

dermanostic

Instruction for Use - ENGLISH

DAPP01 dermanostic App

1. Product description

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

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

The case creation process consists of four steps: the intro, the questionnaire, the selection/creation of the sponsor profile, and the diagnosis and treatment recommendation.

1.1. Purpose

The "dermanostic" app is used for the asynchronous examination of skin changes by means of recording, storing, displaying and transmitting digital image material of the affected skin areas, as well as answering a medical history questionnaire and communication (chat) with medical specialists.

1.2. Intended patient group

The study is not restricted to any patient population.

Children and elderly patients-, people with impairment, may not be able to operate the smartphone camera or the app/ a smartphone. In this case, the examination can be performed by providing assistance to a third person.

Breastfeeding and pregnant persons, or persons with a suspected pregnancy, can use the app, but it is mandatory to indicate this condition in the medical history form.

The same applies to persons with known allergies, pre-existing conditions and/or drug intolerances.

1.3. Intended user group

The dermanostic app is designed to be used by lay users for the intended purpose.

The resulting image material is assessed by a dermatology expert user. For this purpose, Dermanostic GmbH cooperates with specialist practices in private practice or with specialists employed in hospitals.

1.4. Intended place of use

The dermanostic app can be used anywhere and does not foresee a specific place of use.

1.5. Features

The app can be used for Android or iOS smartphones. Alternatively, the app can also be started directly via the browser.

2. Indication

Examination of dermatological disease patterns/skin changes from the entire human skin - including the hairy head and all skin folds that can be identified by gaze diagnosis. Gaze diagnosis means that the physician can already make a diagnosis and give a therapy recommendation with a few questions and a short look at the skin change.

3. Contraindication

- The "dermanostic" app is not intended for examining damaged skin regions and open wounds.
- Likewise, it must not be used in acute life-threatening situations, emergencies and allergic reactions with respiratory distress.
- Teledermatological procedures must not be performed when treatment pre-sence seems to be necessary.
- In the case of heavily tattooed skin, it may not be possible to diagnose the skin lesion.
- Teledermatological procedures must not be used if the patient is overwhelmed by them or does not consent to them.

4. Side effects

There are no known side effects when used properly.

5. Residual risks and precautions

- Use of the dermanostic app should be discouraged in the event of a medical emergency. In the event of a medical emergency, the appropriate emergency medical service should be consulted immediately.
- Use of the dermanostic app cannot replace skin cancer screening in the presence of treatment.
- Incomplete information in the medical history form (e.g. suspected pregnancy, allergies, pre-existing conditions and / or drug intolerances) may lead to an incorrect diagnosis and / or inadequate therapy recommendation.
- The specialist consultation is carried out by the dermatologists employed by the practice of Dr. Lang within approximately 24 hours from the transmission of the photographs and the medical history form to Dermanostic GmbH. However, Dermanostic GmbH does not guarantee a specific response time to inquiries.
- In individual cases, remote treatment may remain the exclusive option, provided that the specialist diagnosis can already be made conclusively on the basis of the photographs and the completed medical history form, while observing the necessary medical care, in particular through the manner in which the findings are ascertained, consultation, treatment and documentation of the treatment process. In this case, the treating dermatologist will inform the patient about the particularities of a purely remote treatment.
- If medical aftercare is required, it will be carried out by me-medical staff of Dermanostic GmbH on behalf of Dr. Lang's practice. In this case, the me-medically trained specialist contacts the patient via the app or by phone.

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- In view of the risk of incorrect findings, the quality assurance at Dermanostic provides for the interdisciplinary expert committee of the practice of Dr. Lang to be consulted in an advisory capacity if the dermatologists treating the patient consider a second professional assessment of the specific treatment case to be necessary.
- The discussion of cases in the interdisciplinary expert panel can lead to a delay in the diagnosis.

6. Application notes

6.1. Intro

The first step of the intro is to specify the purpose of the examination with the app. Here you can select between different pathological skin changes and other skin problems.

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

The last step of the intro is the photo upload. Three photos of the affected skin region / 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 region), which can either be uploaded from the smartphone gallery or taken directly with the smartphone camera.

6.2. Anamnesis questionnaire

In the second step, a standard dermatological anamnesis questionnaire is filled out, which was developed in cooperation with the University Hospital of Göttingen.

6.3. Selection/creation of the patient profile

To create an account, the patient's e-mail address is required. All patient data will be treated confidentially according to DSGVO standards. Alternatively, registration can be done at a later date.

The medical treatment costs 25€.

The submitted images and medical history questionnaire will be displayed to the affiliated dermatologists in the dermanostic dashboard (Next case on hold). Detection and treatment recommendation of skin diseases are performed independently by dermatology specialists without exception.

6.4. Diagnosis and treatment recommendation

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

For further questions and follow-up care, the patient support is available to the patients in the chat.

7. Special handling instructions

- Do not install or use the dermanostic app on a device with non-original iOS or Android software.
- Before taking a picture, check that the camera lens is clean and not covered by anything. If necessary, gently wipe the lens with a soft cloth if it is dirty.
- Do not cover the flash light source or camera while taking photos.

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- Do not upload or transmit content of any kind that may infringe the rights of third parties.
- Disabling, modifying, "hacking" or interfering with the manufacturer's intended functionality of this software is not permitted.

8. Minimum hardware requirements

Almost all cameras of today's smartphones are suitable for the dermanostic app. A total of three photos are taken from different distances and angles. If the photo quality is not sufficient for dermanostic, you will be informed via the app that new photos are needed. This ensures that the diagnosis is always based on good photo quality.

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 |
|  | Serial number |
|  | Date of manufacture |
|  | UDI number (Unique Device Identifier) |
|  | Electronic Instruction for Use (eIFU) |
|  | Medical device |
|  | 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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