

Instructions for use - English

DWAPP01 dermanostic Webapp

Valid for:

- Basis-UDI-DI: 426242531DWAPP01A8
- Webapp version 0.0.10 and newer, as long as there is no revision!

1. Product description

The [dermanostic webapp](#) is provided by Dermanostic GmbH (manufacturer). It is a medical device software in the field of teledermatology, which is used to examine the physiological or pathological condition of the human skin.

The webapp serves as an easy access to the teledermatology treatment of Dermanostic GmbH and can be used in a standard browser. It covers case creation, the first step of teledermatology treatment. The case creation takes place in the following steps: the selection/creation of the patient profile, the intro, the uploading of images and the answering of an anamnesis questionnaire, as well as the payment.

After paying for a case, the mobile dermanostic app (accessory to the dermanostic web app) is required to view the findings. The dermanostic app can be downloaded from the Google Play Store or Apple App Store.

The webapp "dermanostic" is a medical device software that serves the structured data collection of medical information (medical history form + images) and the improvement of patient management in the field of teledermatological examination of potentially pathological skin areas. The "dermanostic" web app also supports communication between patients and medical professionals by recording and transmitting digital images of the affected skin areas and recording a medical history form.

1.1. Medical indication

Examination of dermatological clinical pictures/changes to the entire human skin, including the hairy head and all skin folds and mucous membranes that can be identified by the patient at a glance. The doctor can then make a diagnosis based on the medical history form completed by the patient, the visual assessment of the skin/mucous membrane changes and make a treatment recommendation.

1.2. Intended patient group

The study is not limited to a specific patient population.

Children and elderly patients as well as people with disabilities may not be able to operate the (smartphone) camera or a device (desktop PC, tablet, smartphone) on which the web app is running. In these cases, the web app can be used with the support or on behalf of another person.

Breastfeeding and pregnant patients, or patients who may be pregnant, can use the web app, but must indicate this in the medical history form. The same applies to people with known allergies, pre-existing conditions and/or drug intolerances. Failure to do so could result in incorrect diagnoses and inadequate treatment recommendations.

1.3. Intended user group

The **dermanostic webapp** is designed in such a way that it can be used by non-experts for the intended purpose.

The case created by the lay user is assessed by a dermatology specialist. To this end, Dermanostic GmbH cooperates with specialist practices in private practice or with specialists employed by the hospital.

1.4. Intended use environment

The **dermanostic web app** must be used in combination with an end device - consumer electronics device (smartphone or tablet) or desktop computer - that is connected to the Internet. No installation is required to use the **dermanostic web app**. It can be used in any environment in which the end device is normally used. Use in medical facilities is not required.

2. Indication

Examination of dermatological clinical pictures/changes to the entire human skin, including the hairy head and all skin folds and mucous membranes that can be identified by the patient at a glance. The doctor can then make a diagnosis based on the medical history form completed by the patient, the visual assessment of the skin/mucous membrane changes and make a treatment recommendation.

3. Contraindication

- The **dermanostic webapp** is not used to examine damaged skin areas and open wounds.
- Nor is it intended for the assessment/diagnosis of acute life-threatening situations, emergencies and/or allergic reactions with shortness of breath. In such cases, the emergency medical service should be contacted and/or visited immediately.
- In the case of heavily tattooed areas of skin, it may be difficult or impossible to diagnose the skin change.
- Teledermatology procedures may not be performed if:
 - a personal presence of the patient appears necessary.
 - the technical equipment available to the patient is not expected to provide sufficient (image) quality for diagnosis,
 - the patient is overwhelmed by the use of the app or does not consent to it.

4. Side effects

No side effects are known when used correctly.

5. Warnings and residual risks

5.1. Warnings

- The **dermanostic web app** should not be used in the event of a medical emergency. In the event of a medical emergency, the appropriate emergency medical service should be contacted immediately.

- The use of the [dermanostic web app](#) cannot replace skin cancer screening in a doctor's practice or outpatient clinic.
- Specialist medical advice is provided by the dermatologists employed by the cooperating specialist practices within approximately 24 hours of the photographic images and medical history form being sent to Dermanostic GmbH. However, Dermanostic GmbH does not guarantee a specific response time to inquiries.
- In individual cases, remote treatment may remain possible, provided that the specialist diagnosis can already be conclusively made on the basis of the photographs and the completed medical history form, while maintaining the necessary medical care, in particular through the manner of diagnosis, consultation, treatment and documentation of the treatment process. In this case, the treating dermatologists will inform the patients about the special features of purely remote treatment.
- If medical follow-up care is required, this is carried out by Dermanostic GmbH medical specialists on behalf of the cooperating specialist practices. In this case, the medically trained specialist staff will contact the patient via the [dermanostic app](#) (accessory) or by telephone.
- In view of the risk of incorrect findings, quality assurance at Dermanostic GmbH provides for the interdisciplinary expert committee of the cooperating specialist practices to be consulted in an advisory capacity if the dermatologists treating the patient consider a second expert assessment of the specific treatment case to be necessary.
- The discussion of cases in the interdisciplinary panel of experts can lead to a delay in diagnosis.

5.2. Relevant residual clinical risks

- Incomplete information in the medical history form (e.g. suspected pregnancy, allergies, previous illnesses and/or medication intolerances) can lead to an incorrect diagnosis and/or inadequate treatment recommendation.
- Just as in a personal consultation with a specialist, there is a residual risk of misdiagnosis.

6. Instructions for use

6.1. Creation of patient profile

The patient profile can either be for the user themselves or for another person. For example, parents can create a patient profile for their baby, toddler or child or their parents, as they do not have or cannot use a suitable end device (smartphone, tablet, desktop PC), making the parents not the patient but a patient assistant.

