# dermanostic

## Instructions for Use - ENGLISH
DAPP02 dermanostic App

## 1. Product description

The dermanostic app 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 human skin. In addition to the examination of skin changes, the app includes a function in which an AI determines the skin condition based on a photo of the face. In another feature of the app user can find out about digital health topics and dermatological topics such as diseases, therapies and active ingredients of medications.

Patients download the app from the Android Play Store or Apple App Store. They then create an account consisting of an e-mail address and password. After registering the user account in the app, patients can create a new case.

The case is created in the following steps: selecting/creating the patient profile, the intro, uploading images and answering an anamnesis questionnaire, as well as payment.

### 1.1. Intended Purpose

The dermanostic app is used for the asynchronous examination of skin changes by recording, storing, displaying, and transmitting digital images of the main areas affected, as well as answering an anamnesis questionnaire and communicating (chat) with specialists.

### 1.2. Intended Patient Group

Use is not restricted to any patient population.

Children and elderly patients, people with disabilities, may not be able to operate the smartphone camera or the app/smartphone. In this case, the examination can be carried out with the help of a third person.

### 1.3. Intended User Group

The dermanostic app is designed in such a way that it can also be used by laypersons for the intended purpose.

The case created by the lay user is assessed by a dermatology specialist. For this purpose, Dermanostic GmbH cooperates with specialist practices in private practice or employed in hospitals.

### 1.4. Intended Use Environment

The dermanostic app must be used in combination with a smartphone that is connected to the internet. The dermanostic app can be used as a mobile app in any environment where smartphones are normally used. The app can therefore be used anywhere and is not limited to indoor use or a specific location.

### 1.5. Performance Characteristics

The app can be used for Android or iOS smartphones.

## 2. Indication

Examination of dermatological disease patterns/changes on the entire human skin, including the hairy head and all skin folds and mucous membranes, which can be identified by the patient at a glance. The doctor can then make a diagnosis and recommend treatment based on the medical history form completed by the patient and the visual assessment of the uploaded images of the skin/mucous membrane changes.

## 3. Contraindication

- The dermanostic app is not intended for examining damaged skin areas and open wounds.

- It must also not be used in acute life-threatening situations, emergencies and allergic reactions with respiratory distress.

- In the case of heavily tattooed areas of skin, it may be difficult or impossible to diagnose the skin change.

- Teledermatology procedures must not be carried out if:

  o a personal presence of the patient appears necessary.

  o the technical equipment available to the patient is not expected to provide sufficient (image) quality for diagnosis,

  o the patient is overwhelmed by the use of the app or does not consent to it.

## 4. Side Effects

There are no known side effects when used properly.

## 5. Warnings and Residual Risks

### 5.1. Warnings

- The dermanostic 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 app cannot replace skin cancer screening in a doctor's surgery or outpatient clinic.

- Specialist medical advice is provided by the dermatologists employed by the cooperating specialist practices within approximately 24 hours of the photos and anamnesis form being sent to Dermanostic GmbH. However, Dermanostic GmbH does not guarantee a specific response time to requests.

- In individual cases, exclusive remote treatment may remain the case, provided that the specialist diagnosis can already be conclusively made based on 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 staff on behalf of the cooperating specialist practice. In this case, the medically trained specialists contact the patients via the app or by telephone.

- In view of the risk of incorrect findings, quality assurance at Dermanostic GmbH provides for the interdisciplinary expert panel of the cooperating specialist practices to be consulted in an advisory capacity if the dermatologists treating the patient consider a second expert opinion on 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 anamnesis questionnaire (e.g. suspected pregnancy, allergies, previous illnesses and/or drug 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. Applications notes

### 6.1. Registration and Selection of Patient Profile

To be able to use the app, the user must register with a user account using an e-mail address and a password. Multiple patient profiles can be created under a user account for the creation of a new case. For example, parents can create a patient profile for their baby, toddler or child or their parents, as they may not own or be able to use a smartphone, making the parents not the patient but a patient assistant.

If the patient assistant is not the legal guardian of the patient, the patient must consent to the use of the app for their skin change 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. There you can either select an existing patient profile or create a new one.

### 6.2. Intro

In the first step of the intro, the purpose of the examination with the app is specified. 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 can either be uploaded from the smartphone gallery or taken directly with the smartphone camera.

### 6.4. Anamnesis Questionnaire

In the last step, the patients fill out an anamnesis questionnaire, which is common in dermatology and was developed in cooperation with the University Hospital Göttingen. The questions of the anamnesis

questionnaire are displayed to the patient one after the other in the app. Some questions are only necessary to a limited extent, based on the answers from the intro and information in the patient profile.

The submitted images and the anamnesis questionnaire are 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.

Medical treatment costs €25.

### 6.5. Diagnosis and Treatment Recommendation

Patients usually receive a doctor's letter within 24 hours with the diagnosis and a treatment plan recommendation from the dermatologists treating them, as well as their explanations. As part of the treatment recommendation, the dermatologist responsible can issue a private prescription for the patient, which can be sent to the patient's home by post or to the pharmacy of their choice or a partner online pharmacy.

For further queries and follow-up care, patient support is available to patients via chat.

### 6.6. Deleting the App and the Account

- The account can be completely deleted under Account settings under *Delete account*. This will delete all personal data from the Dermanostic GmbH servers in accordance with the GDPR standard.

- By uninstalling the app, the product is securely removed from the mobile device.

## 7. Special Handling Instructions

- -Do not install or use the dermanostic app on a device with non-original iOS or Android software.

- 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 dermatologist, you will be informed via the app that new photos are required. This ensures that the diagnosis is always based on good photo quality.

- Do not cover the flash source or the camera while the 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, may use the app, but must indicate this condition in the medical history form.

- Persons with known allergies, pre-existing conditions and / or drug intolerances may use the app but must indicate this in the medical history form.

- Deactivating, modifying, "hacking" or interfering with the functionality of this software as intended by the manufacturer is not permitted.

## 8. Minimum Technical Requirements

- Software requirements:
  - Android: 7.0,
  - iOS: 12.0;

- Hardware requirements:
    - Storage space: 150 MB;
    - Camera resolution: 5 MP;
- Internet connection

## 9. Data Protection

Patient data is processed and secured on servers in Germany (Deutsche Telekom) in accordance with data protection regulations. The examining dermatologist receives only the medical information relevant for him to make the diagnosis. 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.

## 10. Reporting Obligations
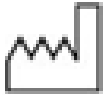
All serious incidents occurring in connection with the app must be reported to Dermanostic GmbH and the competent authority of the EU member state in which the user and/or patient resides.

## 11. Declaration of Conformity

We declare under our sole responsibility the conformity of the dermanostic app in accordance with the requirements of MDR 2017/745.
The dermanostic app is a medical device of risk class I according to rule 11 (11.5), complies with the

relevant provisions of MDR 2017/745 and is CE marked.

## 12. Symbols for marking the dermanostic App

| Symbol | Symbol title |
|---|---|
| | Manufacturer |
| SN | Serial number |
| | Date of manufacture |
| UDI | Unique Device Identifier (UDI) number |
| | Electronic Instruction for Use (eIFU) |
| MD | Medical device |
| CE | CE marking : (EU) MDR 2017/745 |

If you need the operating instructions in paper format, please contact our customer service at info@dermanostic.com. We will be happy to send you a copy free of charge. It is also possible to download and electrical Instruction of Use.

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