

Instructions for use – ENGLISH



DAPP04 – dermanostic App

Valid for:

- Basis-UDI-DI: 426242531DAPP04WZ
- Softwareversion: The respective released software version, as indicated by the current product label



Please read these instructions carefully! If you have any questions or need clarification, please contact our app support team.



WARNING! This symbol indicates a potentially dangerous situation.

Notes on the Scope of These Instructions for Use

These instructions for use apply exclusively to the dermanostic app (DAPP04). The app enables users to create a case, specifically by selecting or creating a patient profile, specifying the reason for the examination, identifying the affected body region, uploading images, completing the medical history questionnaire, paying for and submitting the case, and receiving the findings.

Other components of the dermanostic system that do not fall within the intended purpose of the dermanostic app as described in Chapter 1.1 are not covered by these instructions for use. In particular, the available skin type determination via AI analysis is a separate function. It is intended solely for informational purposes to guide the user and does not constitute a medical function, diagnosis, or treatment recommendation.

1. Product description

The Dermanostic app is provided by Dermanostic GmbH (the manufacturer). It is a medical device software application in the field of teledermatology designed to assess the physiological or pathological condition of human skin. In addition to its medical functions, the app includes other features that are not intended for medical use. In an information section, users can learn about digital health topics and dermatological topics such as clinical presentations, therapies, and active ingredients in medications. There is also a section where users can have their skin type (normal skin, dry skin, oily skin, combination skin) analyzed.

Patients download the app from the Android Play Store or the Apple App Store. The dermanostic app is currently available in app stores only for Germany and Austria. The availability of the download depends on the country or region settings of the respective app store or user account, and not solely on the user's current location. If the app store or user account is set to a region outside of Germany and Austria, the app cannot be downloaded.



Next, users must create an account consisting of an email address and password. After registering their user account in the app, patients can create a new case. They then create an account using an email address and password. After registering their user account in the app, patients can create a new case.

Case creation involves the following steps: selecting or creating the patient profile, the introduction, uploading images, completing a medical history questionnaire, and making payment.

1.1 Intended use

The dermanostic app is a medical device software designed to facilitate the structured collection of medical information (medical history forms + images) and to improve patient management in the field of teledermatological examination of potentially pathological skin areas. Furthermore, the dermanostic app supports communication between patients and medical professionals by capturing, storing, displaying, and transmitting digital images of the affected skin areas, collecting a medical history form, and facilitating conversations with specialists (chat function).

1.2 Intended patient group

The examination is not limited to any specific patient population.

Children, older patients, and people with disabilities may not be able to operate the (smartphone) camera or the app/smartphone. In these cases, the app can be used with the assistance of another person. Additionally, multiple patient profiles can be created on the same smartphone, allowing patients without their own smartphone or the dermanostic app to also use the asynchronous teledermatology assessment.

Breastfeeding and pregnant patients, or patients who may be pregnant, may use the app but must indicate this on the medical history form. The same applies to individuals with known allergies, pre-existing conditions, and/or medication intolerances. Otherwise, this could lead to incorrect diagnoses and inadequate treatment recommendations.

1.3 Intended user group

The Dermanostic app is designed to be user-friendly, allowing non-medical users to use it for its intended purpose.

Cases submitted by non-medical users are reviewed by a dermatology specialist. To this end, Dermanostic GmbH collaborates with private dermatology practices and hospital-based dermatologists.

1.4 Intended use environment

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

1.5 Key Features

The app is available for Android and iOS smartphones.



2. Indication

Examination of dermatological conditions and changes affecting the entire human skin, including the scalp, all skin folds, and mucous membranes, which the patient can identify at a glance. Based on the medical history form completed by the patient and the visual assessment of the skin and mucous membrane changes, the physician can then make a diagnosis and recommend a course of treatment.

3. Contraindication

- The dermanostic app is not intended for examining damaged skin areas or open wounds.
- Nor is it intended for assessing or diagnosing acute life-threatening situations, emergencies, and/or allergic reactions accompanied by shortness of breath. In such cases, emergency medical services should be contacted immediately and/or sought out.
- In areas of heavily tattooed skin, it may be difficult or impossible to diagnose the skin condition.
- Teledermatology procedures must not be performed if:
 - the patient's in-person presence appears necessary.
 - the technical equipment available to the patient does not allow for 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



- Do not use the dermanostic app in the event of a medical emergency. In the event of a medical emergency, seek immediate medical attention from the appropriate emergency services.
- Use of the dermanostic app cannot replace skin cancer screening at a doctor's office or clinic.
- Incomplete information in the medical history form (e.g., suspected pregnancy, allergies, pre-existing conditions, and/or medication intolerances) may lead to an incorrect diagnosis and/or inadequate treatment recommendations.
- Before taking a photo, check that the camera lens is clean and not obstructed by anything. If necessary, carefully wipe the lens with a soft cloth if it is dirty.