If the patient assistant is not the patient's legal guardian, the patient must consent to the use of the app for their skin condition with a signature.

All patient data is treated confidentially in accordance with the GDPR standard. The patient profile is created in the first step of case creation.

6.2. Intro

The first step of the intro is to specify the purpose of the examination with the [dermanostic web app](#). Here you can choose between different pathological skin changes and other skin problems.

The skin change is then localized by clicking on the corresponding body region on the representation of a human body.

6.3. Photo upload

The next step is the photo upload, here three photos of the affected skin area / skin change are required (1x at a distance of 30 cm and 2x at a distance of 10 cm with two different angles between the lens and the affected skin area), which must be uploaded from the end device.

6.4. Medical history questionnaire

The last step is to fill out the medical history questionnaire, which was developed in cooperation with Göttingen University Hospital. The questions of the medical history questionnaire are displayed to the user one after the other in the [dermanostic web app](#). Once the questionnaire has been answered and payment has been made, the case can be sent off.

6.5. Registration and payment

In order to be able to submit the created case via the [dermanostic webapp](#), the user must register with a user account (e-mail address and a password). After successful registration and verification of the e-mail address and payment, a patient profile can be created in the user account, the submitted images and the anamnesis questionnaire can be displayed to the connected dermatologists in the dermanostic dashboard (next case in the queue). The detection and treatment recommendation of skin diseases is carried out independently by the dermatology specialists without exception.

6.6. Download the dermanostic app and register

After submitting the case, the [dermanostic app](#) must be downloaded from the Google PlayStore or App Store in order to receive the doctor's letter and clarify any queries. After logging into the [dermanostic app](#) with the previously created user account, the status of the submitted case can be viewed.

6.7. Diagnosis and therapy recommendation

In the [dermanostic app](#) (accessory), users usually receive a doctor's letter with the diagnosis and a therapy plan recommendation from the treating dermatologists, as well as their explanations, within 24 hours. The user is notified by e-mail when the doctor's letter is available or if there are any queries during the diagnosis. As part of the therapy recommendation, the dermatologist responsible can issue a private prescription, which can be sent either by post to the user's home or to the pharmacy of choice or a partner online pharmacy.

For further questions and follow-up care, patient support is available to patients in the [dermanostic app](#) chat.

6.8. Deletion of the app and the account

- The account can be completely deleted under Account settings, [Delete account](#). This will delete all personal data from the Dermanostic GmbH servers in accordance with the GDPR standard.
- Alternatively, the account can be deleted manually by Dermanostic GmbH upon request to datenschutz@dermanostic.com.
- It is not necessary to uninstall the [dermanostic web app](#), as no software needs to be installed. The [dermanostic app](#) (accessory) can be safely removed from the mobile device by uninstalling it.

6.9. Special instructions for use

- The data will only be transmitted to Dermanostic GmbH after successful payment. All data entered will be deleted when the case creation process is canceled and cannot be restored.
- Before taking pictures, check that the camera lens is clean and not covered by anything. If necessary, wipe the lens carefully with a soft cloth if it is dirty.
- If the photo quality is not sufficient for the dermatologists, you will be informed via the [dermanostic app](#) (accessory) and by e-mail that new photos are required. This ensures that the diagnosis is always based on good photo quality.
- Do not cover the flash light source or the camera while photos are being taken.
- No content of any kind may be uploaded or transmitted that could infringe the rights of third parties.
- Breastfeeding and pregnant persons, or persons suspected of being pregnant, can use the app, but must indicate this condition in the medical history form.
- People with known allergies, pre-existing conditions and / or medication intolerances can use the app, but must specify these in the medical history form.
- Deactivating, modifying, "hacking" or interfering with the functionality of this software as intended by the manufacturer is not permitted.

7. Minimum technical requirements

The software can run on all end devices that meet the following specified minimum requirements.

- 2 GB RAM, 100 MB free memory
- Smartphones, tablets, desktop computers and laptops
- Suitable browsers:
 - Google Chrome
 - Safari
 - Firefox
- Internet connection

8. Data protection

The patient data is processed and secured on servers in Germany (Deutsche Telekom) in compliance with data protection regulations. The dermatologist carrying out the assessment only receives the medical information relevant to him in order to make the diagnosis. The personal data (name, date of birth, address, etc.) is pseudonymized and stored separately in encrypted form. Data protection is regularly checked and certified by TÜV Saarland. Further information can be found in the privacy policy.

9. Reporting obligations









All serious incidents occurring in connection with the app must be reported to Dermanostic GmbH and the competent authority of the EU Member State in which the user and/or patient is resident.

10. Declaration of conformity

We declare under our sole responsibility the conformity of the **dermanostic webapp** with the requirements of MDR 2017/745.

The **dermanostic webapp** is a medical device in risk class IIa, complies with the relevant provisions of MDR 2017/745 and is CE marked.

11. Symbols to identify the dermanostic app

Icon	Symbol title
	Manufacturer
	Serial number
	Date of manufacture
	UDI number (Unique Device Identifier)
	Electronic instructions for use (eIFU)
	Medical device
	MDR 2017/745
	Warning sign



Dermanostic GmbH
Merscheiderstr. 1
42699 Solingen
Germany
Phone: +49 (0) 211 9425 5860
E-mail: info@dermanostic.com
SRN: DE-MF-000034712

If you require the instructions for use in paper format, please contact our customer service team at info@dermanostic.com. We will be happy to send you a copy free of charge **within one week**. It is also possible to download and print out the electronic instructions for use.