible decision for you.

Medical History & Visual Examination

The clinician will ask about your relevant medical history and visually examine the lesion.

Image Capture

A dermatoscopic image will be taken by a smartphone in the Dermalyser app.

AI Analysis

Dermalyser processes the dermatoscopic image and returns an AI-based clinical decision-support output, which the clinician will use to determine the next steps.

Discussion of Results

Your healthcare provider will explain the assessment and recommended follow-up care, including whether further referral is necessary.

AI Medical Technology

3. What Happens Next?

If Dermalyser Identifies Evidence of Melanoma:

You may be referred to a specialist (e.g. dermatologist) for urgent or routine assessment.

Most referrals are precautionary, and many lesions are later confirmed as benign.

If Dermalyser Suggests No Evidence of Melanoma:

The healthcare provider may advise no further action.
You should still monitor the lesion and your skin for changes.

4. Important Exclusions

Dermalyser should not be used if:

- You are under 18 years old
- The lesion is ulcerated, open, too large, or obstructed by tattoos, hair, or scarring
- The lesion is on mucosal surfaces, under nails, on palms/soles, or near the eye
- The lesion has previously been biopsied
- Your healthcare professional will assess if Dermalyser is appropriate for your case.

6. Data Privacy

Your images and health data are handled in compliance with the EU General Data Protection Regulation (GDPR) and are securely stored. Your data will not be used for any other purpose without your explicit consent.

View our privacy policy: https://www.aimedtech.com/privacy-policy

7. Manufacturer Information

Dermalyser is manufactured by:

AI Medical Technology, Universitetsvägen 8, 114 18 Stockholm, Sweden

- Notified Body Number: 0123
- CE Marking: Conforms to MDR 2017/745
- Device Classification: Class IIa
- Quality Certification: ISO 13485:2016

8. More Questions?

Please contact your healthcare provider for clinical questions.
For feedback or inquiries, contact: *support@aimedtech.com*
www.aimedtech.com/contact