- Just as with an in-person consultation with a specialist, there is a residual risk of a misdiagnosis.

Attention!

- Do not install or use the dermanostic app on a device running non-genuine iOS or Android software.
- The data is transmitted only after the photo has been successfully uploaded. If the case creation process is canceled before payment is made, the data entered will be deleted and cannot be recovered—unless the case was previously saved as a draft. The data is made available to a doctor for evaluation only after payment has been successfully processed.
- If the photo quality is insufficient for the dermatologists, you will be notified via the app that new photos are needed. This ensures that the diagnosis is always based on high-quality photos.
- Do not cover the flash or the camera while taking photos.
- You may not upload or transmit any content that could infringe on the rights of third parties.
- Breastfeeding and pregnant individuals, or those who suspect they may be pregnant, may use the app but must indicate this status on the medical history form.
- Individuals with known allergies, pre-existing conditions, and/or medication intolerances may use the app but must indicate this on the medical history form.
- Disabling, modifying, “hacking,” or interfering with the functionality of this software as intended by the manufacturer is not permitted.
- There is a small residual risk that the confidentiality of patient data may be compromised due to cyberattacks or unauthorized access by third parties to the dermanostic Dashboard or the connected backend systems. This could result in unauthorized access, disclosure (publication), or theft of health data. In the event of data disclosure, this may lead to adverse effects and/or harm for those affected.
- Using an insecure or unprotected network (e.g., open public Wi-Fi, outdated or missing Wi-Fi encryption) may allow third parties to intercept, view, or tamper with transmitted data, including health data.
- If the network connection is interrupted, the case must be resubmitted manually. However, the upload time may be delayed due to buffering.
- In view of the risk of incorrect findings, the quality assurance process at Dermanostic GmbH provides for consulting the interdisciplinary expert panel of the cooperating specialist practices in an advisory capacity, provided that the treating dermatologists deem a second professional assessment of the specific treatment case to be necessary.
- Discussing cases within the interdisciplinary expert panel may lead to a delay in diagnosis.



6. Instructions for use

6.1 Registration and Selection of Patient Profile

To use the app, users must register for an account using an email address and a password. Multiple patient profiles can be created under a single user account to establish a new case. For example, parents can create a patient profile for their baby, toddler, or child, or for their own parents, since the latter may not own or be able to use a smartphone; in such cases, the parents are not the patients but act as patient assistants.

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 by signing a consent form.

All patient data is treated confidentially in accordance with GDPR standards.

Creating the patient profile is the first step in creating a case. There, you can either select an existing patient profile or create a new one.

6.2 Intro

The first step of the introduction involves specifying the reason for the examination using the app. Here, you can select from various pathological skin lesions and other skin problems.

Next, you will need to locate the skin lesion. To do this, the app displays an image of the human body. Select the area of the body where the skin lesion to be examined is located by clicking on the corresponding spot or body region in the image.

6.3 Photo-Upload

The next step is to upload photos. You will need three photos of the affected skin area or lesion (one taken from a distance of 30 cm and two taken from a distance of 10 cm, with the camera at two different angles relative to the affected skin area). These photos can either be uploaded from your smartphone's gallery or taken directly with your smartphone's camera.

Please ensure that the images are suitable for medical evaluation. The affected skin lesion should be clearly visible, in full view, in sharp focus, and properly exposed. The camera lens should be clean and unobstructed before taking the photo. Blurry, severely over- or underexposed, or obscured photos can make the medical evaluation more difficult. If the image quality is insufficient, new or additional photos may be requested.

6.4 Medical history questionnaire

In the final step, the medical history questionnaire—developed in collaboration with the University Hospital of Göttingen—is completed. The questions on the questionnaire are displayed to the user one at a time in the dermanostic app.

6.5 Registration and payment

To submit a case via the dermanostic web app, you must first register a user account using an email address and password. Once you have successfully registered and verified your email address, you can create a patient profile. The case will be submitted once payment has been completed.

6.6 Diagnosis and therapy recommendation



Patients typically receive a medical report within 24 hours from their treating dermatologists, containing the diagnosis, a recommended treatment plan, and an explanation of the findings. The user is notified by email when the medical report is available or if any questions have arisen during the evaluation. As part of the treatment recommendation, the treating dermatologist can issue a private prescription, which can be sent either to the patient's preferred pharmacy or to a partner online pharmacy.

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

6.7 Deletion of the app and the account

- The account can be completely deleted by selecting "Delete Account" in the Account Settings. This will delete all personal data from Dermanostic GmbH's servers in accordance with GDPR standards.
- Alternatively, the account can be manually deleted by Dermanostic GmbH upon request sent to datenschutz@dermanostic.com.
- Uninstalling the app will securely remove the product from your mobile device.

7. Special instructions for use

- Consultations with medical specialists are provided by dermatologists employed at the participating specialist practices within approximately 24 hours of the photographs and medical history form being submitted to Dermanostic GmbH. However, Dermanostic GmbH does not guarantee a specific response time for inquiries.
- In individual cases, treatment may be provided exclusively via telemedicine, provided that the specialist's diagnosis can be conclusively made based solely on the photographs and the completed medical history form, while maintaining the required standard of medical care—particularly with regard to the manner in which the diagnosis is made, consultation, treatment, and documentation of the treatment process. In this case, the treating dermatologists will inform the patients about the specific aspects of treatment conducted exclusively remotely.
- If medical follow-up care is required, it will be provided by medical staff of Dermanostic GmbH on behalf of the cooperating specialist practices. In this case, the medically trained staff will contact the patients via the app or by phone.

8. Minimum Technical Requirements

8.1 Device and Software Requirements

- Software requirements:
 - Android: 11.0,
 - iOS: 13.0;
- Hardware Requirements:
 - Storage space: 150 MB;
 - Camera: We recommend a camera like the one that comes standard in newer, commercially available smartphones. There is no specified minimum



resolution. The key requirement is that the image capture requirements described in Section 6.3 can be met.

- Internet connection

8.2 Network Security Requirements

- Use only secure and trusted Internet connections.
- Do not use open or unprotected public Wi-Fi networks.
- When using Wi-Fi: Use at least WPA2 encryption, preferably WPA3.
- Always keep your operating system and browser up to date and install security updates promptly.
- Keep the device's built-in security features (e.g., operating system firewall) enabled.
- On desktop computers, also use up-to-date antivirus software. On smartphones, traditional antivirus scanners have limited technical functionality and are therefore not generally required.
- In practice or corporate networks, also use a network-level firewall.
- Do not use rooted or jailbroken devices.
- Do not ignore security and certificate warnings from the browser.

9. 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.

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 is resident.

11. Declaration of conformity

We declare under our sole responsibility the conformity of the dermanostic app with the requirements of Regulation (EU) 2017/745.

The dermanostic app is a medical device in risk class IIa, complies with the relevant provisions of Regulation (EU) 2017/745 and is CE marked.



12. Explanation of the symbols used



The CE marking indicates compliance with the European Medical Devices Regulation (EU) 2017/745.



Manufacturer



Date of manufacturing



Medical Device



Unique Device Identification



Serial number



Follow the instructions for use



Attention



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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.



13. Revision History

Revision	Date	Description
Rev. 06	2026-08-05	Removal of the DACH-Region. The app is only available in Germany and Austria.
Rev. 05	2026-07-22	Addition of a warning regarding the risks of unsafe network use in Chapter 5. Renaming of Chapter 8 to Subsection 8.1 "Requirements for End Devices and Software" and addition of the new Chapter 8.2 "Network Security Requirements." Adjustments to the camera requirements in Chapter 8.1. Addition of the section "Notes on the Scope of Application of These Instructions for Use." Addition of a note regarding app store availability. Clarification of the procedure for localizing body regions in Chapter 6.2, as well as the addition of a note regarding image quality when uploading photos in Chapter 6.3.
Rev. 04	2026-06-08	Adjustment of the date format to ISO 8601.
Rev. 03	2026-05-22	Formal and regulatory revision of the instructions for use. Comprehensive restructuring and expansion of the document. Addition of enhanced safety and residual risk information. Clarification and expansion of the intended patient group and use scenarios. Addition of detailed process descriptions for registration, payment, case submission, diagnosis workflow, notifications, and account deletion procedures. Update of the software version information to "Software version 3.99.0 and higher." Revision and expansion of the symbol explanations. Addition of a dedicated revision history section. Editorial and linguistic revision of all major chapters and instructions for use.
Rev. 02	2024-10-17	Update of the document metadata by adding the Basic UDI-DI and software version applicability ("App version 3.43.0 and newer"). Revision of the minimum technical requirements. Editorial correction and clarification of the paper instructions for use request process. Minor editorial and linguistic revisions throughout the document.
Rev. 01	2024-09-13	Initial approval